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Defendant Dolly's Opposition Reply to Plaintiff's Motion for Summary Judgment

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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF CALIFORNIA

NUGENERA, INC., a California Corporation, Plaintiff, vs. SALVADOR DOLLY and DOES I-X, Defendants.	CASE NO. MHP-01-9999 **DEFENDANT DOLLY'S OPPOSITION REPLY TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT** Date: Nov. 9, 2001 Time: 2:30 pm Courtroom: Ramo Auditorium

Defendant, SALVADOR DOLLY, by and through his counsel of record, respectfully submits this Reply in opposition to Plaintiff's Motion for Summary Judgment.

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I. INTRODUCTION

Plaintiff incorrectly states that Defendant Dolly "has no legal or inherent rights to his excised tissue, and, therefore, no entitlement to profits that have arisen from the research that Plaintiff has conducted" (Pl.'s Mem. Supp. Summ. J. at 981) and attempts to convince this Court to disregard NuGenEra's violation of Dolly's constitutional and inherent rights to privacy. Despite well-established guidelines requiring that expressed and informed consent be obtained from all individuals providing tissue samples, Plaintiff not only disregarded established informed consent policies, but they also try to convince this Court that such consent is unnecessary and too burdensome, and that the Court should overlook or excuse Plaintiff's misconduct in the interest of public good.

Plaintiff also focuses their argument on the issue of who has ownership rights to excised tissue, and thus, rights to dispose of such tissue. Defendant Dolly's ownership rights to his excised tissue and right to control how his excised tissue is disposed is not at issue here. There is no dispute in fact that Dolly's tissue sample contained his genetic material and genetic information. What is at issue is one's right to his genetic information and genetic privacy. Technological advances now allow for the easy sequencing of Deoxyribonucleic Acid (DNA) from a tissue sample. DNA is the highest level of biological information available for each individual. A finding that Plaintiff's U.S. Patent No. F6,635,271 ('271 patent) is valid is equivalent to granting Plaintiff exclusive rights over not only Dolly's genetic information as is presently known, but also exclusive rights over *future* information on Dolly. As technology increases, the amount of information that can be extracted from a DNA sample also increases. Allowing any person or entity access or rights to this level of information would be the gravest breach of every individual's *a priori* right to control his or her own genetic information. Despite this, Plaintiff urges this Court to not only find Claim 1 and Claim 2 valid, but also to ignore current public and policy goals that reflect one's fundamental right to genetic privacy. For the reasons set forth in Defendant Dolly's Points and Authorities and further herein, Defendant Dolly has inherent ownership rights to his genetic material. Furthermore, Defendant Dolly alone has the constitutional and common law right to his own genetic material, including the

right to use it. Without having specifically relinquished any of these rights, Defendant Dolly cannot infringe Plaintiff's '271 patent.

II. DEFENDANT DOLLY'S REPLY

A. Defendant Dolly Does Assert That He Has Legal and Inherent Rights to His Excised Tissue

In the Introduction to Plaintiff's Points and Authorities, Plaintiff incorrectly states that Defendant Dolly "has *no* legal or inherent rights to his excised tissue and, therefore, no entitlement to profits that have arisen from the research that Plaintiff has conducted." (Pl.'s Mem. Supp. Summ. J. at 981 (emphasis added).) This statement is not supported by the record. In fact, Defendant Dolly *does* assert that he *alone* has the inherent and all legal (i.e., constitutional and common law) rights to his tissue and *all* the genetic material and genetic information contained in his tissues (including excised tissues).

Only Defendant Dolly has the constitutional and common law right to the use or sale of his own genetic material. Furthermore, because Defendant Dolly has a property interest in his tissue samples, he is constitutionally protected to profit from any productive use of those samples. Enforcement of the '271 patent would not only deny Dolly his fundamental right to disconnect his body from the public domain (i.e., to control his genetic lineage and reproduction), it would also violate Dolly's right to genetic privacy and control over his own genetic information.

B. Defendant Dolly Retains All Ownership and Legal Rights to His Genetic Material Including the Information for Which It Inherently Encodes

Plaintiff asserts that "Dolly gave up the rights to the blood sample when he gave the sample to AGTC. AGTC then transferred the blood to NuGenEra, giving NuGenEra the blood and the right to perform research on it." (Pl.'s Mem. Supp. Summ. J. at 13.) Defendant Dolly gave up none of his legal or inherent rights to the genetic material and genetic information contained in his blood sample when he entrusted his blood sample to AGTC for testing. As stated clearly on the *only* consent form Dolly signed at the time of blood sampling, the blood sample was for purposes of genetic testing

only and "all information will be confidential and will not be disclosed by Advanced Genetic Testing staff." (Pl.'s Compl., App. A.)[1]

1. Dolly gave up neither ownership rights nor any other rights by entrusting a blood sample to AGTC for genetic testing

Plaintiff contends that it performed no wrong in obtaining a sample of Salvador Dolly's blood and that Dolly gave up the right to the blood sample when entrusting it to AGTC. Further, that AGTC's subsequent transfer of the blood to NuGenEra transferred ownership rights over the blood sample along with the right to perform genetic research on it.

a. Plaintiff's purchase and subsequent use of the blood sample amounts to clear and unambiguous misconduct

NuGenEra knew of the confidential relationship between AGTC and Dolly. They were also aware of the health code regulations regarding proper disposal of biological material. Their actions in violation of both the confidentiality agreement between AGTC and Dolly and section 7054.4 of the California Health and Safety Code amounts to clear misconduct by NuGenEra. This is further reason for why this Court should find Plaintiff's patent invalid and unenforceable. To do otherwise would be to further reward Plaintiff's misconduct and improper behavior in breach of Defendant Dolly's inherent rights to his genetic material.

b. Dolly retained all rights to his genetic material as well as the information contained in the DNA within the blood sample

Dolly's relationship with AGTC is clearly spelled out in the consent form (*see* Pl.'s Compl., App. A), which Dolly signed at the time he provided his blood sample. Nowhere in the agreement are any of Dolly's rights assigned to AGTC or abandoned outright.

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1. The *Loyola of Los Angeles Law Review* will not be publishing the Complaint referenced in Defendant Dolly's Reply. The Complaint also contains Appendix A, which contains NuGenEra's Consent Form at issue in this case. To obtain a copy of the Complaint and NuGenEra's Consent Form, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.

Ownership rights must be affirmatively transferred. Since no such transfer is evident in the record, Dolly retains all proprietary rights to his blood sample and the information therein. Even if the physical tissue sample is determined to be appropriately transferred to NuGenEra, that does not extinguish Dolly's constitutionally protected privacy rights, and therefore, control over the ultimate disposition of his genetic material and the information contained in that material. (*See* Def.'s Answer (discussing Defendant Dolly's constitutional and common law rights to his genetic material and genetic information).)[2]

DNA is information. *See In re O'Farrell*, 853 F.2d 894, 896-97 (Fed. Cir. 1988); BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 99 (1983). As such, Dolly still has a constitutionally protected right to the confidentiality of his genetic information because transfer of his physical property (blood samples) does not imply transfer of the rights to informational property contained within the blood samples. The United States government, when issuing and enforcing patent rights, becomes a "state actor" for purposes of constitutional challenges. *See Shelley v. Kraemer*, 334 U.S. 1, 14-18 (1948). Therefore, the government's disclosure of Dolly's genetic information by issuing the '271 patent violates his constitutionally protected right to privacy under the Fourth Amendment (right to confidentiality). *See Doe v. City of New York*, 15 F.3d 264 (2d Cir. 1994).

c. AGTC could not have transferred the right to perform research on the blood sample because it did not have this right to begin with

The consent agreement specifies an explicit limited use, which does not include the right to perform research. The consent agreement clearly states the limited nature of AGTC's right to use the blood sample: to "attempt to assess the likelihood that I [Dolly] have inherited genes that increase the risks to my offspring of developing several known genetically-based diseases." (Pl.'s Compl., App. A) The consent agreement makes no reference to

2. The *Loyola of Los Angeles Law Review* will not be publishing the Answer referenced in Defendant Dolly's Reply. To obtain a copy of the Answer, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.

scientific research, therefore restraining AGTC, and any subsequent licensee, implied or otherwise, from asserting any rights to perform such research. Informed consent must be secured. (*See* Expert Test. Richard M. Myers, Ph.D.)[3] Therefore, it is impossible for AGTC to transfer such rights to NuGenEra because AGTC's permitted use of Dolly's blood sample was contractually limited to "testing" per the consent agreement. (*See* Pl.'s Compl., App. A.)

2. AGTC failed in its fiduciary responsibility when it transferred the blood sample to NuGenEra

Contrary to Plaintiff's assertion, AGTC did fail in its fiduciary responsibility when it transferred Dolly's blood samples to NuGenEra. The consent agreement clearly states an understanding "that all information will be confidential and will not be disclosed." (Pl.'s Compl., App. A.) By transferring tissue samples containing Dolly's DNA to NuGenEra, AGTC knowingly violated the contract between Dolly and AGTC. AGTC violated the inherent trusted relationship and the fiduciary responsibility between a doctor and a patient. Fiduciary responsibility requires informed consent.

The medical and research community recognizes their public policy and ethical duties to an individual's inherent property and privacy rights by requiring every patient's expressed consent prior to any research, testing or use of the patient's tissue and/or DNA samples. (*See* Expert Test. Richard M. Myers, Ph.D.; Def.'s Reply, Ex. A, Parts 1 and 2.)[4]

It is standard practice in the medical and research industries to secure explicit and informed consent before any medical or scientific activities are performed on a patient or before using any bodily

3. The *Loyola of Los Angeles Law Review* will not be publishing the Expert Testimony of Richard Myers referenced in Defendant Dolly's Reply. To obtain a copy of Richard Myers' Expert Testimony, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.

4. The *Loyola of Los Angeles Law Review* will not be publishing Exhibit A referenced in Defendant Dolly's Reply. Part 1 of Exhibit A contains a sample consent form. Part 2 of Exhibit A contains the University of Southern California's Institutional Review Board (IRB) Application. To obtain a copy of Exhibit A, Parts 1 and 2, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.

material provided by the patient. (*See* Expert Test. Richard M. Myers, Ph.D.; Def.'s Reply, Ex. A, Part 1 and 2.) By failing to secure appropriate informed consent to perform scientific research and to commercialize the results thereof, AGTC and NuGenEra both failed in their inherent fiduciary responsibility to Defendant Dolly. *See Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). Furthermore, this activity was a breach of AGTC's contractual obligations to Dolly as it violated the terms of the initial consent agreement between Dolly and AGTC.

3. Dolly's continuing interest in "excised cells" requires that the cells within the blood sample be properly disposed subsequent to performance of genetic tests

Plaintiff cites *Moore* to uphold their assertion that Dolly had a limited continuing interest in excised cells. However, Plaintiff's cited reference also outlines the requirement that such cells be disposed of properly. Transfer to NuGenEra for the purposes of research does not constitute proper disposal under any reading of section 7054.4 of the California Health and Safety Code.

The California Health and Safety Code delineates that cells, "following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department to protect the public health and safety." CAL. HEALTH & SAFETY CODE § 7054.4 (West Supp. 2001). Therefore, cells are in a condition for disposal only "following conclusion of scientific use." *Id.* The scientific use of Dolly's cells had not reached a conclusion by the time that AGTC transferred Dolly's cells to NuGenEra. The record does not support Plaintiff's contrary assertion in their Statement of Facts. (*See* Pl.'s Mem. Supp. Summ. J. at 981-82.) In fact, by Plaintiff's own admission, Dolly's blood cells were transferred to NuGenEra for further research. (*See* Pl.'s Mem. Supp. Summ. J. at 981-82.) Thus, Dolly's blood cells were still being used for "scientific use" and were, therefore, not in condition for disposal. Assuming arguendo, if the blood samples were in condition for disposal, AGTC did not properly dispose of them by interment, incineration, or any other method protecting the public health and safety. *See* § 7054.4. Instead, AGTC transferred Dolly's blood cells to NuGenEra in direct violation of the consent agreement.

4. Granting ownership to Dolly will not impose any hardship to medical research

Plaintiff claims that informed consent for transfer of such rights as ownership would present a "colossal burden." (Pl.'s Mem. Supp. Summ. J. at 983.) Respectfully, Defendant Dolly points out that transfer of ownership without informed consent is commonly known as theft and that limiting such activity is a burden only to those who steal. Moreover, Plaintiff relies solely on *Moore* as its source of referenced policy arguments. This is fatal because the policy behind the decision in *Moore* is concerned with the extension of the conversion theory of tort law. Here, Dolly is not alleging a claim for conversion. Rather, he is asserting his constitutional rights to property and privacy of his genetic material and information. Accordingly, the *Moore* opinion is grounded in markedly different polices and has little relevance to the instant case.

5. NuGenEra had reason to know of the impropriety of acquiring Dolly's DNA

Plaintiff asserts that NuGenEra "had no reason to question the valid ownership of the cells they obtained from AGTC." (Pl.'s Mem. Supp. Summ. J. at 984.) However, it is a matter of record that NuGenEra did in fact know that AGTC entered into a confidential relationship with the client as described in the consent agreement, and therefore, did knowingly misappropriate the tissue sample in contravention of that agreement. (*See* Pl.'s Compl., App. A at 5.) Therefore, NuGenEra has no claim to any right to use or perform tests on said sample or to use, copy, or distribute the information contained in that sample. In fact, such misappropriation may be subject to the Economic Espionage Act of 1996 and, if so found, all such information and any products derived therefrom, including the '271 patent, would be forfeited. *See* 18 U.S.C. §§ 1831-1839.

C. Even if Claim 1 and Claim 2 Are Valid, Dolly's Sale of His Own Whole Blood Is Not an Infringing Act Because a Whole-Blood Sample Does Not Satisfy the Statutory Subject Matter Requirement for Patentability and Therefore Cannot Fall Within the Scope of the Claimed Invention

Plaintiff asserts that the '271 patent satisfies the statutory subject matter requirement under 35 U.S.C. § 101. However, the issue is

whether Defendant Dolly's sale of his whole blood is an infringing act under 35 U.S.C. § 271. A sample of whole blood is a product of nature and as such cannot satisfy the statutory subject matter requirement under § 101. Living things resulting from human inventive effort are patentable subject matter if they are a product of human ingenuity. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308-13 (1980). Indeed, we do not dispute Plaintiff's assertion that isolated and purified DNA sequences are patentable subject matter. However, whereas certain DNA sequences as compositions of matter may qualify as patentable subject matter when in their *isolated and purified* form, whole blood is not an isolated or purified genetic composition. Therefore, Plaintiff has failed to "make a showing sufficient to establish the existence of an element essential" to their case as required under Federal Rule of Civil Procedure 56 for granting of summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also* FED. R. CIV. P. 56.

Furthermore, Claim 1 of Plaintiff's patent is directed to Dolly's complete genomic sequence. While patent laws have been broadly applied to biotechnology, a complete human genomic sequence is widely regarded by both the scientific and legislative communities as outside the range of patentable subject matter. (*See* Expert Test. Richard M. Myers, Ph.D.) This is largely because there is no specific, substantial or credible utility associated with the ownership of the particular complete genetic combination unique to a given individual. As expressed by Todd Dickinson during the Gene Patents and Other Genomic Inventions Hearing before the Subcommittee on Courts and Intellectual Property: "As with any other invention, genomic products must be useful in order to obtain a patent. Raw DNA sequence data, such as that recently generated by the Human Genome project and by various corporate endeavors, is not patentable as it stands. There is *no utility* associated with it." *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary*, 106th Cong. 6 (2000) (statement of Todd Dickinson, under secretary of commerce for intellectual property and director of the United States Patent and Trademark Office, Department of Commerce) (emphasis added).

Furthermore, whereas a given individual may carry interesting gene variants requiring scientific and epidemiological verification (to

establish a particular practical and credible utility), such gene variant sequences may fall into patentable subject matter; however, an entire human genome (which includes noncoding sequences), has only one obvious utility—to generate a genetic clone of the source individual (human cloning). We need not discuss further here, that human cloning carries with it ethical, moral, and social policy issues. Not only is the act itself prohibited in the United States, but as a society, we have deemed such activities unethical and abhorrent. (*See* Expert Test. Richard M. Myers, Ph.D.)

Plaintiff takes care to note that, in all three claims, the material that is claimed is an isolated or manufactured composition of matter that is not found in nature. We point out that while this is a necessary condition for patentability, it is not sufficient grounds for awarding a patent. Statutory requirements for patentability also require that the invention have patentable utility, be nonobviousness, and that the patent specification be enabling to one skilled in the art.

1. Only Claim 1 and Claim 2 are at issue here, both of which are invalid for failure to meet long-established legal standards of patentable utility

As asserted by Plaintiff, the utility of the invention of Claim 1 and Claim 2 is in its further use for advancing "research"—a use that *Brenner v. Manson*, 383 U.S. 519, 532-36 (1966), explicitly stated as lacking *patentable* utility.

As Plaintiff notes, utility is defined as a requirement to benefit society; patents are intended to motivate and award inventors for doing public good. However, so as to protect against abuse of the patent system by patent-seekers looking to preemptively exclude others from a fruitful area of research, the United States Patent and Trademark Office (PTO) patent guidelines require a "specific, substantial, and credible" utility. As Plaintiff asserts, Claim 1's utility is in "propagating conditions that permit further, advanced research, rather than on a separate, 'immunity-boosting mechanism,'" (Pl.'s Mem. Supp. Summ. J. at 989), the goal of future advanced research being to use the genome as a "valuable source of anti-HIV compounds, which can be used to develop anti-HIV drugs." (Pl.'s Mem. Supp. Summ. J. at 988.) In other words, Plaintiff believes that there are genetic elements (other than the P sequence)

with anti-HIV properties within Defendant Dolly's genome, and thus states the utility of Claim 1 as a research tool.

The Supreme Court explicitly states that "a patent is not a hunting license." *Brenner*, 383 U.S. at 536. In adhering to this standard, the new PTO biotechnology patent guidelines specifically do not acknowledge the future use of the invention as a research tool to be a patentable utility—it is expected to have some present utility that will immediately begin to benefit society. Furthermore, Plaintiff's stated utility for Claim 1 lacks credibility in that it has not indicated how the genome will be used or what particular genetic loci are candidate sites of interest. Essentially, Plaintiff wishes to assert that § 101 be read so broadly as to allow the patenting of three billion base-pairs of genetic sequence that have yet to be characterized, annotated, and understood. This is akin to granting exclusive patent rights for the identification of the letters used to write a book containing three billion letters, but the order and location of the words are scrambled and the meaning of ninety-nine percent of the words is unknown. Only when the words and sentences are unscrambled can the contents and substance of the book be understood.

Finally, Claim 1 lacks specific utility because the asserted utility applies to a whole category of genes (all the genes contained in Dolly) and the intended uses have only been generally claimed. If such a broad claim were to be allowed by United States patent law, the result would be that Plaintiff would preemptively block future research and innovation related to the anti-HIV properties of Dolly's genome. As an illustration, it would be as if the inventor of a new and useful fishing pole would not be entitled to a patent because a patented utility exists (catching fish) that applies to an entire category of inventions (nets, clubs, dynamite, etc.), as well as to the catching of all unspecified fish. If Plaintiff were to be awarded such a broad utility claim, ironically, the very purpose of patent law, which is to promote research and innovation that would benefit society, would be subverted, since the patent would only act as a barrier to suppress further research by other scientists in this still nascent field.

Similarly, Claim 2 lacks a credible and specific utility. Plaintiff's stated utility for a "specific gene combination may also act as a diagnostic tool for HIV susceptibility." (Pl.'s Mem. Supp.

Summ. J. at 988.) This very language reveals that the claim lacks credibility—Plaintiff has no evidence one way or the other whether there is a substantial diagnostic utility for this gene combination, and cannot claim as such. Like its suggestion of the use of the allelic combination for gene therapy, these ideas lie in the domain of future projections and predictions with no evidence that these utilities will ever be realized.

Claim 2 also lacks a specific utility. Because Plaintiff has yet to develop or pilot a diagnostic assay that makes use of the gene combination P, the claim cannot be made that P can be used for this particular purpose. Even if this were the case, the scope of Claim 2 should be narrowed to the use of these alleles for diagnostic purposes. Because Plaintiff does not know the biological targets of the ten alleles in Claim 2, it cannot begin to make a specific claim for the use of these alleles. As such, its suggested utilities, for instance, applications to gene therapy, diagnostics, or development of anti-HIV pharmaceuticals, are unfounded and lie in the domain of imagination. Furthermore, because these ten alleles are identified from only a *single* individual (Dolly), even if Plaintiff asserts its patentable utility to be in the potential use of these alleles as diagnostic tools, for what or against whom can these alleles diagnose? In other words, unless the variant or novel sequences of Claim 2 are shown to *also* exist in other HIV resistant individuals, how can they be used to diagnose or probe for alleles in anyone else but Dolly himself?

Clearly, substantial further research (e.g., epidemiological and genetic linkage studies) will be required before the claimed P sequences will be useful to anyone other than Dolly himself. Nevertheless, Plaintiff wishes to control that research by claiming exclusive ownership of the gene combination for which it currently has no credible use. Again, the assignment of ownership rights of the allelic combination to Plaintiff would serve only to hinder future research and invention by other parties who could develop specific and genuine utilities for the gene combination (e.g., use as a diagnostic probe because the gene combinations do in fact exist in other HIV resistant individuals).

There are no infringement charges on Claim 3, so its validity is not directly relevant to this case. However, we simply wish to note that because we consider Claim 1 to be invalid based on the

discussion above, the stated utility of Claim 3—as a continuous source of the Dolly Genome—is inappropriate because we consider the whole Dolly Genome to be unpatentable subject matter. The only credible utility of the cell line described in Claim 3 is as a research tool; however, as also discussed above, utility as a research tool does not merit patentability. *See Brenner*, 383 U.S. at 532-36.

2. Dolly's isolated blood does not fall within the scope of Claim 1 and Claim 2 and, as a product of nature, cannot fall within the subject matter of Claim 1 and Claim 2

As repeatedly affirmed throughout Plaintiff's Points and Authorities, the isolated genetic composition and the sequences of nucleotides of Claim 1 and Claim 2 are not products of nature. Therefore, a product of nature cannot infringe on the claims. Since Defendant Dolly's blood is in fact a product of nature, the sale of Dolly's blood cannot infringe on patent '271.

D. As a Matter of Public Policy, Plaintiff Should Not Be Rewarded Nor Allowed to Profit from Research Derived from Unethical Conduct and Misappropriated Tissue

Dolly's fundamental, constitutional, and common law rights to his genetic property and privacy preclude any possible "right to profit" claimed by NuGenEra when such profit arises from misappropriation. Protecting these individual rights will aid, not hinder "future research by removing necessary incentives for companies to perform genetic research." (Pl.'s Mem. Supp. Summ. J. at 996.) Plaintiff asks: "What company would expend limited resources of time and money if it had no chance of profiting from its labor?" (Pl.'s Mem. Supp. Summ. J. at 996.) This question is irrelevant because it assumes that protecting individual rights equates to loss of a company's possibility of profit from its labor. Rather, contract law can easily secure economic profitability.

The real question is, what individual would delegate his body and genetic material to research without assurances of his constitutional rights to property and privacy? Answer: No one. Indeed, this reality, more than any other, identifies a hindrance to "future research" to a fatal degree. Standard practice in the field, therefore, respects this right by requiring informed consent be

obtained for *all* studies using human subjects. (*See* Def.'s Reply, Ex. A. Part 2.)

1. Clear rights to one's own genome will aid, not hinder, further research and commercialization

Plaintiff asserts that if individuals had clear rights to their own genome, "[t]he obvious result would be a disaster to both ongoing research and future research." (Pl.'s Mem. Supp. Summ. J. at 996.) The facts do not bear out this dire warning of chaos and doom. In fact, current practice among ethical practitioners presupposes the patient's right to control the use of his or her own body—including the right to control his or her DNA, as exemplified in the attached consent form (*see* Def.'s Reply, Ex. A. Part 1) and discussed in Dr. Myer's testimony (*see* Expert Test. Richard M. Myers, Ph.D.). In fact, the record does not support the supposed damage caused by acknowledging in this court the commonly understood rights of patients.

In fact, Defendant Dolly believes that clear and unambiguous rights will reduce the chaos and confusion in this rapidly emerging field. Both companies and individuals need clear, bright lines to delineate the rights and responsibilities of every party to medical and biological research and testing in genetics. As our society progresses from the industrial age into the information age—where even the basic building blocks of life are studied, manipulated, and developed as bits of information—a new regime of property rights must emerge. Protecting the right of an individual to control his own body—and the information that is uniquely his own—affirms centuries of common law and constitutional rights in this brave new world of modern technology.

2. Granting Plaintiff exclusive rights will stifle, not promote, further research and commercialization

Contrary to Plaintiff's assertion that exclusive rights for Defendant Dolly will stifle research, it is clear that the converse is true. Plaintiff has a noncredible claim to an astonishing trait—resistance (HIV resistance) to what may fairly be described as the worst medical crisis at the turn of the millennium. The global public, and the pharmaceutical companies who provide medical cures and treatments, will clearly benefit from a rapid and thorough

investigation of Dolly's DNA. Instead, Plaintiff seeks a monopoly on such research despite a failure to offer the public any specific credible utility beyond use of the claimed invention for further research upon itself. Indeed, Plaintiff has patented the entire genome in the hopes of finding additional sequences that play a role in Dolly's HIV resistance.

In the name of profit, Plaintiff seeks to create an "empty sandbox" where they, and they alone, are allowed to explore the vast potential of Dolly's DNA. This is unthinkable. Every researcher with an interest, every lab with the motivation and the talent (and Dolly's expressed consent), should be free to investigate and discover unique applications of Dolly's DNA. When such investigations lead to specific, credible applications of substantial public benefit, then let us issue and acknowledge patents for drugs, treatments, and compositions—for those inventions that can be applied to real people in the real world. If Plaintiff's request for recognition of its exclusive monopoly over Dolly's genome is granted, the clear and unequivocal result will be the lessening of research, a slowing of the pace of innovation, and a real and specific loss of public benefit; indeed it could well lead to the continued unnecessary suffering and death of Acquired Immune Deficiency Syndrome (AIDS) sufferers for decades ahead.

3. Recognition and enforcement of Claim 1 denies research in other areas of Dolly's genome that are completely unrelated to his HIV resistance

Plaintiff seeks exclusive rights over Dolly's entire genome, including those sequences that do not confer HIV resistance but instead are involved in other generic and heretofore unknown, but required, biological life processes. Granting that exclusivity without demonstrated specific utility will hinder further research and development of benefit to our society, without providing any benefit other than a privilege for those retaining the research rights. Such a decision would restrict the investigation into the use of the 99.99% of Dolly's genes whose functions are yet to be discovered. Clearly, granting Plaintiff's request for a legal monopoly in Dolly's genome would serve only to stifle research.

III. CONCLUSION

For the foregoing reasons, Defendant Dolly respectfully submits that his Motion for Summary Judgment be granted.

Dated: October 19, 2001

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Exhibit A-1[5]
Exhibit A-2[6]

5. The *Loyola of Los Angeles Law Review* will not be publishing Exhibit A-1, which contains a sample consent form. To obtain a copy of Exhibit A-1, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.

6. The *Loyola of Los Angeles Law Review* will not be publishing Exhibit A-2, which contains the University of Southern California's Institutional Review Board (IRB) Application. To obtain a copy of Exhibit A-2, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, *at* http://techlaw.lls.edu/atc3/pleadings.html.