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At the Crossroads of Law & Technology: Third Annual Conference—Introduction

Karl Manheim

AT THE CROSSROADS OF LAW & TECHNOLOGY: THIRD ANNUAL CONFERENCE

INTRODUCTION

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I. INTRODUCTION

Salvador Dolly (Dolly) has a rare and valuable genetic trait.[1] Something in his genome makes him immune to the HIV virus. This is, of course, good news not just for Dolly, but also for medical researchers around the world. If they could only map his genome and find the specific genes that confer immunity, they might be able to develop genetic therapies that would counter the deadly AIDS contagion. Indeed, this is well underway. A cutting-edge biotechnology firm, NuGenEra, Inc., has sequenced Dolly's genome and has isolated regions of his DNA that confer HIV resistance. Naturally, NuGenEra patented its discoveries before announcing them and making them available to genetic scientists. To be more precise, NuGenEra patented Dolly's genome and ten of his genes. When Dolly started marketing his own genome, NuGenEra sued him for patent

* Professor of Law, Loyola Law School, and Co-Director, Program for Law & Technology. I wish to thank my colleagues Lawrence Solum and Edward McCaffery for their tireless work on the conference, my research assistant, Andrea Lin, for helping me with this Introduction, Samuel Tiu, for writing the mock patent, and James Warren, for his assistance with Judge Patel's Memorandum and Order. Additional thanks go to Jennifer Kefer, law clerk to Chief Judge Patel, and Susan Vaughan, judicial extern to Chief Judge Patel, both of whom were indispensable in turning this academic exercise into a realistic and fascinating case.

1. NuGenEra v. Dolly, (W.D. Cal. 1999) (No. MHP019999) is a hypothetical case. The Court Order, Points and Authorities, and Reply Briefs immediately follow this Introduction.

infringement. As one might imagine, the *NuGenEra v. Dolly* case has attracted considerable attention in the press and scientific and legal communities.

The *NuGenEra* case is only slightly preposterous. It is undoubtedly fictional, but not all that far-fetched. The case was the focal point for this year's *At the Crossroads* Conference, sponsored by the Program for Law and Technology (Program) at California Institute of Technology (Caltech) and Loyola Law School (Loyola). As with previous mock cases, the Program constructed *NuGenEra v. Dolly* to explore emerging issues at the intersection of law and technology.

The Program has recently completed its third year as a joint effort by Caltech and Loyola. Conceived by a joint alumnus, Henry C. Yuen,[2] President and Chief Executive Officer of Gemstar-TV Guide International, the Program promotes dialog among students, faculty, and industry leaders in the realms of law, science, and technology. It is premised on the belief that law and technology are in an intensely interactive stage of development, where each profoundly influences the other. Academics and practitioners in these disciplines must learn each other's languages in order to negotiate the growing complexity of modern society.

In its first two years, the Program focused on the legal problems of cyberspace, clearly an area where technology is forcing a reexamination of legal precepts, and vice versa. In one mock case, *Closed Corp. v. Open Sesame*,[3] an Internet users' group, consisting of anonymous volunteers who collaborated online, was sued for infringing Closed Corporation's patented computer operating system. After a hearing on Defendant's motion to dismiss, the Honorable Diarmuid O'Scannlain[4] ruled that the case could go forward against the Internet users' group, using e-mail for service of process.[5] That ruling was affirmed on appeal by the Honorable Richard A. Posner,[6]

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2. Ph.D., California Institute of Technology, 1974; J.D., Loyola Law School, 1979.

3. David J. Steele & Karl Manheim, *Closed Corp. v. Open Sesame: A Simulated Infringement Case Arising in Cyberspace*, 33 LOY. L.A. L. REV. 1055, 1057 (2000).

4. U.S. Court of Appeals for the Ninth Circuit (sitting by designation).

5. *See* Hon. Diarmuid F. O'Scannlain, *Reporter's Transcript of Bench Ruling: First Annual At the Crossroads of Law & Technology Conference*, 33 LOY. L.A. L. REV. 1157, 1164 (2000).

6. U.S. Court of Appeals for the Seventh Circuit (sitting by designation).

who held that the Internet users' group was a suable entity with the Internet as its principal place of business.[7]

This year's mock case—*NuGenEra v. Dolly*—was no less challenging. Now that the human genome has been mapped[8] and nearly all human genes have been sequenced, there is a gold rush to patent these "inventions."[9] While still controversial among the public, gene patents have become both routine and accepted in the legal and biotech communities. Even entire organisms, such as bacteria[10] and mice,[11] have been patented. A full human genome, however, has yet to be patented. The prospect raises profound questions of law and morality.

It also raises serious practical questions, as *NuGenEra v. Dolly* demonstrates. Nothing in patent law limits the grant of a patent to a party whose "property" served as the basis for the invention. NuGenEra claims to have legitimately acquired tissue samples from Dolly, and invested considerable time and financial resources in isolating the genetic material. The finished product—isolated and purified DNA sequences—may have been derived from Dolly's tissue, but it is not that tissue. It is something different. Indeed, it is not a tangible product at all, but pure information—the stuff of intellectual property.

Dolly, of course, has a different view of the whole episode. Not only does the patent violate his privacy and personal autonomy, it is a misuse of the property right he enjoys in his own body. Moreover,

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7. *See* Hon. Richard A. Posner, *Court Opinion: Second Annual At the Crossroads of Law & Technology Conference*, 34 LOY. L.A. L. REV. 1345, 1351 (2001).

8. *See* Human Genome Project Information, *Sequencing: DNA Sequencing and Sequence Variation, at* http://www.ornl.gov/hgmis/research/sequencing.html (last modified Nov. 7, 2001).

9. Every human gene has been patented or is the subject of a pending application. *See* Douglas Steinberg, *Will Genomics Spoil Gene Ownership?*, THE SCIENTIST, http://www.the-scientist.com/yr2000/sep/steinberg_p1_000904.html (Sept. 4, 2000).

10. A patent on a new strain of *Pseudomonas* bacteria was upheld in *Diamond v. Chakrabarty*. *See* 447 U.S. 303, 317-18 (1980). The case is credited with ushering in a new era of biotechnology patents.

11. In April 1988, inventors from Harvard Medical School obtained the first patent for a higher-order animal called a "transgenic mammal"—a mouse carrying human cancer genes—commonly referred to as the "Harvard mouse" or "Oncomouse." *See* U.S. Patent No. 4,736,866 (issued Apr. 12, 1988), *available at* http://patft.uspto.gov.

public policy should preclude the patenting of a human genome, especially without consent. It may be a brave new world out there when it comes to genetic science, but the law still protects fundamental individual rights. Or does it?

Advancements in science and technology often challenge our legal regimes and traditional understanding of rights. As the Information Revolution speeds forth with the aim of benefiting society's general health, growth, and economic prosperity, it also ushers in an era of legal uncertainty. So too exotic advances in biotechnology, among other rapidly expanding scientific frontiers, raise difficult questions in intellectual property and personal rights. These questions have spawned new concerns in bioethics, which have yet to be fully discussed in legal, political, and social arenas. It is only through open, interdisciplinary discourse among the affected communities that society will be ready to answer the hard questions, such as who owns Dolly's genome?

This was the question that the packed courtroom at Caltech's Ramo Auditorium wanted answered. The parties in *NuGenEra v. Dolly* called renowned genetic experts, Dr. Noriyuki Kasahara[12] and Dr. Richard Myers,[13] to help the Honorable Marilyn Hall Patel[14] resolve the difficult question. I will not presage her answer, but instead invite you to read the Court's Order, as well as the briefs filed in support of cross-motions for summary judgment, that follow this Introduction.

In addition to the testimony and argument presented at the hearing,[15] this year's *At the Crossroads* Conference featured academic panels on Genetic Property, Genetic Privacy, and Genetic Progress.

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12. Assistant Professor of Pathology, Biochemistry & Molecular Biology, at the Institute for Genetic Medicine of University of Southern California/Norris Comprehensive Cancer Center.

13. Professor of Genetics at Stanford University and Director of the Stanford Human Genome Center.

14. Chief Judge, United States District Court for the Northern District of California (sitting by designation).

15. Plaintiff, NuGenEra, Inc. was represented by Loyola students Olga Kay and Andrea Lin, and Caltech students, Katharine Ip and Paul Updike. Advising the students were Robert Berliner and Margaret Churchill, of Fulbright, Jaworski and Walker, LLP, Los Angeles. The Defendant, Dolly, was represented by Joe Andrieu and Elizabeth Hong of Caltech, Lir Burke and Mimi Chiang of Loyola, and advisors Catherine Polizzi of Morrison and Foerster, LLP, Palo Alto, and Michael Wise, Lyon & Lyon, LLP, Los Angeles.

Noted scientists, including Caltech President David Baltimore,[16] joined legal academics to debate difficult issues attendant to recent genetic advances—among them, cloning and stem cell research. A full description of this year's Conference, including biographical information on panelists and participants, can be found on the Program website.[17] While agreement was reached on some of the issues, the dispute between NuGenEra and Salvador Dolly is unresolved. Perhaps the following materials will assist you in reaching your own conclusion.

II. OVERVIEW OF NuGenEra v. Dolly

This year's mock trial posed several fundamental questions concerning the boundaries of property, privacy, and patentability, which arose from breakthroughs in medicine and biotechnology. The case begins with Salvador Dolly, an ordinary individual who sought a genetic test prior to fathering a child. Upon conclusion of the testing, and through a routine acquisition of discarded tissue samples, a medical research company, NuGenEra, stumbled upon an invaluable discovery—that a particular gene sequence within the man's DNA increased resistance to HIV. Realizing its enormous potential for both a hefty contribution to science and commercial profitability, NuGenEra decided to invest time and effort toward isolating the sequences, and eventually obtained a patent on its invention. The patent was comprised of three claims, including one that encompasses Dolly's entire genomic sequence, one that identifies the particular gene combination that confers the demonstrable increase in resistance, and an immortalized in vitro cell line derived from the isolated gene combination.

NuGenEra, thinking it was performing a public service, cheerfully notified Dolly of his special genetic makeup. This immediately caused him to wonder where he fit in the big picture of such a scientific achievement. Understanding the commercial appeal of this newfound characteristic, he decided to market its research appeal and sold two blood samples to university scientists. After it learned of the sales, NuGenEra sued Dolly for patent infringement. In his motion for summary judgment, Dolly made several affirmative de-

16. David Baltimore is a Nobel Laureate in genetic engineering.
17. *See* http://techlaw.lls.edu.

fenses, which challenged conceptions of property, privacy, and the general validity of a patent that claims the sequence of a human genome.

The first affirmative defense was that Dolly retained a property interest in his excised tissue. It is true, from a legal and intuitive standpoint, that an individual has the right to protect and control one's bodily autonomy prior to removal of tissue. However, once one has voluntarily surrendered a blood sample, how much control may that person exert over the ultimate disposition of this tissue? Under the landmark case of *Moore v. Regents of the University of California*,[18] a patient does not have a continuing right to control the disposition of excised cells under traditional property principles.[19] The Defendant in this case, however, stressed a constitutional property right that attached not only to the physical material, but also to the information stored within his DNA. In essence, he claimed a property right to his genome.

This property right, though currently unsupported in case law, may be more easily understood by examining another constitutional right that it affects: privacy. Privacy is now consistently upheld in principle by the Court through the right to marry,[20] the right to refuse medical treatment,[21] and the right to procreate.[22] By similar logic, can we also extend our privacy right to bar the use of a tissue sample

18. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

19. *See id.* at 142-44, 793 P.2d at 493-94, 271 Cal. Rptr. at 160-61.

20. *See generally* Zablocki v. Redhail, 434 U.S. 374 (1978) (holding that the state's interest in ensuring compliance of a court ordered child support agreement is insufficient to restrict the right to marry); Loving v. Virginia, 388 U.S. 1, 12 (1967) (stating that denial of the fundamental freedom of marriage on the basis of race is "subversive of the principal of equality at the heart of the Fourteenth Amendment"); Skinner v. Oklahoma, 316 U.S. 535, 541 (1941) (defining marriage as one of the "basic civil rights of man").

21. *See generally* Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990) (holding that a state may choose to defer only to a patient's wishes rather than entrust the decision to close family members); Bouvia v. Superior Court, 179 Cal. App. 3d 1127, 225 Cal. Rptr. 297 (1986) (holding that a person's right to privacy encompasses a virtually absolute right to refuse medical treatment); In re Quinlan, 355 A.2d 647 (N.J. 1976) (stating that a guardian of an incompetent child can seek termination of life support).

22. *See generally* Skinner v. Oklahoma, 316 U.S. 535 (1942) (stating that sterilization of habitual criminals invidiously discriminates by exacting unequal punishments upon those who have committed intrinsically the same type of offense).

solely because it contains our DNA? What kind of consequences would this have on the pace and economics of biomedical research?

This question of control over excised tissue also implicates the idea of informed consent. It is well established in the law that informed consent is necessary prior to the taking of bodily tissue,[23] but what is not so clear is how to ensure that the patient receives and fully understands the scope of this consent.[24] Indeed, *Moore* reinforced the requirement of informed consent but never specified what the appropriate remedy should be in the event of inadequate consent. How should we construct our informed consent forms, and, as in this case where the tissue sample was ultimately purchased for biomedical research, how far down the line of scientific utility should the duty extend? As concluded by the Conference panel on Genetic Property, informed consent is an area which must be further clarified, and it must take into account particular factors such as the comprehension level of various cultures both overseas and in the United States.

The focus of the mock trial, however, resulted in spotlighting and reevaluating our current system of granting patents. Because patents embody a government grant of ownership of information, it is necessary to carefully define what inventions may be patented. The Supreme Court has always construed patent laws broadly,[25] in concert with the idea that the nature of inventions is one of unpredictability and cannot be legislatively predetermined. This leaves the general details of patentability to be decided as a matter of public policy. The current thinking on patenting genes, by both the Supreme Court and the U.S. Patent and Trademark Office (PTO), appears to be flexible. On the one hand, research companies require

23. *See Moore*, 51 Cal. 3d at 128-29, 793 P.2d at 483, 271 Cal. Rptr. at 150.

24. In *NuGenEra*, Dr. Myers testified for Defendant that standard medical practice required fully informed consent in this context. *See* National Human Genome Research Institute, *Model Consent for Use of Tissue Samples for Human Genome Project Cell Lines*, *at* http://www.science.doe.gov/ober/humsubj/doenchgr.html (last modified Jan. 3, 1997).

25. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 n.6 (1980) (citing the Committee Reports accompanying the 1952 Patent Act as indicating that Congress intended statutory subject matter to "include anything under the sun that is made by man"); *see also* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 122 S. Ct. 593, 598 (2001) (supporting the notion that Congress intended that patent laws be given wide scope).

the incentive of patent protection to make the huge investment in the infrequently successful, risky venture that is biotechnology. Yet, on the other hand, giving these companies the right to exclude others may either grant patent owners a license to charge excessive fees for necessary drug products,[26] or worse, give them the unilateral right to prevent further research whatsoever on the patented matter.[27] Affordability problems concerning the AIDS vaccine in Africa and the recent threat by the Canadian government to thwart the patent on the drug Cipro illustrate the importance of worldwide access and need.[28]

We have long chosen a patent system of privatization, subject to regulatory oversight that is political at its core. Given our new found wariness of monopolistic practices, is it time to make a change in our balance of policy considerations? Is the system still serving the public interest, and can it do so on a global scale, or have individual rights fallen secondary to the general good? And finally, because some drugs are simply undiscoverable without patent protection, is it advisable to make the decision to grant a patent on pure policy principles or should we approach each patent application on a case-by-case basis?

Perhaps the current practice of granting patents is simply too broad. In the mock trial, out of the original three claims, the Defendant succeeded in invalidating Claim 1, which encompassed an entire

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26. The price Bayer charges for Ciprofloxacin ("Cipro") varies greatly around the world, ranging from $1.29 (U.S. $) per 500 mg tablet in New Zealand, to $4.67 (U.S. $) for the same product in the United States (wholesale price). *See Selected Prices for Ciprofloxacin, at* http://www.cptech.org/ip/health/cl/cipro/ciproprices.html (last modified Oct. 25, 2001). Generic equivalents are as cheap as 3¢ (U.S. $) per tablet in some countries, such as India. *See id.*

27. *See generally* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001) (arguing that patent law needs to preserve competition in the biopharmaceutical industry by limiting the scope of patents). In at least one case, this was the intended result. *See generally* Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 190 n.269 (2000) (discussing efforts by opponents of genetic research to obtain a patent for a human-animal hybrid in an effort to block research into certain human genes).

28. *See* Patent Act R.S.C. ch. P-4, § 19 (1985) (Can.), http://www.cptech.org/ip/health/cl/canada1.html (last visited Jan. 23, 2002). Patented Cipro costs $1.58 (U.S. $) per 500 mg tablet in Canada, while the generic version costs 95¢ (U.S. $). *See Selected Prices for Ciproflaxacin, supra* note 26.

genomic sequence. Judge Patel held that the Defendant had demonstrated enough evidence to show a lack of utility to overcome the presumption of validity afforded to patents.[29] This holding was clearly case specific, as the standard of evidence regarding patentability would have been lower had the patent not yet been granted. Additionally, while the judge in this case had a remarkable grasp of genetic science, it is possible that the plaintiff's expert testimony of utility could have convinced a different trier of fact.

The constitutional rights of privacy asserted by the Defendant were dismissed as a defense, as the court found that the right to sell blood did not conform to traditional notions of privacy. The court did, however, acknowledge a right to privacy of genetic information but could not answer the question of whether this could provide a basis for overturning the patent. In a sense, this question embodies the general social concern with genetic privacy. How do we weigh the value of biomedical advancements against an individual's expectation of genetic privacy? A classic situation is that of an employee who is reluctant to undergo genetic testing for fear of losing his job, which places one's reputation, insurability, and health at risk. As discussed in the panel on genetic privacy, this fear could be adequately addressed with public education. Yet if we are to effectively deal with genetic discrimination, more research is certainly needed into the genesis of genetic disease in order to understand to what extent an individual's genes may predict his behavior.

III. THE COURT'S FINDINGS

Overall, the mock trial ruling followed case law and general PTO rules in requiring satisfaction of each prong of patentability. While the court acknowledged the ethical and policy issues that must be answered, it could not offer us a decision, for many aspects of these issues are undoubtedly yet to be realized. Indeed, in the judge's concluding remarks, she notes that the role of the court is to enforce laws, rather than to create them, and that this is particularly problematic in the case at hand due to a lack of legislation regarding genetic information and ethics as they relate to patents.

29. *See* 35 U.S.C. § 282 (1994) ("A patent shall be presumed valid"); American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1358-59 (Fed. Cir. 1984).

This ruling instead sets the stage for purposeful debate, similar to the one which concluded the Conference. As Professor Erwin Chemerinsky noted while moderating the panel on Genetic Privacy, the law must either apply longstanding principles to new technologies or agree to make a radical change in the conceptual framework that surrounds the interplay of these two areas. While it is not certain that society will ever come to a true consensus on how the law should be interpreted or if it should be changed at all, the pace of biotechnology will not stop to let us catch up. It is a "law-forcing" phenomenon of great magnitude. We must therefore allow ourselves ample opportunity to ensure that we are prepared to address the inevitable conflicts between the rapidly emerging, divergent interests of an increasingly high-tech society and the individuals who live in it.