

IN THIS ISSUE

Page 1

*Genome Patent Has
Day In Court*

*The Future of
Television*

Page 2

*Third Annual
At the Crossroads
Conference:
Law, Technology &
the Human
Genome*

Profile:

2003 Yuen Fellow

Page 3

Who Owns You?

Update:

*Genome Patent
Case Appealed*

Page 4

Coming Events

Genome Patent Has Day In Court

Scientists have patented all sorts of life forms, from bacteria to mice. Is it time to start patenting humans? We're probably not ready to enter that brave new world, but how about something a little less controversial - the human genome. Is an individual's genetic makeup patentable?

That was the question in an unusual trial before Marilyn Hall Patel, Chief Judge of the Western District of California, on November 9, 2001 in *NuGenEra v. Dolly*, a biotechnology company patented the genome of an individual found to be HIV-resistant, then sued for patent infringement when he began selling his own blood.

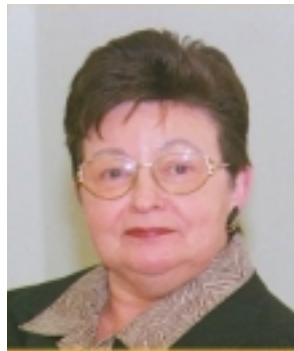
In cross-motions for summary judgment, Judge Patel upheld patent claims on gene sequences found to confer HIV resistance. But she found that a claim on

the entire genome lacked utility and was thus invalid. The infringement case was allowed to proceed on the valid claims.

Fortunately, this was only a mock case. No one will be required to forfeit his or her genome, at least any time soon. Still, the case before Judge Patel was so groundbreaking that it was written up in *Scientific American* (see page 3) and the *Times of London*.

The mock case is now on "appeal." Oral argument is scheduled for **November 1, 2002**, in the new high tech courtroom at Loyola Law School. A special appellate panel - Hon. Ming Chin, Hon. Alex Kozinski,

and Hon. Kim Wardlaw - will hear the appeal. Please see page 3 for registration details. This is an event you won't want to miss."



Honorable Marilyn Hall Patel

Symposium Explores the Future of Television

We are more than half-way into the decade-long transition from standard analog television to high definition digital TV. Yet the programming, broadcast and consumer electronics industries are far below 50% deployment and build-out. Indeed, less than 1% of American consumers have purchased HDTV sets so far. Why has this revolutionary technological improvement failed to catch on as anticipated? Congress wants to know and is considering new technology-forcing laws.

Many factors have contributed to the lackluster acceptance of HDTV. Among them are the high cost of equipment, the lack of digital content, regulatory uncertainty, a general economic malaise, and cultural impediments to new home video parameters.

At the same time that HDTV struggles to get off the ground, the broadcast industry is itself in the midst of major upheavals. Few Americans get their video content via conventional over-the-air means. Industry restructuring and rapid technological
(continued on page 2)

The Future of Television Technology, Markets and Content

Spring, 2003
Caltech, Pasadena

For more information call:
626-395-3586
or visit <http://techlaw.lls.edu>

Profile

Next Yuen Fellow - Professor Richard Epstein

We are quite fortunate to have as our Spring, 2003 Yuen Fellow, Professor Richard Epstein, the James Parker Hall Distinguished Service Professor of Law, University of Chicago.

Professor Epstein has been a Fellow at the Center for Advanced Studies in the Behavioral Sciences at Stanford, and editor of the Journal of Legal Studies. He is a Fellow of the American Academy of Arts and Sciences.

Professor Epstein will speak to students, faculty and the public at Caltech and Loyola on February 5 and 6, 2003.

He will discuss his recent work on biotechnology patents telecommunications and intellectual property.

Genetic Property, Privacy & Progress

The Program's signature event is the annual At the Crossroads conference held each fall. Last November's conference spanned two days and included the mock trial of *NuGenEra v. Dolly*, as well as panels on Genetic Property, Privacy and Progress. The conference was our largest and most successful ever; more than 500 people attended. The panel on Genetic Property debated the question presented in the mock trial – Who owns the human genome? Less sensational, but just as far reaching, is whether life forms and human genes are patentable. Panelists included President David Baltimore of Caltech, Stephen Kunin (Patent & Trademark Office), Rebecca Eisenberg (University of Michigan Law School), Leroy Hood (Institute for Systems Biology), Daniel Kevles (Yale University & Caltech (emeritus), and Mark Rohrbaugh (National Institutes of Health). Erwin Chemerinsky (USC Law School) moderated.

The panel on Genetic Privacy tackled the thorny issues of privacy, consent and genetic discrimination. The panelists approached these topics on a large-scale level, predicting a trend toward greater probabilistic

diagnosis and preventative measures as a direct result of increased genetic testing. Panelists included Jane Cohen (University of Texas Law School), Colin Diver (University of Pennsylvania Law School), Henry Greely (Stanford Law School), Leroy Hood, J. Alexander Lowden, (LabOne, Canada), and Edward McCabe (UCLA Medical School). Andrew Pollack (New York Times) moderated.

The panel on Genetic Progress focused on the recent debate over stem cell research, a debate that has sprouted from changing social attitudes on the creation and destruction of life. Panelists included David Baltimore, Alta Charo (University of Wisconsin Law School), Miriam Cotler (Cal State University, Northridge), and Richard M. Doerflinger (Conference of Catholic Bishops). Manny Medrano (KNBC News) moderated.

At the Crossroads of Law & Technology 3rd Annual Conference

One thing the panelists could all agree on – both law and politics must take notice of new science and emerging technologies. Modern conditions have spawned a brave new age where ethical issues must be debated and legislation considered in order for law and technology to advance safely and efficiently alongside one another.

The Future of Television (continued from page 1)

change have left the future of television in doubt. The Program for Law & Technology is pleased to co-sponsor a symposium on The Future of Television to be held at Caltech in spring, 2003. Also co-sponsoring is The Center for Communications Law & Policy at USC Law School and USC Annenberg School for Communication.

The symposium will tackle 3 major issues affecting television as we know it:

- Who will own and control video content? Is

digital content protectable?

- Does broadcast television have a future, or will it be replaced by subscription services (cable, satellite) or broadband video?
- Will HDTV catch on, or will standard definition (analog) TV survive beyond its scheduled termination date (Dec. 31, 2006)?

Please join us for an exciting panel discussion, including a demonstration of existing and emerging video technologies.

Visit the Program website: <http://techlaw.lls.edu>



WHO OWNS YOU?

By Gary Stix
Scientific American,
 March 2002

A mock trial explores the intersection of patents and genetic-property rights

A man named Salvador Dolly gives blood for a routine genetic test to determine his fitness to father a child. The testing company, Advanced Genetic Testing Company (AGTC), then sells the remains of the sample to NuGenEra, a biotechnology company. NuGenEra discovers that Dolly's genes make him resistant to HIV.

The company responds to this discovery by taking out a patent on both Dolly's genome and a series of gene sequences that confer resistance. When NuGenEra informs Dolly that his genes guard against the deadly virus, he decides to set up a business to market his blood to research institutions. To protect its patent, NuGenEra sues Dolly for patent infringement, saying that it owns his genome.

Does the patent mean that Dolly must forgo any rights to his own genome? Does it violate his privacy or property rights? Should these rights be balanced against society's need for the tests and therapies for HIV that might be derived from NuGenEra's research on Dolly's genome? These issues were highlighted last November in a mock trial at the California Institute of Technology as part of the school's Program for Law and Technology, in collaboration with Loyola Law School.

During arguments made by students from both schools, Judge Marilyn Hall Patel, who presided over the Napster copyright case, had to decide whether to invalidate the NuGenEra patent and throw out the

company's suit against Dolly for violating the patent on his own genes. Many of the arguments centered on the usefulness of Dolly's genes--utility being one of the principal criteria for granting a patent. In its patent, NuGenEra claimed that both Dolly's entire genome and 10 genes within it, called the P sequences, could be employed to create diagnostic tests for determining resistance to HIV and to produce gene therapies to cure the disease.

Dolly's attorneys argued that the genome--and even the P sequences--consisted of DNA for which the specific genes that conferred resistance had not yet been identified, a lack of utility that meant the patent should be declared invalid. They also contended that the patent violated Dolly's rights to privacy, property and personal autonomy.

In her decision, Patel allowed the mock case to move forward to a jury trial (see <http://techlaw.lls.edu/atc3/order.pdf>). In doing so, she affirmed that the P sequences had a legitimate use as a diagnostic tool to ascertain HIV resistance. But she invalidated the part of NuGenEra's patent that covered Dolly's whole genome because of a lack of any clear-cut applications.

Acknowledging an aversion to judge-made law, Patel would not embrace privacy or other public policy arguments made by Dolly's attorneys, citing the absence of legislation and case law to guide her. But she did seem inclined to find some means of suggesting protection for genetic property within the bounds of existing law. The judge noted that genetic material is unique to each individual. Thus, Dolly may have the right to sue in California for misuse of his likeness for commercial purposes.

The case illustrates how the genomics era may affect existing patent law. "I think that if this were a real opinion and it carried weight, it would mean that the patent laws are going to be aggressively pursued irrespective of these countervailing social policy issues," says Karl Manheim, who directs the law and technology program at Loyola. So if NuGenEra v. Salvador Dolly is any portent, whatever part of one's self that is locked up in the genetic code may be eligible to be owned and bottled by someone else.

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Update Appeal Filed in Genome Patent Case

NuGenEra, Inc. and Salvador Dolly, respectively plaintiff and defendant in the landmark case of patenting the human genome, have filed cross-appeals in the case. The appeal will be heard before a special judicial panel consisting of Judges Alex Kozinski and Kim Wardlaw (Ninth Circuit, U.S. Court of Appeals) and Justice Ming Chin (California Supreme Court). The case is docketed for oral argument on Nov. 1, 2002.

Court will convene at the Girardi Advocacy Center on the campus of Loyola Law School, 919 S. Albany St., Los Angeles. For more information, please call 213-736-1407, or reserve your seat on our web site, <http://techlaw.lls.edu>

MCLE Credit is available.

Admission is free.

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Upcoming Events

Nov. 1, 2002

At the Crossroads – Fourth Annual Conference –
Patenting the Human Genome. Dolly v. NuGenEra,
Inc., on appeal to the United States Supreme Court

Feb 5 & 6, 2003

Yuen Fellow Speaker Series presents Professor
Richard Epstein, University of Chicago Law School

Spring, 2003

**Symposium: The Future of Television - Technology,
Markets and Content.** What's In Store for T.V.? Will
broadcast television survive? Who owns digital
content?

NuGenEra v. Dolly

featured in

“16 Minutes”

(the video) now showing online
<http://techlaw.lls.edu>

Starring:

Michael Badalucco David Brancaccio
Jason Kravits Barbara Wold
Laurie Levenson

Plus

Cameo appearances by
Caltech and Loyola students

A Steven Kingsbury Production
Written and Produced by
Edward McCaffery & Karl Manheim

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