

# **Boston University Journal of Science & Technology Law**

## Symposium

Probing the Human Genome: Who Owns Genetic Information?

Lawrence Wittenberg, Edmund Pitcher, Dean Charles DeLisi,  
Michael Gollin, and Wendy McGoodwin

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# Probing the Human Genome: Who Owns Genetic Information?†

Edmund Pitcher, Dean Charles DeLisi, Michael Gollin,  
and Wendy McGoodwin

## Lawrence Wittenberg:<sup>1</sup>

1. We have a big agenda and a lot to discuss about a fascinating topic. First, I would like to introduce today's panelists: Edmund Pitcher, Dean Charles DeLisi, Michael Gollin, and Wendy McGoodwin.

## Edmund Pitcher:<sup>2</sup>

2. The topic is "Probing the Human Genome" or "Who Owns Genetic Information." There are several types of genetic information, and I think it is helpful if we clarify these at the outset. First, there is natural information content. Every cell of every organism has a genome that consists of a few thousand to hundreds of thousands of genes.<sup>3</sup> These genomes direct the development of the organism: its survival, its metabolism, and its behavior. These genomes profoundly affect its

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<sup>2</sup> Edmund Pitcher is the head of the biotechnology patent law department at the Boston law firm of Testa, Hurwitz & Thibeault, LLP and has extensive experience in patenting human genetic materials and other biotechnology-related matters. Testa, Hurwitz & Thibeault, LLP owns the copyright to the following Edmund Pitcher comments, such comments being made within the scope of his employment at Testa, Hurwitz & Thibeault, LLP.

<sup>3</sup> See David Cove, *British Association: Annual Festival of Science: Gene and Tonic Genetic Engineering Is a Good Thing*, GUARDIAN, Sept. 4, 1997, at 8 (cells contain some "hundred thousand different genes").

being.<sup>4</sup> In one sense, a large portion of genetic information is just “natural content.” Deciding who owns this natural content is pretty philosophical; it is like asking who owns the stars. I do not think that anybody owns natural content information anymore than they own the information involved in explaining a natural phenomenon.

3. The second type of genetic information is that derived from personal diagnosis. Let us suppose I go to the doctor and have a comprehensive genetic test done. The doctor takes some cells from me, screens my genome, and performs recently developed tests on my cells. As a result, analysts can now predict my personal future in terms of my propensities for certain diseases.<sup>5</sup> This type of personal genetic information is not my topic for today. It raises all sorts of ethical, political, social, financial, and insurance issues that are beyond the scope of my presentation.<sup>6</sup>

4. Today, I will discuss the third type of genetic information, which involves the association and, more importantly, functional relationship between genetic sequences and what they do. It is only in this way that one can find the keys to diagnosing and/or curing diseases. This topic is hard to understand unless you have at least a general idea of the science involved. Therefore, I will give a brief primer on the science involved.

5. Every individual is made up of cells. Cells in eukaryotic organisms<sup>7</sup> contain nuclei<sup>8</sup> and within these nuclei are chromosomes.<sup>9</sup> The chromosomes are

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<sup>4</sup> See Margaret Munro, *City Firm Creates Designer Chromosomes: Company's Production Facility a World First*, VANCOUVER SUN, Apr. 12, 1997, at A1, available in 1997 WL 6110933 (stating that genes control the growth and function of cells and organisms); see also Chris Bond, *Bond Secures \$40 Million to Begin New Plant, Genome Initiative for the 21st Century*, Government Press Releases by Federal Document Clearing House, July 15, 1997, available in 1997 WL 12101065 (“Scientists have to be able to find the location of the genes that control a given characteristic—such as size, color, or resistance to disease.”).

<sup>5</sup> See Linton Weeks, *Science's Mr. Green Genes: William Haseltine Sees the Future in His Labs*, WASH. POST, Feb. 17, 1998, at E1 (stating that genes may be used “to fashion a blood test that can predict or detect disease”).

<sup>6</sup> See generally Symposium, *Gene Therapy: Legal, Financial and Ethical Issues*, 4 B.U. J. SCI. & TECH. L. 3 (1998) (discussing the implications of gene therapy and genetic testing).

<sup>7</sup> A eukaryote is defined as “an organism composed of one or more cells with visibly evident nuclei.” WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 782 (1976).

<sup>8</sup> See John O. Corliss, *Eukaryotae*, in 6 MCGRAW-HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 579, 580 (8th ed. 1997) [hereinafter ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY].

<sup>9</sup> See *id.*

made up of deoxyribonucleic acid (“DNA”).<sup>10</sup> Some of the DNA is called “junk DNA” because no one really knows what it does.<sup>11</sup> The other DNA is transcribed by the cell into messenger RNA (“mRNA”),<sup>12</sup> which brings a message to the cell to make proteins<sup>13</sup> such as hormones and various enzymes. In humans there are 23 pairs of DNA strands for 23 chromosomes.<sup>14</sup> Perhaps you are familiar with the basic fundamental components of DNA: adenine, cytosine, guanine, and thymine.<sup>15</sup> In humans there are six billion base pairs of DNA.<sup>16</sup>

6. This is an introduction to a brand new science, to which I am exposed almost daily. It is called genomics<sup>17</sup> and is the business of developing inventions and making products that will best fit the needs of people using genetic information. The first step in the generally accepted process is to discover a sequence of human DNA.<sup>18</sup> Then, you find a gene involved with the disease you wish to study. Since there are more than one hundred thousand genes,<sup>19</sup> the chance of finding that gene is next to zero. If you do find the gene, you then measure gene expression patterns to detect DNA mutations; from this you can develop new protein drugs that will be used to aid in the therapy or prevention of the disease and new diagnostics used to

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<sup>10</sup> See Orlando J. Mille & Dorothy A. Mill, *Chromosome*, in 3 ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY, *supra* note 8, at 671.

<sup>11</sup> See Lawrence A. Shapiro, *Junk Representations*, 48 BRIT. J. FOR PHIL. OF SCI. 345, 345 (1997) (“[Junk DNA] takes up room in the nuclei of an organism’s cells, but it contributes nothing to the phenotype of the organism.”).

<sup>12</sup> See Mille & Mill, *supra* note 10, at 672.

<sup>13</sup> See *id.*

<sup>14</sup> See *id.*

<sup>15</sup> See *id.* at 671.

<sup>16</sup> See *id.* at 672.

<sup>17</sup> See Rochelle K. Seide, *Drafting Claims for Biotechnology Inventions*, in SIXTH ANNUAL PATENT PROSECUTION WORKSHOP: ADVANCED CLAIM & AMENDMENT WRITING, at 373, 391 (PLI Pats., Copyrights, Trademarks, & Literary Prop. Course Handbook Series No. G4-3977, 1996) (“[G]enomics is directed at determining DNA sequences from particular organisms and in turn using this information to find, isolate and purify the encoded protein.”).

<sup>18</sup> See *id.*

<sup>19</sup> See Cove, *supra* note 3.

determine genetic predispositions.<sup>20</sup> There are associated developments being made in population genetics for determining what diseases a population is likely to suffer on an epidemiological basis.<sup>21</sup>

7. This progress is not simple. There are hundreds of thousands of researchers all over the world making incremental progress. They are trying to make quality products that people will buy. What they face is three billion bases.<sup>22</sup> Politicians often say, "\$1 billion here and \$1 billion there [and] pretty soon you are talking about real money."<sup>23</sup> Well, nobody really realizes how big a billion is. To illustrate that immense task, consider a page of a book. If you added up all the letters on a page having 40 characters by 60 lines there would be 2400 bases on a page. Seven hundred and twenty thousand bases would make up a book that is about one inch thick. Representing the entirety of the human genome would create a stack of books as high as a 35-story building. Researchers are trying to find sequences somewhere within this incredibly large genome. Finding these sequences in a stack of books 35 stories high is a very daunting task. New techniques are being developed to make this task a simple and possible one. Nevertheless, it is still far from trivial.

8. In January 1997, the *Boston Globe* printed an article stating that researchers identified another gene for breast cancer.<sup>24</sup> In addition to the discovery of BRCA1 and BRCA2,<sup>25</sup> another gene has been found which is now known to be

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<sup>20</sup> See Pat Youden, *Intek Sale to PPDI Helps Firm Bridge Drug-Testing Gap*, TRIANGLE BUS. J., Jan. 23, 1998, at 24, available in 1998 WL 9198038 ("[A]dvances in the field of human genetics . . . have led to identifying certain gene mutations that cause some people to have a predisposition for certain diseases.").

<sup>21</sup> See *Major Gene Study in Iceland*, CHEMICAL BUS. NEWSBASE, Feb. 24, 1998, available in 1998 WL 7718129 (discussing a collaborative agreement between Hoffmann-La Louch and DeCode Genetics to study "the Icelandic population's unique genetic properties[,] to map and discover the genes that cause disease," and to "concentrate on the discovery of genes with alleles or mutations that predispose people to the development of 12 common diseases").

<sup>22</sup> The Human Genome Project and the National Institutes of Health are attempting to determine all three billion bases of the human genome by 2005. See Eliot Marshall, *Physicists Urge Technology Push to Reach 2005 Target*, 279 SCIENCE 23, 23 (1998).

<sup>23</sup> This statement is attributed to Senator Everett Dirksen and is often quoted by politicians. See, e.g., 141 CONG. REC. H15565 (daily ed. Dec. 21, 1995) (statement of Rep. Horn) (quoting Sen. Dirksen); 140 CONG. REC. S9506 (daily ed. July 22, 1994) (statement of Sen. Smith) (quoting Sen. Dirksen).

<sup>24</sup> See Judy Foreman, *Another Gene with Breast Cancer Role Identified*, BOSTON GLOBE, Jan. 16, 1997, at A23.

<sup>25</sup> See Michael Krainer et al., *Differential Contributions of BRCA1 and BRCA2 to Early-Onset Breast Cancer*, 336 NEW ENG. J. MED. 1416, 1416 (1997).

associated with a propensity to develop breast cancer.<sup>26</sup> This means that we can take blood cells from a woman in a high-risk population and see whether a particular genome sequence is present in that individual's genome to determine whether or not that woman is likely to get this disease.<sup>27</sup> That information, and what people do with it, raises further issues that I am not going to speak about today. Nevertheless, we can conclude that molecular biology and the genomic sciences are making it possible to know these answers.

9. DNA research provides sequence bands of nucleic acids.<sup>28</sup> Once all the sequences and genes are known, the amino acid sequence of the gene and its proteins are also known.<sup>29</sup> You can now produce these genes and determine their uses. A tremendous number of products are possible, given a complete map of the human genome, including using DNA in criminal proceedings, in agriculture, in disease testing, in defining species habitats, and in doing DNA probes and gene detection for diagnosis.

10. There is a tremendous diversity in what people are going after. If you are in business and want to get into genomics, you need to hire smart scientists. Your company then has the daunting task of developing something that can pass through the required testing of the Food and Drug Administration ("FDA") and that the public is willing to buy. If the invention is not protected, however, the moment your company is successful in demonstrating the value of what it developed, your company will have competition and the price of your company's product will drop. The competition, which does not have the start-up and research costs that your company incurred while developing the product, can undercut your company's prices. That is why we see news reports with titles such as, "Analysts expect an avalanche of biotechnology offerings for the new year." This means that when a new company gets to a stage where underwriters<sup>30</sup> believe that the public will buy the new

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<sup>26</sup> See Sheila Zrihan-Licht et al., *Association of Csk-homologous Kinase (CHK) (formerly MATK) with HER-2/ErbB-2 in Breast Cancer Cells*, 272 J. BIOLOGICAL CHEMISTRY 1856, 1856 (1997).

<sup>27</sup> See Weeks, *supra* note 5.

<sup>28</sup> See Lynn Pasahow & Andrew Kumamoto, *Human Genome Project Raises Patenting Issues*, NAT'L. L. J., Oct. 20, 1997, at C31.

<sup>29</sup> See Thomas Barlow, *The Real Workers Behind the Genes*, FIN. TIMES, Oct. 11, 1997, at 2 ("The sole purpose of most genes is to prescribe an amino acid sequence for a particular protein."); see also Paul L. DeAngelis et al., *Hyaluron Synthase of Chlorella Virus PBCV-1*, 278 SCIENCE 1800, 1801 (1997) (describing how a protein type is determined after discovering its amino acid sequence).

<sup>30</sup> An underwriter "insure[s] the satisfaction of an obligation, such as an insurance contract or the sale of bonds. . . . To underwrite a stock or bond issue is to insure the sale of stocks or bonds by agreeing to buy, before a certain date, the entire issue if they are not sold to the public, or any part of the issue remaining after the sale." BARRON'S LAW DICTIONARY 531 (1996).

company's stock, they sell equity in the new company. That brings money back to the company to pay its expenses, in the hope that someday the product will pay off.

11. It is important to get "ownership," in the form of patents, for the information that a company develops. This is really not ownership at all. At best, it is the right to exclude others from making, using, or selling the company's development<sup>31</sup> for a period of twenty years after the date the patent is filed.<sup>32</sup> At the end of the twenty years, the patented product is available to the whole world.<sup>33</sup> When patents expire, others who have not incurred the research and development or FDA costs are free to make the drug.<sup>34</sup> That is why the bottom falls out of the market price for generic drugs, resulting in a price that is very good for patients.<sup>35</sup>

12. United States law requires three basic prerequisites to obtain a patent. The first is disclosure.<sup>36</sup> In return for complete disclosure of how to make or use the development, the inventor or his assignee is given the right to exclude others.<sup>37</sup> This right to exclude others, a fundamental doctrine supported in the Constitution,<sup>38</sup> has led to the publication of over five-and-one-half million patents.<sup>39</sup> The Patent and

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<sup>31</sup> See 35 U.S.C. § 271(a) (1994).

<sup>32</sup> See 35 U.S.C. § 154(a)(2) (1994).

<sup>33</sup> See *id.*; see also *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964) ("[A] projection of the patent monopoly after the patent expires is not enforceable."); Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 299 (1994) ("When a patent's term expires, the patented invention is no longer protected, and anyone may freely make, sell, or use the invention.").

<sup>34</sup> See *Brulotte*, 379 U.S. at 32.

<sup>35</sup> See Stephen D. Moore, *Astra's Successful Ulcer Drug May Become Bellyache*, WALL ST. J., Nov. 26, 1996, at B4 ("Loss of patent protection—and competition from generic copycat versions—usually slashes the U.S. price of a medicine by 80% within a few months."); see also Elyse Tanouye & Robert Langreth, *With Patents Expiring on Big Prescriptions, Drug Industry Quakes*, WALL ST. J., Aug. 12, 1997, at A1 (noting that when the patent on Capoten, a heart drug from the Bristol-Myers Squibb Company, expired, "the 57-cent-a-pill brand was competing with generics selling for three cents a pop").

<sup>36</sup> See 35 U.S.C. § 112 (1994).

<sup>37</sup> See *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944).

<sup>38</sup> See U.S. CONST. art. I, § 8, cl. 8 (giving Congress the power "to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

<sup>39</sup> See U.S. Patent No. 5,712,098, HEREDITARY HEMOCHROMATOSIS DIAGNOSTIC MARKERS AND DIAGNOSTIC METHODS (issued Jan. 27, 1998) [hereinafter '098 Patent].

Trademark Office (“PTO”) organizes patents by subject matter,<sup>40</sup> and anyone can search and secure copies of any issued patent. Without the patent system, it is possible that no one would disclose their inventions because they could exploit their developments as trade secrets.<sup>41</sup> If the information was not a trade secret, no one would exploit it because the investor could never recoup the investment needed to get the product to the market. Competitors would see what the investor did, copy it, and cause the profit margins to drop.

13. I have heard critics of the patent system say that this system interferes with the free flow of scientific information.<sup>42</sup> My consistent response is that this is not and need not be so. There is no reason why publication of the newest discoveries cannot go out right on time. You have to file a patent application within one year of publicizing the information<sup>43</sup> and you need patent lawyers with fast feet. But the patent system promotes, rather than hinders, the overall flow of information.

14. Built into patent law are a number safeguards, such as the novelty requirement.<sup>44</sup> I am not sure these safeguards were established because of the issues we have in mind at today’s discussion, but they do exist. A patent cannot extract from the world something that is already there.<sup>45</sup> Any patent claim that proposes to prevent others from doing, making, using, or practicing something that they were doing prior to invention is invalid.<sup>46</sup> That is the real meaning of the so-called “novelty requirement.” The claim must be for something that has never been

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<sup>40</sup> See U.S. PAT. & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 902-03 (6th ed. rev. 3 1997).

<sup>41</sup> Trade secret laws protect the holder of the trade secret “against the disclosure or unauthorized use of the trade secret by those to whom the secret has been confided under the express or implied restriction of nondisclosure or nonuse.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 475 (1974) (citing OHIO REV. CODE ANN. § 1333.51(c) (Supp. 1973)). Without “minimal novelty,” a trade secret is “usually known”; novelty, however, is not a prerequisite for trade secret protection. *Id.* at 476.

<sup>42</sup> See, e.g., Eric M. Lee, 35 U.S.C. § 287(c)- *The Physician Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC’Y 701, 702-703 (1997) (detailing the American Medical Association’s condemnation of patenting medical procedures, calling such patents unethical and a burden on the free flow of information).

<sup>43</sup> See 35 U.S.C. § 102(b) (1994).

<sup>44</sup> See *id.* § 102(a)-(b); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (stating that the novelty requirement is expressed in 35 U.S.C. § 102(a)-(b) (1994)).

<sup>45</sup> See *Bonito Boats*, 489 U.S. at 148.

<sup>46</sup> See generally 35 U.S.C. § 102(a)-(b).

available to the public.<sup>47</sup> One of the purposes of the patent lawyer's search in the PTO is to see if the invention is novel. For example, over 60 years ago scientists discovered that cortisone combats inflammation in the body.<sup>48</sup> Purified cortisone is now made for use as a drug, which is patented. But there is no way that these patents can ever cover or prohibit the natural process going on in your body.

15. The second requirement for patentability is non-obviousness to a person skilled in the art at the time of the invention.<sup>49</sup> Thus, an inventor cannot make only minor changes to the prior art; the invention must involve what Europeans call the "inventive step."<sup>50</sup>

16. The final requirement for obtaining a patent is traditionally quite simple and uncontroversial: utility.<sup>51</sup> In the field of genomics, however, the definition of utility is vague, and in my opinion, the law needs to be sharpened to prevent potential abuses. The utility requirement provides that you cannot get a patent on a new invention, such as a new DNA sequence, unless you have disclosed a utility for that sequence. What utility means is not entirely clear, especially in biotechnology.

17. This brings to mind a story in a legal newspaper several years ago<sup>52</sup> that involved patent applications filed by Craig Ventner.<sup>53</sup> Ventner invented a very quick way to sequence mRNA, listed these sequences, and filed thousands of patent applications on actual human genetic sequences.<sup>54</sup> Reportedly, he was not aware of

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<sup>47</sup> See *id.* (stating that a patent will be denied if the invention was previously "known or used").

<sup>48</sup> See, e.g., U.S. Patent No. 3,928,568, AMPLIFYING FACTOR OF CORTISONE INDUCTION AND PROCESS OF THE PRODUCTION THEREOF (issued Dec. 23, 1975).

<sup>49</sup> See 35 U.S.C. § 103 (1994); see also *Graham v. John Deere Co.*, 383 U.S. 1, 3-4, 17 (1966). The court in *Graham* held that, while 35 U.S.C. § 103 codifies judicial precedents requiring a degree of innovation, it also requires "inquiries into the obviousness of the subject matter sought to be patented." *Id.* at 17.

<sup>50</sup> "Judging an invention as useful, novel and non-obvious is synonymous with saying that this creative, inventive step has successfully occurred." Gary Dukarich, *Patentability of Dedicated Information Processors and Infringement Protection of Inventions That Use Them*, 29 JURIMETRICS J. 135, 157 (1989).

<sup>51</sup> See 35 U.S.C. § 101 (1994).

<sup>52</sup> Victoria Slind-Flor, *Patents Pending?*, NAT'L. L.J., June 8, 1992, at 1.

<sup>53</sup> Craig Ventner is a noted scientist at the National Institutes of Health ("NIH").

<sup>54</sup> See *id.*

the functions of the mRNA he was sequencing.<sup>55</sup> I do not understand how patents can be granted for lists of mRNAs. What is the utility? How do these applications meet the non-obviousness requirement? What are these genes for?

18. What I am told, and this is second-hand, is that ultimately the NIH abandoned these applications.<sup>56</sup> These applications will never be made available to the public, unless evidence is leaked from the NIH, because patent applications are secret.<sup>57</sup> I have heard that the PTO rejected Ventner's case because he had insufficient utility. Ventner asserted that the utility was well known because RNA is one-half of the double helix DNA strand; thus, by knowing one-half of the double helix strand, you can reconstruct its complement to determine the entire DNA strand.<sup>58</sup> The PTO was not persuaded.

19. This does mean that there should be some sharpening of the law. What do we mean by utility? In one sense, utility encompasses anything that has mass and can be put in a bottle or used as a door stop. But that is not what the PTO means by utility. The PTO's utility has to relate to the structure that you are inventing.<sup>59</sup> This requirement, therefore, needs some improvement.

20. Another brief story about utility concerns the PTO and its bureaucratic ways. For approximately three years, the PTO would not allow patents for any therapy unless there was proof of clinical testing with the FDA.<sup>60</sup> Several patent examiners admitted that for some time, "utility" involved a demonstration of utility in a clinical setting, as required by the FDA.<sup>61</sup> That has never been the law. This policy was modified only a year ago.<sup>62</sup>

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<sup>55</sup> See Christopher A. Michaels, *Biotechnology and the Requirement for Utility in Patent Law*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 247, 252 (1994).

<sup>56</sup> See *US NIH Abandons Gene Patent Plans*, MARKETLETTER, Feb. 21, 1994, available in 1994 WL 2621667.

<sup>57</sup> See 35 U.S.C. § 122 (1994); *Meese v. Eaton Mfg. Co.*, 35 F.R.D. 162, 165 (N.D. Ohio 1964); 37 C.F.R. § 1.14 (1997).

<sup>58</sup> See Michaels, *supra* note 55, at 251.

<sup>59</sup> See *Brenner v. Manson*, 383 U.S. 519, 534-535 (1966) (stating that until an invention is "refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field").

<sup>60</sup> See *Patents: Patent Wall Comes Down*, APPLIED GENETICS NEWS, Jan. 1, 1995, available in 1995 WL 8249240.

<sup>61</sup> *Cf. id.*

<sup>62</sup> See *id.*

21. There are many ethical and complex issues involved in the ownership of genomics and the proper handling of the information derived therefrom. But getting patents is not terribly controversial from my perspective, which of course, is from the perspective of the biotechnology industry, which pays my bills.

22. The last subject that I want to address is one unique to biotechnology: self-replicating products.<sup>63</sup> These products raise some unique legal issues from the point of view of ownership. Because I do not know the answers to these questions, I will leave you with a hypothetical for others to discuss. Suppose investigator A reads an article about investigator B, who discovered a useful gene. That gene is now cloned into a virus. Investigator B carefully propagates the virus and manipulates it properly so that it expresses the gene and can be reproduced whenever he wants. Another researcher writes him and says, "Dear Joe, I read your wonderful article. Please send me a sample of your virus. I want to play with this. I want to do some experiments. I have some great ideas on what your new protein can do." The researcher writes back and says, "I am very sorry. We have patent applications out on this and we never let our viruses out of the lab under any circumstances. You are my competitor, and it is not fair to send you the sample." The recipient of the letter looks at it with sadness, but he is a very good at deriving genetic material. He knows that the viruses that infect bacteria spore regularly and that those seeds land all over the place. A takes B's letter, extracts the virus, and pulls out the DNA. What are the rights of the parties? I do not know the answer.

**Lawrence Wittenberg:**

23. We will not make Dean DeLisi answer that last question, nor will we hold him completely responsible for all the questions raised by the Human Genome Project ("HGP").

**Dean Charles DeLisi:**<sup>64</sup>

24. When the HGP began in 1987,<sup>65</sup> large scale DNA sequencing was funded almost entirely by the Federal Government. During the past ten years, patterns of funding have shifted and the shift is accelerating. The completion of the human

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<sup>63</sup> Cf. Ed Bjurstrom, *Biotechnology Fermentation and Downstream Processing*, CHEMICAL ENGINEERING, Feb. 18, 1985, available in 1985 WL 2163902 (citing plasmids as examples of self-replicating biotechnology products).

<sup>64</sup> Dr. Charles DeLisi is the Dean of the College of Engineering at Boston University and has been involved in biotechnology for many years. In 1986, he was the Director of the Department of Energy's ("DOE") Health and Environmental Research Program and was the founder of the DOE's Human Genome Project.

<sup>65</sup> The HGP is an international effort to map the positions of all the human genes on chromosomes. See *Human Genome Project Information* (visited May 25, 1998) <<http://www.ornl.gov/TechResources/HumanGenome/home.html>>.

genome will be carried out largely by a few specialized biotechnology companies. The biotechnology industry is supported primarily by venture capital and pharmaceutical money, with only about one-third of its funding derived from federal sources.<sup>66</sup> Because starting such companies is costly, a drive to recover costs and make profits should not be surprising. As of 1996, patents had been sought on more than 1200 human genes and many more were sought on DNA fragments,<sup>67</sup> entire genomes, and cell lines from inbred populations. Has the drive for profit increased to the point that our ethical values are being compromised?

25. The patenting of cell lines from inbred populations has been a major source of controversy. Inbred groups<sup>68</sup> of people tend to be much less genetically diverse<sup>69</sup> than the population as a whole. Working with biological tissue from such groups simplifies the task of mapping the genes (i.e. finding their chromosomal locations) responsible for certain traits. Examples include resistance to heart disease in the Limone Village of Northern Italy, resistance to leukemia among the Guaymi Indians of Panama, and reduced incidence of malaria in Africa's Sudan. In some instances cell lines have been used without informed consent. The Guaymi Indians and the case of John Moore<sup>70</sup> are examples. Nor is it clear what informed consent means to a group whose culture is inherently different than our own.

26. Similar problems were initially present even in the Human Genome Diversity Project ("HGDP"). The HGDP's goal is to sample people in 722 indigenous and isolated communities in order to preserve their history before they vanish;<sup>71</sup> clearly a noble undertaking. Nevertheless, it seems plausible that the project will spin off important medical information.

27. One of the more fundamental issues is the availability of the benefits of the new knowledge and technologies to the people who need them the most, as well as to the public at large. One can imagine a scenario in which people contribute

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<sup>66</sup> See Steve Ginsberg, *The New Resume: Jobs, Schools, Genetic Makeup?*, S.F. BUS. TIMES, Nov. 21, 1997, at 8A, available in 1997 WL 15945933.

<sup>67</sup> See generally Melissa L. Struges, Note, *Who Should Hold Property Rights to the Human Genome?*, 13 AM. U. INT'L L. REV. 219 (1997) (discussing some of these patents).

<sup>68</sup> See generally, e.g., Arlen L. Rosenbloom et al., *The Little Women of Loja—Growth Hormone-Receptor Deficiency in an Inbred Population of Southern Ecuador*, 323 NEW ENG. J. MED. 1367 (1990) (discussing a study of an inbred Spanish population in southern Ecuador with a high incidence of Laron-type dwarfism).

<sup>69</sup> See WILLIAM M. SHIELDS, PHILOPATRY, INBREEDING, AND THE EVOLUTION OF SEX 67-68 (1982) (suggesting that outbred populations experience greater fitness than inbred populations).

<sup>70</sup> See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482-84, 497 (Cal. 1990). For a more thorough discussion of the circumstances surrounding *Moore*, see *infra* notes 83-91 and 117-28.

<sup>71</sup> See *id.*

cells, those cells are used for important discoveries, and the resulting newly developed therapies are expensive and inaccessible to the very people who were the contributors. Guidelines for truly informed consent<sup>72</sup> and for equitable distribution of profits need to be developed, while still ensuring that profit incentives remain available for the development of new drugs.

28. An ethical question of a different sort is whether patenting genes denigrates, in some sense, human dignity. My own feeling is that this concern attributes too much to human genes. The genome alone does little more than encode biological development; whereas what gives us humanity is socialization.

29. Another issue concerns the effects of patenting on progress. Although the purpose of a patent is information dissemination, patenting too early can slow the pace of R&D. First, the costs of licensing a patent can be very high, making emergence of new companies difficult. Second, new technologies are often complicated, with different companies holding patents for different components of the technology. Under such circumstances infringements, law suits, and the concomitant gridlock are almost inevitable. The history of the electronics industry, however, tells us that such obstacles can be overcome.

30. A related question is whether information is being restricted too early in the drug discovery process.<sup>73</sup> When in the discovery process should a patent be applied for? What controls if any should be placed on the commercial ownership of generic data?

31. I believe that all the problems now being experienced by the biotechnology industry are a natural phase in the growth of a new industry. We can expect mistakes along the way, but if history is a guide, most problems will soon be resolved.

**Michael Gollin:**<sup>74</sup>

32. I have been practicing in Washington, D.C., and have been involved in issues related to intellectual property rights. I would like to go beyond discussing how to obtain and enforce intellectual property rights and consider how strong those rights should be, what those rights should apply to, and what some of the impacts of ownership of intellectual property rights are. Particularly, this is related to what I

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<sup>72</sup> See, e.g., *Moore*, 793 P.2d at 483-487.

<sup>73</sup> This restriction is due, at least in part, to a provision of the Patent Act that denies patent protection to inventions that were in public use more than one year before the inventor applied for a patent. See 35 U.S.C. § 102 (1994).

<sup>74</sup> Michael Gollin is a patent attorney and partner at Spencer & Frank in Washington, D.C. He has more than a decade of experience assisting clients with intellectual property and biotechnology matters. He has prosecuted patents involving pharmaceuticals and gene therapy and is also involved in bioprospecting policy.

refer to as “bioprospecting,”<sup>75</sup> which means the exercise of looking through nature’s wealth of information and material and finding useful products and processes from it. That includes, of course, plant and animal prospecting and, of relevance here today, the activities we have heard about relating to human bioprospecting. The term “prospecting” is used in the same sense as with the extraction of minerals: namely, looking through a lot of material and searching for the mother lode. It is difficult enough trying to understand how to apply intellectual property rights in this regime. That certainly takes a great deal of our time on a day-to-day basis, and much effort is spent in that allocation of resources. I want to proceed a step beyond that and add my own perspective on who should own genetic information, how we should decide whether intellectual property rights are strong enough, and whether they apply to the right things.

33. If you look at genetic information as an exercise in prospecting, you must look from the raw material to the end product and try to understand who has the rightful claims to each. Thus, you look for sources of law in various places. There is very little law that deals specifically with the issue of who owns human genetic material. There have been a couple landmark decisions,<sup>76</sup> but very little legislative activity.<sup>77</sup> I think this is a hot topic because there is no consensus.

34. When you deal with a situation such as the HGDP, you begin with an individual’s genetic information. I believe that the first genome sequenced in the HGDP was from a researcher in the project who donated his or her genome to the study voluntarily.<sup>78</sup> In this common situation, the issue of who owns that particular genome is not difficult to resolve. It becomes more difficult, as Charles DeLisi was saying, when you have a less clear-cut type of consent.

35. In a case that I understand Wendy McGoodwin will discuss,<sup>79</sup> a patient went to the University of California to have his spleen removed.<sup>80</sup> After examining

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<sup>75</sup> See generally Michael A. Gollin & Sarah A. Laird, *Global Policies, Local Actions: The Role of National Legislation in Sustainable Biodiversity Prospecting*, 2 B.U. J. SCI. & TECH. L. 16 (1996).

<sup>76</sup> See generally Moore, 793 P.2d at 479; *University of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q. 1225 (S.D. Ind. 1995), *rev’d in part*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

<sup>77</sup> New Jersey has passed a bill preventing consumers from losing insurance as a result of genetic testing. See N.J. STAT. ANN. § 10:5-12 (West Supp. 1998); *Whitman Signs Comprehensive Genetic Privacy and Anti-Discrimination Bill*, HEALTH LEGIS. & REG. WKLY., NOV. 27, 1996, available in 1996 WL 11279654 [hereinafter *Whitman Signs*].

<sup>78</sup> For a proposal mandating informed consent, see Proposed Recommendations of the Task Force on Genetic Testing; Notice of Meeting and Request for Comment, 62 Fed. Reg. 4539, 4540 (1997) (proposed Jan. 29, 1997).

<sup>79</sup> See *infra* notes 117-28 and accompanying text.

<sup>80</sup> See Moore, 793 P.2d at 481.

the spleen, the researchers isolated a cell line, patented it, and made a lot of money.<sup>81</sup> The patient, John Moore, sought a share of those profits through the California courts, claiming conversion, unjust enrichment, and various other types of torts.<sup>82</sup> The Supreme Court of California held that he only had a claim for breach of the duty to obtain informed consent against the doctors who treated him because they did not tell him what they were taking or what they were doing to his spleen; hence, there was no informed consent.<sup>83</sup> He had not agreed that they could use the spleen for commercial purposes, but the court threw out the other claims, including conversion.<sup>84</sup>

36. Taking the simplest approach, it would seem appropriate to find that the spleen was property, that his doctors used it, interfered with his rights, and thus, should pay damages. But the court was unwilling to go so far as to say that people have a property right in their human cells.<sup>85</sup> The unique human essence is not subject to property rights, and this view is based on the Thirteenth Amendment's slavery prohibitions.<sup>86</sup> But the irony of this case is that the individual source of the genetic material for the cell line, and here I am using a slightly broader definition of genetic information than we heard at the beginning, was found to have no right to the benefits from that material, whereas those who misappropriated it were given the right to do so.<sup>87</sup> That is certainly an ironic outcome, and there has been no resolution of that irony.

37. I next look at an area of law that is just evolving as a source of guidance, the Convention on Biological Diversity (the "Convention").<sup>88</sup> The Convention applies to plants, animals, and microorganisms.<sup>89</sup> It deals with biological resources that are

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<sup>81</sup> See *id.* at 482.

<sup>82</sup> See *Moore v. Regents of Univ. of Cal.*, 249 Cal. Rptr. 494, 498-99 (Cal. Ct. App. 1988).

<sup>83</sup> See *Moore*, 793 P.2d at 497.

<sup>84</sup> See *id.*

<sup>85</sup> See *id.* at 489.

<sup>86</sup> See U.S. CONST. amend. XIII, § 1 ("Neither slavery nor involuntary servitude . . . shall exist within the United States.").

<sup>87</sup> See *Moore*, 793 P.2d at 498.

<sup>88</sup> See Convention on Biological Diversity, *opened for signature* June 5, 1992, 31 I.L.M. 818.

<sup>89</sup> See *id.* art. 2, 31 I.L.M. at 824 (defining "genetic material" as "plant, animal, microbial or other organisms containing functional units of heredity").

the common heritage of mankind.<sup>90</sup> This is analogous to the first type of genetic information that Edmund Pitcher referred to as the natural information you would own in your DNA. Plants, animals, and microorganisms as they exist in nature would seem to be freely available without restriction. The Convention changed that, making them subject to sovereign national rights and creating a mechanism for countries to regulate access to commonly-held biological resources.<sup>91</sup> This has led to bioprospecting agreements whereby those who wish to prospect and use such biological resources to find useful substances agree to share the benefits that might result from commercialization.<sup>92</sup> This includes money and sustainable development.<sup>93</sup> Another aspect of this new regime is that the benefits should flow back to enable the nation to conserve the biological resources.<sup>94</sup>

38. While the analogy is not perfect, the notion of a sovereign's right over a natural resource is somewhat analogous to the notion of the individual's essential right of control over his or her body. The Convention says that no biological resource should be taken without informed consent.<sup>95</sup> This issue of informed consent is still evolving in the Convention context as it is evolving in the human context. We need much more help from ethicists in defining exactly in what situation there has been consent and to what extent it is informed. That leaves us with perhaps a helpful framework, although one that is not yet fully developed.

39. Let me just use my time for a couple more points. Let us say that there has been an involuntary use of information, or of genetic material, such as tissue. What are the limitations on the property rights of somebody who is prospecting for that material? I think that claims for conversion could be made for this

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<sup>90</sup> See *id.* art. 2, 31 I.L.M. at 823 (defining "biological resources" as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity").

<sup>91</sup> See *id.* art. 15, 31 I.L.M. at 828.

<sup>92</sup> See *id.* art. 19, 31 I.L.M. at 830; see also WALTER V. REID ET AL., BIODIVERSITY PROSPECTING 1-2 (1993) (discussing bioprospecting activity); John R. Adair, Comment, *The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources*, 24 *ECOLOGY L.Q.* 131, 153-155 (1997) (discussing current domestic bioprospecting activity).

<sup>93</sup> See Convention on Biological Diversity, *supra* note 92, arts. 19-21, 31 I.L.M. at 830-832; see also BIODIVERSITY PROSPECTING, *supra* note 96, at 290 (noting that the first article of the Convention on Biological Diversity contains three explicit objectives: "conservation of biodiversity, sustainable development of genetic resources, and 'fair and equitable sharing' of the resulting benefits").

<sup>94</sup> See Convention on Biological Diversity, *supra* note 92, arts. 19-21, 31 I.L.M. at 830-832; BIODIVERSITY PROSPECTING, *supra* note 96, at 290.

<sup>95</sup> See Convention on Biological Diversity, *supra* note 92, art. 15, 31 I.L.M. at 828.

appropriation in certain jurisdictions. I think that one could also argue the notion of constructive trust: that is, if somebody takes my property and uses it for their benefit, even though we may not have a relationship of trust, the court might impose on them the duties of a trustee and use that relationship as a justification for ordering that the benefits be shared.<sup>96</sup>

40. In a case dealing with human cell lines, also involving the University of California, an interesting point was raised as to whether a patent based on material obtained inappropriately should be invalidated.<sup>97</sup> The District Court in Indiana invalidated a patent because researchers had improperly obtained a cell line and misrepresented to the PTO where they acquired the material that resulted in the patented product.<sup>98</sup> The court said that this was grounds for invalidating the patent, but the Federal Circuit reversed, holding that the misrepresentation was not material.<sup>99</sup> Nonetheless, this case raises another basis for a person who had provided genetic material to attack an ownership claim. Turning the point around, this is another reason why those who are trying to protect intellectual property rights say that they need to be sure that they have a good pedigree for the information that they use.

41. I would like to make just one other point: we should look at how strong intellectual property rights, particularly patents, are from the policy perspective of whether they are doing what we want them to do. We are in an era of transition; there is a lot of pressure to strengthen patent and other laws, and there is pressure to eliminate protection in certain areas. For example, Congress recently proposed an act which essentially eliminated patent protection for medical procedures.<sup>100</sup> There is a tension that has existed for decades and is likely to continue, between calls for more protection and calls for less protection.

42. I will raise several of the pros and cons of intellectual property rights which apply to patents in this area. On the positive side, for example, exclusive rights create an incentive for people to go out and create something and reward people for having done that. In addition to the public disclosure benefit, there is also

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<sup>96</sup> A constructive trust is defined as a “[t]rust created by operation of law against one who by actual or constructive fraud, by duress or by abuse of confidence, or by commission of wrong, or by any form of unconscionable conduct, or other questionable means, has obtained or holds legal right to property which he should not, in equity and good conscience, hold and enjoy.” BLACK’S LAW DICTIONARY 314-315 (6th ed. 1990).

<sup>97</sup> See *University of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q. 1225, 1246-1258, *rev’d in part*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

<sup>98</sup> See *id.*

<sup>99</sup> See 119 F.3d 1559.

<sup>100</sup> See generally *Medical Procedures Innovation & Affordability Act*, H.R. 1127, 104th Cong. (1995).

a labor theory; if you work hard for something, you deserve the product as a justification for your labor.<sup>101</sup> There is a moral rights notion that if you create something, you have a parental-like right to control it. This gives artists in the fine arts the right to prevent their paintings from being cut up, even by a purchaser of the painting.<sup>102</sup>

43. On the negative side, rights that are too strong, or are inappropriate, generate criticism and may lead to pressure for eliminating them in certain areas. If you make an invention but do not file a patent application, it goes into the public domain; but if you file a patent application for it, it might be twenty years before it enters the public domain.<sup>103</sup>

44. We are left with the problem of how to create the appropriate incentives. Patented products are more expensive than generic and, again, the additional expense is part of the reward for the inventor. Thus, inventors tend to concentrate on the protectable rather than things that are in the public domain.

45. We see in the natural products area that there is very little incentive. Products such as herbal extracts are non-researched, and there is no incentive for people to do studies because these products are in the public domain.<sup>104</sup> Research is expensive; it demands infrastructure. Using intellectual property to provide research incentives, however, stimulates complaints from people who think it is morally insupportable to take natural products or aspects of human identity and attach property rights to them.<sup>105</sup> In fact, the United States is one of the few countries that allows any patents on living organisms and one of a clear minority

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<sup>101</sup> See JOHN LOCKE, PHILOSOPHY OF CIVIL GOVERNMENT 133 (Ernest Rhys ed., E.P. Dutton & Co. 1924) (1690).

<sup>102</sup> See 17 U.S.C. § 106A (1994) (“[T]he author of a work of visual art . . . shall have the right . . . (B) to prevent any destruction of a work of recognized stature, and any intentional or grossly negligent destruction of the work is a violation of that right.”).

<sup>103</sup> See 35 U.S.C. § 154(a)(2) (1994).

<sup>104</sup> See James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 176 (1994) (stating that research requires a substantial financial outlay, such outlay only being expended if the researchers feel they can get a return on their investment through patent protection).

<sup>105</sup> See Philippe Ducor, *The Legal Status of Human Materials*, 44 DRAKE L. REV. 195, 258 (1996) (noting the initial outcries, based on moral and ethical reasons, regarding the practice of patenting human cell lines, nucleic acids, and proteins); see also Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 201 (1996) (citing religious leaders that have raised public policy objections to the patenting of human life forms).

that allows patents on genetic information.<sup>106</sup> That is changing, and I will conclude with the point that the changes are in the direction of more protection for some areas of genetic research while rollbacks in other areas are likely.

**Wendy McGoodwin:**<sup>107</sup>

46. I should probably say a little about the organization I represent because it will help illuminate the perspective that I bring. I direct a nonprofit bioethics group called the Council for Responsible Genetics. We are a national organization. Our members include scientists, bioethicists, and concerned citizens. Our mission is to promote public education of ethical issues in genetic technologies and advocate socially responsible uses of those technologies. We are working on a number of issues, and high on our agenda is the issue of gene patents and patents on living organisms. We come down firmly in opposition to this practice. We do not think that it is an appropriate use of the patent system to patent living creatures or their component parts.

47. To illustrate how we come to this position, I would like to share with you a story from one of our members. This woman is a physician who has a genetic disease called hemochromatosis, a genetic disorder that affects the level of iron retained by the body.<sup>108</sup> If it is left untreated, iron levels build up in the blood and can cause damage to the liver that can ultimately be fatal.<sup>109</sup> It is, however, a condition that has an easy and inexpensive treatment.<sup>110</sup> For those people who have a family history of the disease, it is very important that they be identified as having this gene mutation because then they can start treatment as soon as possible.<sup>111</sup>

48. For many years, the only way that doctors could identify this disease was through routine lab work. Elevated concentrations of iron in the blood is indicative of hemochromatosis. Last summer, researchers identified the gene mutation for

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<sup>106</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980) (stating that “Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering,” but because Congress had not done so, the Court could uphold the validity of a bacterium patent).

<sup>107</sup> Wendy McGoodwin is the Executive Director of the Council for Responsible Genetics. Founded in 1983, the Council is one of the nation’s leading organizations working to promote a public interest perspective in biotechnology.

<sup>108</sup> See Bruce R. Bacon, *The Elusive Hemochromatosis Gene and Other Reports on Iron Metabolism* (visited Mar. 25, 1998) <<http://sadio.ucsf.edu/ALF/ALFfinal/proghemochrom.html>>.

<sup>109</sup> See *id.* (noting that hemochromatosis can lead to liver cancer).

<sup>110</sup> See *id.* (“The current treatment for hereditary hemochromatosis is simple and involves reducing the amount of iron in the body by removal of blood (phlebotomy, “bloodletting”) at weekly intervals.”).

<sup>111</sup> See *id.*

hemochromatosis. Mercator Genetics, a biotechnology company, cloned and patented it.<sup>112</sup> This was a great breakthrough and a welcome event for the families of those individuals who had been lost to the disease.

49. Our member, the doctor, called me. She was practically in tears. She said, “Wendy, you will never believe what happened. It is wonderful and terrible. Our gene has finally been found, but they went and patented it.” She shared the process by which this gene discovery took place, and I think that it is quite interesting.

50. The hemochromatosis community is a well-organized community. They have a very strong network of support groups and physician referrals, and our doctor is the coordinator for this genetic disease support group. When she first learned that there were researchers at Mercator Genetics who were interested in working on this disease, she was delighted. She said, “We want to help you. We will do everything that we can to help find this gene mutation.” She rallied the troops. She had everybody in her organization with a family history of this disorder get their blood samples to California. Everybody in their little organization contributed blood specimens so that Mercator could use them in its search for this gene mutation. Never once were they informed that if the gene was identified, the company would claim exclusive patent monopoly on that gene. They were outraged when they learned that this is exactly what had happened. Again, it was elation tinged with despair. They were delighted to hear that the gene was finally sequenced and that there would soon be a test available for it. At the same time, they had a great fear that the test might be too expensive for many of their members, given the fact that the gene sequence information had been patented.

51. Michael Gollin and others here have referred to another controversy in the gene patent debate: the case of the John Moore cell line.<sup>113</sup> For those of you who are not familiar with the concept of a cell line, I can give you a beginner’s introduction. Usually, if you take cells out of their natural environment they die; they need to be in a living body to be considered alive. But, if you put some cells in a petri dish and keep it at the right temperature, give them adequate nutrients, and control a couple other factors, those cells will continue to divide indefinitely. I am not sure if you would consider them alive, but they are considered to be immortalized. That is what scientists refer to when they talk about a cell line. They are talking about a collection of perpetually dividing cells.

52. John Moore was a businessman in Alaska, who, in the mid-1970s, came down with a very rare form of cancer called hairy cell leukemia.<sup>114</sup> He searched all over the country for a top cancer specialist and finally ended up at the University of

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<sup>112</sup> See ’098 Patent, *supra* note 39.

<sup>113</sup> See *Moore v. Regents of the Univ. of California*, 793 P.2d 479 (Cal. 1990).

<sup>114</sup> See *id.* at 481.

California at Los Angeles (“UCLA”) Medical Center in the care of Dr. David Golde.<sup>115</sup> Dr. Golde confirmed his diagnosis and removed John Moore’s spleen.<sup>116</sup> Dr. Golde observed that John Moore’s cells were unique and were capable of producing valuable pharmaceutical products.<sup>117</sup> John Moore was brought back to his doctor’s office on several occasions because the doctor wanted to do more blood work and take more samples.<sup>118</sup> It was never really clear whether this was necessary for John Moore’s treatment or whether this was for the benefit of getting the perfect cell line. Unbeknownst to John Moore, his physician cultured a cell line out of those spleen cells and filed a patent on it.<sup>119</sup>

53. The PTO issued a patent to Dr. Golde and UCLA on the John Moore cell line.<sup>120</sup> John Moore finally found out about this patent, not from his physician, but from an indirect source.<sup>121</sup> As you can imagine, Moore felt betrayed that the person that he turned to for help in saving his life had exploited his cells to develop what turned out to be a multimillion dollar product.<sup>122</sup> As we have heard, John Moore filed a suit asserting his ownership over his cells.<sup>123</sup> This was in the 1980s. I think it is useful to revisit the case and the motivations that John Moore had when he filed that lawsuit because it fits the context of the debate around gene patents.

54. When John Moore learned about the patent, he was angry. He had just found out that another person had a patent on his cells. This was supposed to be someone on his side. Of course, the first thing he did was to contact a lawyer. The first thing the lawyer said was, “We should sue your doctor. The grounds for this suit are that the patent should not have gone to Dr. Golde and UCLA. It should actually go to John Moore because they were your cells.” If you talk with John Moore

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<sup>115</sup> *See id.*

<sup>116</sup> *See id.*

<sup>117</sup> *See id.*

<sup>118</sup> *See id.* at 481.

<sup>119</sup> *See id.* at 481-82

<sup>120</sup> *See id.* at 482.

<sup>121</sup> *See* Michelle J. Burke & Victoria M. Schmidt, *Old Remedies in the Biotechnology Age: Moore v. Regents*, 3 RISK: ISSUES IN HEALTH & SAFETY 219, 223 (1992) (stating that it was through the investigation of Moore’s attorney that the patent was discovered).

<sup>122</sup> *See* John Vidal & John Carver, *Lambs to the Gene Market: What Do Tracy the Sheep and John Moore Have in Common? Millions of Pounds Can Be Made From Cells Taken From Their Bodies*, GUARDIAN, Nov. 12, 1994, at 25.

<sup>123</sup> *See Moore*, 793 P.2d at 482-83.

today, he will tell you that he does not think it is appropriate for anyone to hold a patent on human cells or other biological material.<sup>124</sup> At the time, the suit seemed like the right thing to do. Certainly, the patent should not belong to UCLA. We should fight so that the patent belongs to John Moore. In a sense, Moore has been a victim of circumstances because he was given a very limited choice by the framework of the PTO. The PTO's current practice of granting patents on human genetic information or biological materials looks very narrowly at who the patent should go to, party X or party Y, rather than the much more fundamental question of whether these materials should be patented in the first place.

55. We have seen that the debate around the patentability of human cell lines has not ended with John Moore. There is another very controversial patent application from a cell line that was derived from an indigenous member of the Hagahai Tribe in Papua New Guinea.<sup>125</sup> The Hagahai are members of an ethnic community that are incredibly geographically isolated, and, in fact, it was only twenty years ago that they had their first contact with outsiders. NIH researchers realized that many individuals in this community were infected with a unique viral variant and had cells that produced antibodies to that virus.<sup>126</sup> They took samples of blood and cultured a cell line.<sup>127</sup> The fact that the NIH was granted a patent on a product of not only another human being, but an indigenous person from a politically marginalized community, provoked international outrage.<sup>128</sup> After a one-and-a-half year battle in the courts, the NIH ultimately disclaimed the patent,<sup>129</sup> which I think is a success story.

56. Our organization believes that patents on human genes and other genetic material are inappropriate for a number of reasons. We believe that this practice promotes secrecy within the scientific community and builds up barriers to the free and open exchange of information. The molecular biologists within our organization complain that their colleagues are not willing to talk with them about their research until they have patented it. They are not willing to publish their research until the patent paperwork is in order and are very concerned about the climate of secrecy that has been engendered.

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<sup>124</sup> See Vidal & Carver, *supra* note 126.

<sup>125</sup> See Reginald Rhein, *Canadian Group Is 'Mouse That Roared' on Gene Patents*, BIOTECHNOLOGY NEWSWATCH, Dec. 4, 1995, available in 1995 WL 2197260.

<sup>126</sup> Cf. *id.*

<sup>127</sup> See *id.*

<sup>128</sup> See *id.*

<sup>129</sup> See *NIH Abandons HTLV-1 Patent*, ANTIVIRAL AGENTS BULL., Apr. 1, 1997, available in 1997 WL 9577558.

57. There is also a great deal of concern that these patents exploit what is essentially taxpayer-funded research. Much of the success of the biotech industry has been built up over fifty years of federally-funded biomedical research. In a sense, consumers are being asked to pay twice for these products: first, through tax dollars that have, in some cases, partially or wholly funded the research; and second, in the marketplace, where they are faced with high-priced drugs and other products.

58. There is a great deal of concern that patent monopolies will create systems of overpricing that may render valuable, life-saving treatments too expensive for many consumers. I think that it has been very telling to see the pricing scheme of the diagnostic test for the recently identified gene associated with an inherited risk for breast cancer. Myriad Genetics charges \$2400 for the test to identify this gene mutation.<sup>130</sup> You will have to ask yourself how many women can afford this test.

59. I always need to remind myself when we are in these settings that we are talking about law. But we are talking about laws that were not written by God, but rather, were written by humans. Because of that human agency, we are talking about laws that can be changed if they are not working for us. Thomas Jefferson was one of the drafters of the first United States patent act and was not particularly in favor of monopolies.<sup>131</sup> He thought they were a necessary evil – occasionally necessary to help inventors by giving them a safety cushion so they could continue to provide products that were useful to society.<sup>132</sup> In his original drafting of the patent laws, he clearly said that if patents were ever contrary to the public interest, the public interest should take precedence.<sup>133</sup> For example, the Atomic Energy Act forbids the patenting of nuclear weapons, not because someone cannot invent a nuclear weapon, but simply because it is not in the public interest to patent these sorts of inventions.<sup>134</sup>

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<sup>130</sup> See Michael Waldholz, *Predictive Use of Breast-Cancer Genetic Test Is Disputed*, WALL ST. J., May 15, 1997, at B1.

<sup>131</sup> See *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1966) (noting that Jefferson authored the 1793 Patent Act and that Jefferson, “like other Americans, had an instinctive aversion to monopolies”).

<sup>132</sup> See *id.* at 8 n.2 (quoting VI THE WRITINGS OF THOMAS JEFFERSON, 180-81 (Henry Augustine Washington ed.) (“Society may give an exclusive right to the profits arising from [patents], as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of society, without claim or complaint from any body. Inventions then cannot, in nature, be a subject of property.”)).

<sup>133</sup> See *id.* at 9-10.

<sup>134</sup> 42 U.S.C. § 2181(a) (1994) (“No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.”).

60. There has been very little public debate within the United States about the legality or the appropriateness of patenting human genes or genetic information. I always find it helpful to try and remove some of the blinders that have been imposed within our own country and examine what is happening beyond our borders. There has been an extremely vigorous debate in Europe about the patenting of human genes and genetically engineered life forms.<sup>135</sup> In March 1995, the European Parliament rejected a proposal from the European Commission that would have officially approved the patenting of human genes and genetically engineered life forms.<sup>136</sup> There are rigorous debates on this issue in countries such as India.<sup>137</sup>

61. New Jersey passed an anti-discrimination bill to safeguard consumers from losing their insurance after undergoing genetic testing.<sup>138</sup> The bill said that insurance companies cannot discriminate against you if you have had a bad genetic test and also offered some protections against workplace discrimination.<sup>139</sup> That is an approach that we support. Unexpectedly, an earlier version of the bill had provoked rampant debate about patents. Language was inserted into the bill that declared an individual's genetic information private and that an individual should control this information and decide who has access to it.<sup>140</sup> The bill came under extreme fire by the biotechnology and pharmaceutical industries in New Jersey. These industries supported the anti-discrimination provisions of this bill, but opposed the property rights language because they feared it would hinder their ability to patent genetic information.<sup>141</sup>

62. Unfortunately, that is all I can say about the legislative debate surrounding the patentability of gene fragments in the United States. There is, however, a growing movement within this country opposed to the patenting of human

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<sup>135</sup> See generally Ruth McNally & Peter Wheale, *Biopatenting and Biodiversity: Comparative Advantages in the New Global Order*, 26 *ECOLOGIST* 222 (1996).

<sup>136</sup> See *id.* The European Parliament published a new directive in January 1997. See *Biotech Patents Face Critical Decision in Europe* (visited May 25, 1998) <<http://www.ljextra.com/practice/internationalip/P11biotech.html>>. According to Ms. McGoodwin, in May 1998 the European Parliament issued a new patent directive that permits the patenting of human DNA sequences outside the body, prohibits the patenting of human cloning and germ line manipulation, and permits seed saving by farmers.

<sup>137</sup> See, e.g., G. Ganapathy Subramaniam, *India: Patent Laws: New Government to Have Hands Full*, *BUS. LINE (HINDU)*, May 6, 1996, available in 1996 WL 11679418.

<sup>138</sup> See N.J. STAT. ANN. § 10:5-12 (West Supp. 1998); see also *Whitman Signs*, *supra* note 81

<sup>139</sup> See *Whitman Signs*, *supra* note 81.

<sup>140</sup> See *id.*

<sup>141</sup> See *id.*

genes and life forms.<sup>142</sup> Recently, a coalition of nearly 200 religious leaders went on record in opposition to life-form patents.<sup>143</sup> There is also a stalwart coalition of consumer groups, public interest groups, and others that are in collaboration to raise this issue in communities and call for a moratorium on this practice.<sup>144</sup>

### Question and Answer Session

#### Lawrence Wittenberg:

63. I would like to recommend to everybody an article that discusses this topic in terms that are easy to understand for people like me, who do not practice in this area every day. This article, by Daniel McKay, was in the November 1994 issue of the *Santa Clara Computer and High Technology Law Journal* and describes the background of the previous discussion.<sup>145</sup>

64. First, let me ask one question, and then we will take questions and discussion from the audience. I would like to take the hardest case that Wendy mentioned. I have personally never had any sympathy for John Moore because the doctor had a choice between throwing the spleen out or using it to develop lifesaving drugs, and for some reason John Moore decided that he should complain about that. But let us talk about the woman with the hemochromatosis gene and the use of the blood samples from that group by a biotechnology company to find the gene and the subsequent patenting of the gene. In the absence of patent rights, would that gene ever have been discovered?

#### Edmund Pitcher:

65. No one really knows. I presume that the costs of collecting the blood samples, analyzing them, buying the equipment, and conducting the research carried a healthy price tag. If what was learned was given freely to the public, no money would have been made, and I do not know why anyone would expend these resources without some hope of reaping the rewards. The 200-year history of the United States suggests that the patent system has the effect of promoting discoveries such

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<sup>142</sup> See, e.g., Malinowski & O'Rourke, *supra* note 109, at 201 (citing the opposition of religious leaders).

<sup>143</sup> See *Biology on the Fast Track: Key Developments in Modern Biology*, TRANSPLANT NEWS, May 12, 1997, available in 1997 WL 8941017.

<sup>144</sup> See *Body and Soul: The Price of Bio-tech—The Blue Mountain Declaration: Groups State Their Views on Patenting Life Forms*, SEATTLE TIMES, Aug. 20, 1995, at B5 (reporting on a meeting of groups opposed to life form patents convened by the Council for Responsible Genetics).

<sup>145</sup> See generally Daniel L. McKay, *Patent Law and Human Genome Research at the Crossroads: The Need for Congressional Action*, 10 SANTA CLARA COMPUTER & HIGH TECH. L.J. 465 (1994).

as these and disclosing them to the public.<sup>146</sup> Whether in a given instance it works is hard to say. There is no way to prove it one way or the other.

**Charles DeLisi:**

66. Are you implying that without a patent system, technology development would be impeded? Is there any evidence for that?

**Edmund Pitcher:**

67. Well, there is not a control group, unless you look at the developing countries as the control group. Without a control group to compare results, any evidence would be meaningless.

**Michael Gollin:**

68. There are studies which have been conducted by people at the World Bank<sup>147</sup> and by various academics looking at populations of countries based on their protection of certain rights.<sup>148</sup> They find that there is clearly an association between the level of protection for certain technologies and the level of technology in those countries.<sup>149</sup> There have also been studies showing that biotechnology companies and investors will not invest in companies in countries in which there is not a lot of protection.<sup>150</sup> It is not clear at all, however, whether the association between low levels of intellectual property protection and low levels of investment is one of cause and effect. When a country gets to a certain technological level, it finds that it is in its self-interest to improve its patent protection.

**Charles DeLisi:**

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<sup>146</sup> See generally Michael J. Walsh, Comment, *The Disclosure Requirements of 35 U.S.C. § 112 and Software-Related Patent Applications: Debugging the System*, 18 CONN. L. REV. 855, 857-858 (1986) (stating that in order to receive a patent, full disclosure must be made to guarantee “to the public the full benefits of the discovery”).

<sup>147</sup> The World Bank Group is an umbrella name for multilateral banks that provide financial and economic assistance to developing countries. See John W. Head, *Evolution of the Governing Law for Loan Agreements of the World Bank and Other Multilateral Development Banks*, 90 AM. J. INT’LL. 214, 234 n.1 (1996).

<sup>148</sup> See Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, in International Finance Corporation of the World Bank Group Discussion Paper (1994), available in IFC Discussion Paper Abstracts (visited Sept. 28, 1997) <<http://www.ifc.org/DEPTS/OPS/ECON/PUBS/ABSTRACT.HTM>>.

<sup>149</sup> See *id.*

<sup>150</sup> See *id.*

69. The real hypothetical is: if there was no patent protection anywhere in the world, would technology still develop? I am not sure if there is evidence either way, but I suspect that technology would develop anyway.

**Michael Gollin:**

70. In *Diamond v. Chakrabarty*, Chief Justice Burger stated that patenting certain types of technology might have negative consequences.<sup>151</sup> That was seventeen years ago, but it is a debate that continues. The Supreme Court stated that no more than Canute<sup>152</sup> could command the tides, can the existence of patent protection determine whether there will be research.<sup>153</sup> Without patents there will still be research. In fact, you can look at publicly-funded research and the NIH, which was doing research without patent protection being available until the mid-1980s.<sup>154</sup> Nevertheless, I think it is a simplistic notion that research will continue without patent protection. The real question is: how much research and in what areas? I think from personal experience that people will pour resources into areas where they can get protection, but I would like to see better studies.

**Audience:**

71. The government has limited rights to any research that is publicly funded.<sup>155</sup> In 1971, the government had a policy that it would only license those rights exclusively.<sup>156</sup> President Nixon issued a memorandum suggesting that this policy be changed to allow for other than exclusive rights for the government in

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<sup>151</sup> 447 U.S. 303, 316 (1980).

<sup>152</sup> King Canute was the eleventh century Danish conqueror of England who unsuccessfully commanded the tide to go out and stay away. See Hon. Joseph W. Bellacosa, *Symbols, Slogans, and Cymbals of Criminal Justice: Where's the Substance?*, 36 CATH. LAW. 375, 379 (1996); Russel Glazer, Comment, *The Sherman Amendment: Congressional Rejection of Communal Liability for Civil Rights Violations*, 39 U.C.L.A. L. REV. 1371, 1377 (1992).

<sup>153</sup> See *Chakrabarty*, 447 U.S. at 317.

<sup>154</sup> See Rebecca S. Eisenberg, *A Technology Policy Prospective on the NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 635-636 (1994) (stating that the privatization of research, specifically patent protection, did not begin to emerge until the 1980s).

<sup>155</sup> See generally 35 U.S.C. §§ 200-12 (1994) (outlining limitations on "patent rights in inventions made with federal assistance").

<sup>156</sup> See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1684-85 (1996) (explaining the effect of the Government Patent Policy, 36 Fed. Reg. 16,887 (1971)).

situations in which the government funded research.<sup>157</sup> That was one of the seminal forces in the passage of the Bayh-Dole Act.<sup>158</sup> I think it was also true that if you go back to that period, there was a division between universities and industry. The industry was afraid to collaborate with universities because they knew that if a patentable invention was created with government funding, even with partial government funding, the rights of the developers would be compromised.<sup>159</sup>

**Edmund Pitcher:**

72. I think that is a good example. Since the early 1980s, the government has changed its policy and permitted patents that are invented with government money to be owned by the institutions that get the grant money and to permit those institutions to dispose of the patents as they see fit,<sup>160</sup> the goal being to get the products to the public as soon as possible. The result is that the Massachusetts Institute of Technology, Harvard University, the Massachusetts General Hospital, and other high-quality institutions are giving exclusive licenses to patents covering inventions that were made in part using governmental money.<sup>161</sup> It is not as if these are just keys that make you instantly rich. There is a lot of investment and work involved between the time the patent is issued and the time that you actually get the product to market. I think that recent history has suggested that the best way to get the product to market is through granting exclusive licenses.

**Michael Gollin:**

73. How important is it? I understand that, as far as the facts of that situation actually go, one of the coinventors on the patent in Papua New Guinea was an American researcher who had been living in New Guinea and was funded by the Papua New Guinean government.<sup>162</sup> As far as I have heard, she explained as well as

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<sup>157</sup> See Government Patent Policy, 36 Fed. Reg. 16,887, 16,889-91 (1971).

<sup>158</sup> 35 U.S.C. §§ 200-11 (1994).

<sup>159</sup> See *id.* § 202(c)(4) (granting the federal agency a non-exclusive, non-transferable license that can be sublicensed to any foreign government by the federal agency).

<sup>160</sup> See *id.* § 202(c)(1). This right is not absolute because the patent owner must disclose that the invention was government funded and that the government retains rights in the invention. See *id.* § 202(c)(6) (“An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.”).

<sup>161</sup> See *id.* § 202(c).

<sup>162</sup> See Gary Taubes, *Scientists Attacked for ‘Patenting’ Pacific Tribe*, 270 SCIENCE 1112 (1995).

she could the purpose of the research, and the people were eager to help in finding a cure.<sup>163</sup>

74. After the patents issued, the story received widespread publicity without a clear evocation of the facts.<sup>164</sup> According to the NIH, it filed these patents in the 1980s under a policy that anything that came through NIH's laboratory that was patentable, it tended to patent.<sup>165</sup> I think others in the research community would confirm that that is just general practice. Later, the NIH decided to abandon these patents<sup>166</sup> because, I suspect, they felt there was no commercial viability for them.<sup>167</sup> It finally emerged in the media that the NIH was attempting to patent these cell lines without consent and, thus, exploiting the indigenous people.<sup>168</sup> These patent applications got tangled up with the intent of the prior, completely unrelated, HGDP. The NIH's official agenda is to promote public health, not exploit indigenous people.<sup>169</sup>

75. I think this highlights a quandary that I face as a practitioner: how do you advise people in this area to proceed? Clearly, most of those involved in these research endeavors are not of ill faith. They are folks going about their business on a day-to-day basis. Part of their business, if they are in the commercial sector and, even now, if they are in the academic sector, is trying to make discoveries and bring them to market. One of the issues in bringing discoveries to market is how to protect your intellectual property rights. What are your obligations and how do you make sure you have clear title? It becomes a practical problem of the kind of consent you need and from whom. If you are getting a sample from somebody who got it from somebody else who got it from somebody else, how far back need you check the pedigree?

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<sup>163</sup> See *id.*; *Patent Blather: Biotechnology*, ECONOMIST, Nov. 25, 1995, at 87, 87; see also Rhein, *supra* note 129 (stating that the NIH prosecuted the patent at the insistence of the people of Papua New Guinea).

<sup>164</sup> See *Patent Blather: Biotechnology*, *supra* note 167, at 87; Rhein, *supra* note 129; Taubes, *supra* note 166, at 1112.

<sup>165</sup> See Charles J. Hanley, *U.S. Retreats From Patent for Tribesman's Rare Blood*, SEATTLE TIMES, Sept. 22, 1996, at A24.

<sup>166</sup> See *NIH Abandons HTVL-I Patent*, *supra* note 133

<sup>167</sup> See, e.g., Hanley, *supra* note 169.

<sup>168</sup> See, e.g., Rhein, *supra* note 129; cf. *Patent Blather: Biotechnology*, *supra* note 167, at 87; Taubes, *supra* note 166, at 1112.

<sup>169</sup> See *National Institutes of Health* (last modified Sept. 1997) <<http://www.nih.gov/>> ("The NIH mission is to uncover new knowledge that will lead to better health for everyone.").

**Wendy McGoodwin:**

76. It is clear that the notion of fully informed consent is an awkward one when you are talking about a non-literate community that does not have a system of writing and is obviously not able to sign consent forms. In addition, the Hagahai community has only been in contact with Western society and the other communities in Papua New Guinea for the past twenty years. How can you explain to them for what this research is going to be used?

77. There are certainly great challenges posed to the concept of informed consent.<sup>170</sup> I do not think, however, that you can solve this dilemma with a perfectly crafted informed consent protocol. In many cases you are talking about indigenous communities. For instance, the HGDP is targeting approximately 500 indigenous communities faced with cultural extinction and trying to snap up their DNA before they disappear off the face of the planet.<sup>171</sup> What if researchers are talking to communities that have, as their organizing principle, the basic concept of shared stewardship over community resources? If this is the framework they use to understand their relationship with the world, and the researchers come in and start talking about patent rights and informed consent and bring in a Western-based patent system – which is one based not on principles of shared stewardship of resources, but of private property, and in some cases, may be an issue or a concept that is not central to these communities – then you really do raise difficult questions about cultural translation and how to make this an equitable relationship.

**Michael Gollin:**

78. If I can make just a small response based on personal experiences with a group of people who have a shared stewardship model for natural resources. This is in the context of plant resources, but I think the issue of culture clash is the same. I was involved in negotiating a bioprospecting agreement in Fiji that involved a Fijian village, the University of the South Pacific,<sup>172</sup> and a pharmaceutical company. Part of the exercise was to find common ground or some type of term of agreement that would not impose a Western-type licensing arrangement or contract on a community that has a different regime. It was really quite an intriguing exercise. We spent a lot of time preparing, trying to figure out what their legal system was, what their

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<sup>170</sup> See Darrell A. Posey, *Protecting Indigenous Peoples' Rights to Biodiversity*, ENV'T, Oct. 1996, at 6, 9.

<sup>171</sup> See *Answers to Frequently Asked Questions About the Human Genome Diversity Project*, *supra* note 73.

<sup>172</sup> The University serves twelve member island countries from its location in Suva, Fiji. See David Cohen, *Exodus from Paradise*, GUARDIAN, Dec. 10, 1996, at 106.

cultural values were, and trying to find ways to accommodate any differences. Eighty-three percent of Fiji is held in common trust by the ethnic Fijians.<sup>173</sup>

79. It was interesting to see the way that this was presented. It was really an issue of sustainable development on the one hand and of trading and funding on the other. Of course, they were happy about the trading because trade is an innate human activity. But there was also, I think, a fairly high level of good faith on the part of the village that this might help find ways to improve human health somewhere in the world. They would like to share and participate in its benefits. I think that these types of arrangements can be done, without exploitation, and with real mutuality. This may be very difficult in some circumstances, but I see no real negatives if the people are informed and willing. In the case involving plant resources,<sup>174</sup> and in another case concerning people donating blood samples to be commercially exploited,<sup>175</sup> I see no problems with doing so. If the people most intimately involved do not have an objection, I think we all stand to gain. But that is the very big picture. The small picture concerns how we do this on a day-to-day level. There is very little guidance.

**Audience:**

80. If we no longer recognized gene patents, would that retard genetic research or at least private sector genetic research? If your answer is yes, how do you justify the trade-off?

**Wendy McGoodwin:**

81. If it would be harder for biotechnology companies to raise venture capital,<sup>176</sup> yes it would retard genetic research. Does that mean that all progress in the field of molecular genetics would grind to a halt? No, not at all. First, there are plenty of ways, even if we are still talking about the private sector, for businesses to make money outside the scope of patent monopolies. We have seen that in the sector of the generic drug companies who manufacture effective products at lower

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<sup>173</sup> See Bob Drogin, *Trouble in Paradise: Behind Fiji's Facade, Turmoil Brews*, L.A. TIMES, Sept. 24, 1991, at H/2.

<sup>174</sup> See *supra* notes 176-77 and accompanying text.

<sup>175</sup> See Andrew Kimbrell, *Biotechnology: "Biodemocracy" Needed to Replace "Biopiracy,"* INTER PRESS SERV., Aug. 8, 1996, available in 1996 WL 10768634.

<sup>176</sup> See Deborah H. Hartzog & Jeffery C. Howland, *Raising Cash Through the Venture Capital Network*, PROB. & PROP., Nov./Dec. 1989, at 51 ("At the most basic level, venture capital is an investment by an independent investor in the development of an enterprise. The most common source of venture capital is private venture capital funds.").

costs.<sup>177</sup> Although they may not have the pull of the promise of super profits, business persons may simply need to be content with the promise of regular profits. I think that is certainly an option. The second option, of course, is that of public funding.<sup>178</sup> There is a long tradition of public funding of biomedical research.<sup>179</sup> We have a strong precedent of important products that have come out of that research, such as the development of many human vaccines.<sup>180</sup> Historically, it has been difficult to get the private sector involved in vaccine development because it is hard to make money selling a vaccine that you only need to use once and then everybody is immune.<sup>181</sup> I think that these examples are beacons of hope.

**Audience:**

82. Certainly, generic drugs can be made once existing patents expire, but my question was oriented more towards the drugs that have not been discovered or put onto the market yet. First, I was hoping you might be able to address how we might be able to get to new discoveries. Second, with respect to public funding, how are the smaller, less significant diseases going to be funded? Alzheimer's, of which the public is very aware, would get public funding. Can you explain how, in these days of limited public funding, something without such public awareness would be funded?

**Wendy McGoodwin:**

83. I cannot speak to the intricacies of the decisions of research priorities within the federal funding agencies, so I am not sure if I would be well positioned to answer your second question. Regarding your first question and the incentives available, I have to fall back on the basic principle that if American scientists are not willing or not interested in pursuing the basic research enterprise without the promise of super profits as the gold at the end of the rainbow, then that is a very sad

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<sup>177</sup> See *Competition Drives the Bulk Active Market*, MANUFACTURING CHEMIST, Dec. 1, 1996, available in 1996 WL 10626229.

<sup>178</sup> See, e.g., *Investing in Medical Research Saving Health Care and Human Costs: Joint Hearing Before the Special Comm. on Aging and the Comm. on Appropriations*, 104th Cong. 95 (1996).

<sup>179</sup> See Bruce Furie & Kenneth B. Miller, *Hematology*, 265 JAMA 3128, 3128 (1991) (discussing the importance of public funding to basic biomedical research in hematology).

<sup>180</sup> See *Vaccine Developments*, 337 LANCET 824, 825 (1991). See generally Jaclyn Shoshana Levine, Note, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?*, 4 B.U. J. SCI. & TECH. L. 11 (1998) (discussing incentives for vaccine development).

<sup>181</sup> Cf. Craig D. Rose, *It's No Shot in the Arm: Drug Makers Say Vaccine Program Is Destroying Market*, SAN DIEGO UNION TRIB., June 4, 1995, available in 1995 WL 5721230 (“[V]accine makers still earn profits from their products, but . . . the incentive to develop new products will be destroyed by the government’s reduced purchase prices.”). See generally Levine, *supra* note 184 (discussing incentives for vaccine development).

indictment of the lack of moral fiber in the field of American science. And I simply refuse to believe that is the case. I know that there are people out there, and I have the privilege of working with many of them, who are scientists primarily because they want to help their fellow man. They want to work on the cures and the treatments that will save lives. They want to put bread on their tables, but they do not need to become millionaires in the process.

**Charles DeLisi:**

84. I think science obviously would get done. I think the question becomes one of converting science to commercial products. If there were no patents, I think there would be more trade secrets. I think there would still be commercial development, but it would be a lot more secretive and information flow would decrease. I think venture capitalists, however, would still be willing to take risks. Researchers would just be more secretive about what is going on; that is my guess.<sup>182</sup>

**Michael Gollin:**

85. I would also question the emphasis on patents, as opposed to other types of controls and benefits. The point has been made that an academic researcher, especially one with a good salary at a major institution, who goes into an indigenous group and conducts academic research without any expectation of profit in the commercial patent sense, is nonetheless likely to publish papers and further his or her career.<sup>183</sup> If the researcher is a graduate student, then the research would be important in obtaining a Ph.D. The research could be the subject of academic funding and so forth; even aside from the focus on commercial profitability, there is a whole range of considerations and benefits that people obtain. I do not see a clear, bright line between the benefits that would flow from so-called pure research, as compared to somehow impure commercial exploitation. I think it is a very blurry distinction that has become even more blurry as a practical matter and it is likely to continue to be so.

**Edmund Pitcher:**

86. The question you asked was, "would the elimination of the patent system retard research?" I think that question was carefully side-stepped by everyone that answered. There is no question that it would retard it, but I do not think that it would make it disappear. Generic drug companies would not exist without a patent

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<sup>182</sup> Cf. 35 U.S.C. § 112 (1994) (detailing the specificity requirement for patent applications); *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) (stating that patents must be written in a manner such that those skilled in the art can practice the invention).

<sup>183</sup> See, e.g., Robin White Goode, *On the Brink of Finding a Cure: Young Biologist Banks Her Career on Cancer Research*, BLACK ENTERPRISE, Feb. 1, 1996, at 66 ("Making important discoveries and publishing papers about your findings are crucial to developing an academic science career.").

system because it is only the originators of the drug who expend the enormous amounts of money in developing the drug. I do not think the cost of development is as big as you read in the papers, but I can tell you from first-hand experience that the numbers are immense.<sup>184</sup> The investment to develop a drug from which the company actually makes money is far more than anybody is going to risk unless, when they get the product, they are going to see a return on their investment. For every drug that gets to the market, there are dozens, if not hundreds, that do not.<sup>185</sup> The third point is that the NIH is perhaps, from a standpoint of providing useful drugs for the buck, extremely inefficient. It spends billions and billions of dollars, and if anyone can tell me a drug that they have ever invented I would like to hear it. There must be something.

**Charles DeLisi:**

87. The primary mission of the NIH is to support basic research.<sup>186</sup> We can expect the development of both diagnostics and drug therapies to be accelerated greatly by the revolution of genomics, which will identify large numbers of new targets and accelerate the discovery of drugs themselves.

**Michael Gollin:**

88. The NIH does not promote the development of drugs except on the most basic level; it promotes science, which is appropriate.

**Audience:**

89. Someone made reference to the European Parliament's 1995 action. Does that mean that you cannot file for patents within the European community?

**Wendy McGoodwin:**

90. It does not mean that you cannot file for patents. It does, however, mean that a big question remains whether you will get a patent. There had been a great deal of ambiguity in the European patent law prior to this 1995 directive.<sup>187</sup> The

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<sup>184</sup> Some commentators estimate that producing a drug costs approximately \$200 million. See Tom Werner, *Investors Keep on Riding Biotechnology Rollercoaster*, PHILA. BUS. J., June 14, 1996, available in 1996 WL 8818826; *Financing the Biotechnology Industry*, *supra* note 67.

<sup>185</sup> See MICKEY C. SMITH, PHARMACEUTICAL MARKETING 28 (1991) (suggesting that the investment involved in introducing a drug into the market is prohibitively expensive); *Financing the Biotechnology Industry*, *supra* note 67.

<sup>186</sup> See *National Institutes of Health*, *supra* note 173

<sup>187</sup> See Arthur Rogers, *Death of EU Gene Patents Directive*, 345 LANCET 639, 640 (1995).

purpose of this failed directive was to clarify the law.<sup>188</sup> Because the directive did not pass, we are left with as little clarity as we had two years ago. The European patent office does grant some patents on living organisms and on human genes, but it also refuses and overturns others.<sup>189</sup> The European patent office uses the same three criteria that the United States PTO uses: utility, non-obviousness, and novelty. They have a fourth criterion that we do not have in this country.<sup>190</sup> That criterion focuses on whether those patents run contrary to the mode de public, or the public morality.<sup>191</sup> That means that you can challenge a patent in Europe on the basis that it offends public morality.<sup>192</sup> You can, of course, challenge it on the basis that it is obvious or is not useful or not novel, but you can also bring a challenge on the fourth criterion, moral offensiveness. There have, in fact, been successful challenges brought to patents on living organisms in Europe, which have been overturned on the basis of that complaint.<sup>193</sup>

**Audience:**

91. I have a question for Wendy McGoodwin. I heard your presentation and wonder if you may want to give stronger evidence to support your point. I feel that it is not very practical. It takes money to do basic science that focuses on developing future products. You cannot just hope for money to appear magically.

**Wendy McGoodwin:**

92. Thank you.

**Lawrence Wittenberg:**

93. I guess one question that this gives rise to is whether your group has a suggested alternative somewhere between the system that we have now, which allows patents of living organisms and gene sequences where utility is shown, at least that is the system that we hope we have now, and a system that says nothing living can be patented. Is there a middle ground?

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<sup>188</sup> *See id.*

<sup>189</sup> *See* GERALD PATERSON, THE EUROPEAN PATENT SYSTEM 333-34 (1992).

<sup>190</sup> *See* EUROPEAN PATENT CONVENTION, art. 53 (1973) (“European patents shall not be granted in respect of: (a) inventions the publication or exploration of which would be contrary to the ‘ordre public’ or morality, provided that the exploration shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.”).

<sup>191</sup> *See id.*

<sup>192</sup> *See id.*

<sup>193</sup> *Cf.* PATERSON, *supra* note 193, at 334.

**Wendy McGoodwin:**

94. The scientists in our organization that are engaged in molecular biology and basic scientific research, which eventually may yield new products, are managing to do their jobs without recourse to the patent system. They could have filed for patents if they wanted, but they have elected not to because they do not think that it is necessary. These are individuals who work in academic settings; it is probably obvious to you that this is the case. I would lean on their experience because these individuals, many of whom are quite prominent scientists, have managed to do good jobs without recourse to this practice.

**Charles DeLisi:**

95. Do they try to develop commercial products or are they just doing basic research? You do not need patents to do basic research. Most academics do not patent; they just do research. If you are trying to form commercial products, do you need patent protection?

**Wendy McGoodwin:**

96. Actually, I do not actually use the term “patent protection” to discuss this because, to me, “protection” is about feeling safe and warm, and what we are really talking about in this situation is what I call “patent monopoly.” That is how I refer to it. But, back to the question of whether you need the promise of a patent to do research for the gene for hemochromatosis. The answer is no. After you know the DNA sequence of the gene, it is very simple to develop a diagnostic test for it. I do not see that there would be a problem.

**Edmund Pitcher:**

97. It is hard to talk in the abstract, but what I think that you are alluding to is the discussion that there is room for refinement and sharpening of the law in the area of utility. It is very easy to sequence a piece of DNA; it is a skill held by those in the art.<sup>194</sup> Machines do it.<sup>195</sup> Once you have a sequence, a clever patent lawyer can think of potential uses for this sequence. How does that utility relate to the sequence and how is the law going to adapt itself to make it appropriate? The sequence could have utility as a molecular identifier, and if this is accepted by the PTO, any sequence could be a molecular tag. There is nothing unique to this sequence, and, thus, it should not be allowed as a basis for utility. That is nothing more than getting a patent based on very thin utility, and then blocking everyone

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<sup>194</sup> See *In re Alton*, 76 F.3d 1168, 1173 (Fed. Cir. 1996); *Biogen, Inc. v. Amgen, Inc.*, 973 F. Supp. 39, 44 (D. Mass. 1997); see also 35 U.S.C. § 103 (1994).

<sup>195</sup> See Tim Stevens, *The Big Squeeze*, *INDUSTRY WK.*, Sept. 16, 1996, at 61 (noting that billions of molecules can be created by computer-aided combinational chemistry).

else from even investigating that particular sequence because they cannot use it for anything. I think that you have to do a case-by-case evaluation. I think that you have to see what the utility is in a particular situation. I would be glad to give you my views in particular situations, but in general it is very hard to say. I think the key, as I have said, is the sequence-function relationship. If the utility comes from that, it is probably a proper utility, and the patent should issue. On the other hand, if it has some of these Ventner-type utilities,<sup>196</sup> where you can use this sequence to find other useful things, that is true of any piece of DNA.

**Charles DeLisi:**

98. Perhaps I can add another dimension to that question. Insight sells information. For example, researchers may find certain mRNA expressed in cells that have a pathological condition. Normal cells do not express this mRNA. It is giving you information that may lead to the cause of the pathology. For example, using this mRNA may narrow the cause of the pathology to ten different genes. Is that patentable?

**Edmund Pitcher:**

99. Is what patentable? The mRNA library?

**Charles DeLisi:**

100. Not the library, but let us say that I have identified ten mRNAs that are expressed in the diseased cells, but are not expressed in the normal version of that cell.

**Edmund Pitcher:**

101. Let me tell you what might be patentable about that. You might be able to get a patent on an assay<sup>197</sup> that exploits the concept that this particular cell can expose. For example, does this person have cancer? The way that you tell is to do a test that is straightforward, probably using probes,<sup>198</sup> to find whether those ten mRNAs are present. That might be patentable, I do not know. That does not expropriate the genetic information in the DNAs; for twenty years, the inventor has

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<sup>196</sup> See *supra* notes 52-58 and accompanying text.

<sup>197</sup> An assay is a “method for mapping and/or quantitating RNA transcripts.” ROBERT E. FARRELL, JR., RNA METHODOLOGIES: A LABORATORY GUIDE FOR ISOLATION AND CHARACTERIZATION 308 (1993).

<sup>198</sup> A probe usually includes “labeled nucleic acid molecules, either DNA or RNA, used to hybridize two complementary sequences in a library, or which are among the target sequences present in a nucleic acid sample.” *Id.*

that way of determining the presence or absence of disease, and that may well be patentable.

**Michael Gollin:**

102. Can I clarify a point that Edmund Pitcher made? I may have been unclear because I was moving fairly quickly. Were you referring to the comment that intellectual properties can shift companies away from non-protectable to protectable rights? I am intimately familiar with the natural products research industry and I represent some clients in that field. The point that I was trying to make in that area is that the companies will focus on new purified compounds and new methods of use. They will not invest in the area of bulk extracts because they are not protectable. If I gave the impression that intellectual property rights steer people away from that research, I am sorry.

**Audience:**

103. I know that Wendy McGoodwin talked about patent novelty being the thing that is most offensive. Some countries have instituted an in-between process.<sup>199</sup> Is this in-between process perhaps the result of the problems at both ends, in terms of getting research out there to encourage the innovation, but allowing the compulsory license to bring us ahead?

**Edmund Pitcher:**

104. The system would work like this: a patent holder does not have the right to exclude a researcher if the researcher pays the royalties for the compulsory license. Although it has never been used in the United States, it has been raised at trial a few times.<sup>200</sup> There are some scenarios in which this would be a compelling argument. For example, suppose I have invented an absolute cure for prostate cancer. I know that I can cure it every time and I can demonstrate that. But suppose I am a sadistic person and I do not want anyone to use it, and I get a patent on it. Theoretically, I can prevent everybody from making, using, or selling this thing,<sup>201</sup> and I let people die. What should happen? I think that perhaps a compulsory license would be an appropriate remedy in that type of situation. It is theoretically possible, and it has been brought up to me as a last resort where people have the right to determine whether people live or die because of the patent system.

**Audience:**

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<sup>199</sup> See COMMUNITY PATENT CONVENTION, art. 45-47 (1993).

<sup>200</sup> See PHILIP W. GRUBB, PATENTS IN CHEMISTRY AND BIOTECHNOLOGY 91-92 (1986).

<sup>201</sup> See 35 U.S.C. § 154(a) (1994).

105. I am suggesting a government policy that says that after you have recovered your cost plus some fair profit, it will allow some competition. If you want to hold your prices down you might have your monopoly longer. But you get your money back plus a fair profit. Is it the patent system that offends you, Wendy, or is it the profit?

**Wendy McGoodwin:**

106. It does offend me that we are parceling up bits and pieces of human beings and transforming them, not only into properties, but into property that a single individual or institution can control exclusively. That is the thing that offends me, whether it comes through a patent or not.

**Lawrence Wittenberg:**

107. If the individual from whom the information is derived is a researcher who knows the implications, so he/she freely gives the information to research, is the patenting of such information still offensive?

**Michael Gollin:**

108. Let us assume true voluntarism here. The person involved knows exactly what is going to happen and agrees entirely with the effort to patent research results. Should patents be precluded in those circumstances?

**Wendy McGoodwin:**

109. Would this person be told that this route is the only route that we have available to find a cure for the disease that killed her baby? I mean, we are talking about a situation here, where people are presented with choices, which are in a sense false choices. They are really already stacked against us. I mean certainly, I can conceive of a person telling a researcher, "Yeah, sure you can do research on me, and it is fine with me if you patent it." If that person's main concern is a cure, does that person really have a choice?

**Audience:**

110. I was just wondering if we can return to the discussion of informed consent, and what would be considered acceptable, without getting too focused on the other issues, such as culture clash.

**Wendy McGoodwin:**

111. I do not know if any of you have ever participated in a research protocol and filled out one of those informed consent forms. They are generally pages long. They have many paragraphs, and frequently there is a yes-or-no check box at each paragraph: "I read and I consent to this provision, check yes or no." In a sense, one of those informed consent provisions could conceivably be, "I understand that the researcher may attempt to commercialize this research, I consent to waive all my

rights in this matter.” They have the choice to check yes or no. There are some people who certainly would check “Yes” because they want to be in this research project and that is their choice. There are other people who would check off “No” and not waive their rights to commercial products derived from the research. I am not a scientist, so I cannot tell you whether those people who checked “No” would continue to be enrolled in that research. I am sure it would depend on the individual case. That is one possibility.

**Audience:**

112. Is your organization opposed to all forms of commercial biotechnology development?

**Wendy McGoodwin:**

113. Although our organization does not oppose the commercialization of biomedical research, we do oppose the use of patents on human genes. I do not think the two are inherently linked, as some people would lead you to believe. Though we certainly favor any attempt to restore control or agency to individuals who have been stripped of that, we are still uncomfortable with granting patents on what is essentially a part of the human heritage. The human genome is the result of millions of years of evolution. It is properly said to be our common heritage, and we do not believe it is appropriate to consider it to be personal property.

**Audience:**

114. Do you think that because patents last twenty years, your judgment is more of a generational judgment? That the people that are being used as these subjects for fitting the sample will not be able to see the groups of themselves enter the public domain and possibly their generation? Is that what you are objecting to? Essentially, the information that is acquired from the research and that is used is collected from the public domain. It is more of a generational concern. Am I correct?

**Wendy McGoodwin:**

115. That is not really the basis of our concern. If we are talking about a situation in which people participate in a research project because they want to help find a cure or a diagnostic for a disease that they care about, and they end up in a position where they cannot afford that cure or they cannot afford that diagnostic test because the gene patent renders that diagnostic too expensive, as in the case of the BRCA1 patent on the gene linked to the risk of breast cancer, then that is a sad situation.

**Charles DeLisi:**

116. Are the laws that govern monopolies adequate for the biotechnology industry or do they need to be modified? Are the prices being set fairly or are they

artificially high? How do you ensure that people who need access to new technologies have access to them?

**Edmund Pitcher:**

117. I do not think that you can ever assure that people who need access to technology will have access to it. That is just life; you cannot assure that. That is the way that I see it anyway.

**Audience:**

118. I think that what disturbs me most about this discussion is that many of the questions have been directed towards Wendy McGoodwin and her group, a non-profit group. Every time I have come into a situation where these things were discussed, it was always at the Massachusetts State House when legislation on genetic discrimination was proposed. These are rarefied environments where biotechnology people, researchers, and lawyers are talking. This type of research is barreling along at such speed; patents are being acquired now. It will be very hard to reverse these decisions, if the public truly wants to reverse them. You have all talked about public benefit. Let us hear from the public. Does the public want this? Can we have a really fair, public discourse among sociologists, religious leaders, researchers, and everybody? It is only in these rarefied environments that this is being talked about. What are your thoughts about the way this discourse can take place?

**Audience:**

119. I would like to address that last question. At the 1996 Massachusetts Biotechnology Council<sup>202</sup> annual meeting, bioethics was a major topic of conversation. We held that forum for the public, academia, and lawyers. All of these individuals came together for a day to sit down and talk about the industry perspective, the patient's perspective, and the counselor's perspective. The biotechnology industry founded the Biotechnology Industry Organization, based in Washington, D.C., which is a national organization that engages in that sort of conversation.<sup>203</sup> The industry has often, I think, tried to invite public discourse. Either you are not knowledgeable about public forums or you need to be more open to them. I think that to allege that this discourse does not go on is absolutely false.

**Wendy McGoodwin:**

120. The next time that you have one of those public discourses, I would certainly be very interested in being notified because I would be interested in attending.

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<sup>202</sup> The Massachusetts Biotechnology Council is a "private not for profit trade association representing Biotechnology companies in Massachusetts." *About the MBC* (visited May 25, 1998) <<http://www.massbio.org/aboutMbc.html>>.

<sup>203</sup> For more information about the Biotechnology Industry Organization, see *BIO-Biotechnology Industry Organization* (visited May 25, 1998) <<http://www.bio.org/>>.

**Audience:**

121. I think that you were notified because I think that most of Massachusetts was notified of this meeting.

**Lawrence Wittenberg:**

122. Thank you very much for attending. This discussion raised just a few of the many questions raised by this topic.