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

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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF CALIFORNIA

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

Plaintiff NuGenEra, Inc., by its undersigned attorneys, hereby submits its Reply in Opposition to Defendant Dolly's Motion for Summary Judgment.

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I. INTRODUCTION

Defendant Dolly presents himself as a victim of outdated legislation and patent office guidelines full of loopholes. On the contrary, the United States Patent Office has promulgated new guidelines, effective January, 2001, to keep abreast of developments in science. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). As to the litany of rights presented by Defendant Dolly, they are either a product of his imagination or, if substantive, are not infringed by NuGenEra's U.S. Patent No. F6,635,271 ('271 patent). NuGenEra is a legitimate enterprise engaged in socially beneficial biomedical research. Defendant Dolly's samples were collected and handled in accordance with established California law.

II. NUGENERA'S '271 PATENT IS VALID AND MEETS THE STATUTORY REQUIREMENTS FOR UTILITY AS BOTH USEFUL AND ENABLING

Defendant Dolly argues that the inventions in Claim 1 and Claim 2 (whole genome and gene combination P1-P10) have no utility defined as "well established" or "specific, substantial, and credible." As formulated by the United States Supreme Court, a single credible utility is sufficient to satisfy the requirements of 35 U.S.C. § 101. *See Brenner v. Manson*, 383 U.S. 519, 529-36 (1966). This case remains valid law. We herein present several examples of therapeutic and diagnostic uses that require the materials claimed in the patent. The uses are first introduced as "well established" and following this, are validated as "specific, substantial, and credible." *See* Utility Examination Guidelines, 66 Fed. Reg. at 1092.

A. The Isolated P1-P10 Sequences in Claim 2 Exhibit Well-Established Use

The isolated P1-P10 sequences may be used in gene therapy. As described in the text of the patent, the P1-P10 sequences "confer a dominant trait" of partial HIV resistance (Pl.'s Compl., App. B.)[1] on

1. The *Loyola of Los Angeles Law Review* will not be publishing the Complaint. Appendix B contains United States Patent Number F6,635,271, the patent at issue in this case, which is published at 971. To obtain a copy of the Complaint, 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.

a susceptible cell in vitro and on an experimental animal in vivo. Simply put, a cell supplemented with the P1-P10 sequences can better fight an attack and inevitable destruction by the HIV. (*See* Expert Test. Richard M. Myers, Ph.D.)[2] Gene therapy is a well-established procedure pioneered nearly two decades ago. *See* JAMES D. WATSON ET AL., RECOMBINANT DNA (2d ed. 1992).

In addition, the isolated P1-P10 sequences can be used as a diagnostic tool. Based on the test results quoted in the Detailed Description of the Invention, the P1-P10 genes play a role in HIV resistance observed in Dolly cells. Therefore, the presence of similar sequence variations in other people is predictive of their likelihood of infection or a long-term prognosis with respect to the development of AIDS. The entire isolated sequence in Claim 2 may be used as a probe on a patient's sample. Such DNA-DNA comparison or "hybridization" is a well-established technique. *See* WATSON, *supra*, at 99-133. Alternatively, the P1-P10 sequences can be used to design primers so that the patient's sample may be tested by PCR, another well-known technique. *See id.* at 539-66. It has become common knowledge that gene variations are being used in advising patients on their susceptibility to diseases. The precise predictive value of the variations in the P1-P10 sequences (as compared to, for example, variations in the "breast cancer" (BRCA1) gene sequences) is not at issue here. What is at issue is the existence of a very well-established method of using such sequences for predictions.

B. The Entire Isolated Dolly Genome in Claim 1 Exhibits Well-Established Use

The isolated Dolly Genome likewise can be used in various diagnostic procedures. The general goal of such procedures will be to ascertain the HIV susceptibility and the prognosis on the development of AIDS in patients. A person whose genome harbors some of the variations similar to the Dolly Genome is likely to possess some of the HIV resistance exhibited by Dolly's cells.

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2. The *Loyola of Los Angeles Law Review* will not be publishing the Expert Testimony of Richard Myers referenced in Plaintiff'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.

Contrary to the categorical declarations of Defendant Dolly's expert (*see* Expert Test. Richard M. Myers, Ph.D. at 5), a number of well established genome comparison techniques require the entire (whole) genome as a substrate. One such technique is Restriction Fragment Length Polymorphism (RFLP) analysis. *See* WATSON, *supra*, at 511-37. Many such polymorphisms are "linked" to functional genes, thus the presence of a polymorphism is indicative of the neighboring gene's function. If a patient's sample is analyzed side-by-side with the Dolly Genome and a similar RFLP pattern is observed, a similar function is expected. The aforementioned use is well established as required by the United States Patent and Trademark Office (PTO) since only "well-known" techniques can be used.

C. The Proposed Use of the Claimed Sequences Is Specific, Substantial, and Credible

The burden is on the challenger of the patent to show that the use is "incredible" to the practitioner of the art at the time the application was filed. Such a practitioner must show "rational basis to doubt the truth." (Def.'s Mem. Supp. Summ. J. at 1013.) For the following reasons, we see no rational basis in such doubt.

D. The Use of Isolated P1-P10 Sequences Is Specific, Substantial, and Credible

Defendant Dolly discredits the use in gene therapy on two grounds. First, Defendant Dolly's expert criticizes the technique of gene therapy for its limited success. Secondly, Defendant Dolly doubts whether the P1-P10 sequences work as described (confer HIV resistance on susceptible tissues *in vivo* and *in vitro*). Both arguments lack sufficient ground.

1. Gene therapy is a specific procedure with credible applications

Proof of utility does not require that gene therapy must have cured anyone before the patent on a therapeutic sequence is granted. *See Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980) (concluding that adequate proof of any such activity constitutes a showing of practical utility); *see also Cross v. Iizuka*, 753 F.2d 1040, 1051 (Fed. Cir. 1985) (finding sufficient utility based on in vitro test results in lieu of possible future testing in humans). Courts merely

require a likelihood of success. The challenger, therefore, must explain why a particular sequence is unlikely to work. The fact that the technique itself is uncertain has no bearing on the potential of the claimed sequences in relation to others. Numerous groups are working on various gene therapy projects, including Plaintiff's expert. (*See* Expert Test. Noriyuki Kasahara, M.D., Ph.D.)[3] Therefore, at least some sequences are likely to produce successful results. The expert's criticism is a personal opinion of a general nature. It has no bearing on the credibility of the specific use.

2. The specific performance (function) of P1-P10 sequences is credible

Second, Defendant Dolly doubts that the P1-P10 sequences works as described in the specifications. He demands the description of "the nature of those sub-cellular factors involved in increasing HIV resistance." (Def.'s Mem. Supp. Summ. J. at 1014.) This argument is contrary to established law. According to the PTO Utility Examination Guidelines, it "is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001) (quoting *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989)).

It is ironic that Defendant Dolly quotes *In re Isaacs*, 347 F.2d 887 (C.C.P.A. 1965). The Court of Customs and Patent Appeals reversed the rejection based on lack of utility under 35 U.S.C. § 101. *See id.* at 888-90. The Isaacs' invention comprised a now well-known antiviral compound named "Interferon." *Id.* at 888. The exact mechanisms of action of this substance are still unclear after decades of investigation. *See* FRANK FENNER & DAVID O. WHITE, MEDICAL VIROLOGY 94-97, 130-31 (2d ed. 1976). Nevertheless, Interferon is widely prescribed as an efficient antiviral agent. *See In re Isaacs*, 347 F.2d at 888-90. The PTO in *In re Issacs* found the in vitro testing credible and satisfactory. However, the examiners were deterred by the uncertainty: "What this viral interfering activity

3. The *Loyola of Los Angeles Law Review* will not be publishing the Expert Testimony of Noriyuki Kasahara referenced in Plaintiff's Reply. To obtain a copy of Noriyuki Kasahara's 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.

amounts to and the nature and extent of its interference are not specified in the claims . . . ." *Id.* at 892. The appellate court disagreed and held that "an applicant need not understand the theory or scientific principle underlying his invention." *Id.* (citing *In re Storrs*, 245 F.2d 474, 478 (C.C.P.A. 1957)). "All that an applicant need do is enable a person skilled in the art to duplicate his efforts . . . ." *Id.*

The facts of NuGenEra's invention are virtually identical to those found in *In re Isaacs*. The record indicates that NuGenEra performed standard procedures to generate and test transgenic cells and animals carrying P1-P10 sequences. A valid result was obtained (reduced HIV infection upon challenge as measured by valid methods). No scientific fact is presented to suggest the impossibility of such outcome. No fraud is alleged, much less proven. The criticism has no requisite "rational basis." If anything, the incredulous tone of Defendant Dolly's response suggests non-obviousness of the invention. In conclusion, the results of the aforementioned tests provide sufficient basis for finding the therapeutic use of the P1-P10 sequences "specific, credible, and substantial" under established law.

Likewise, the diagnostic use of P1-P10 sequences involves well-established procedures (RFLP analysis with P1-P10 sequences as probes or a source of PCR primers). No explanation is provided as to why the procedures may not succeed. To discredit the use in standard techniques, Defendant Dolly must explain why the isolated Dolly P1-P10 sequences will not hybridize to the P1-P10 sequences from other people when used as probes (contrary to the described chemical properties of DNA). *See* RICHARD R. SINDEN, DNA STRUCTURE AND FUNCTION 1-57 (1994). The predictive value of the obtained results in regard to HIV need not amount to absolute certainty. Some traits like Huntington's disease invariably develop if a particular sequence is present. Other sequences only increase the likelihood of a certain outcome. For the test to be useless, the sequence has to have no bearing whatsoever on the trait in question. Given the results of in vitro and in vivo tests, one cannot argue that the P1-P10 sequences have absolutely no relation to the trait of HIV resistance.

3. The use of the isolated Dolly Genome is specific, substantial, and credible

The diagnostic procedure that employs the entire isolated genome is as standard as those employing the P1-P10 sequences (RFLP analysis). No evidence is presented as to why the isolated Dolly Genome will not react with probes when run side-by-side with another person's DNA. The substantial value of such experiments depends on the probe used. A variety of probes may be obtained from countless public and private sources. For example, if a probe such as P1-P10 sequence is involved in HIV resistance, one's isolated genome may be probed with it to predict whether the resistance exists. The result will be meaningless unless the RFLP pattern of the test sample is compared to that of the Dolly Genome. The use in RFLP analysis is credible.

In summary, Defendant Dolly offers no evidence of technical impossibility ("incredulousness") of the standard procedures encompassed by the disclosed term "diagnostic use." The objection then is limited to the substantiality of the result. The predictive value of the analysis is doubted as unsupported by linkage analysis that requires the analysis of numerous samples. There is no evidence that such analysis has not been done. Since, when in doubt, the claims must be read as to preserve their validity under 35 U.S.C. § 282, Plaintiff interprets "isolated" in Claim 2 to be a standard result of a linkage analysis and gene-finding procedure performed using the large number of samples in possession of NuGenEra. *See* WATSON, *supra*, at 511-37 (describing the details of the standard procedure). Defendant Dolly's expert belittles NuGenEra suggesting that this task would have been insurmountable. However, NuGenEra had the resources to sequence the entire genome. It took many years for the Human Genome Project and Celera to accomplish the same task.

E. The "Combinatorial Issue" Is Moot

Lastly, Defendant Dolly engages in a futile mental exercise attacking the term "sequence combination." The validity of the gene combination P1-P10 is being challenged as not having been sufficiently tested. The further suggestion is to perform "a minimum of 1.8 billion separate assays," (Def.'s Mem. Supp. Summ. J. at 1016), to rule out other gene combinations (possibly less than ten) and the role of background DNA. This argument is without merit.

First, the role of background DNA is ruled out by a "negative control" that is an integral part of every scientific experiment. There is no evidence to suggest that NuGenEra's procedures are grossly inadequate so as not to have control. Likewise, it is preposterous to suggest the existence of PTO examiners not familiar with the elementary rules of the scientific method.

Second, the "combinatorial argument" is moot as it is based on a literal misreading of the language of the specification. Defendant Dolly alleges that what is claimed is "'one or more' P gene combination [that] confers HIV resistance." (Def.'s Mem. Supp. Summ. J. at 1016 (emphasis added).) However, the specification reads: "One or more genes *in* combination 'P' [that] confer . . . ." (Pl.'s Compl., App. B (emphasis added).) Defendant Dolly's wording suggests a code-like "combination" of which "one or more" are claimed. However, the use of the verb "confer" in its singular form necessarily connects it to "genes." "One or more *genes* confer" is grammatically correct. "One or more *combination* confer" is not. The combination does not do anything and has no independent meaning. What is claimed is a group (combination) of genes. The genes confer resistance. It is not unusual for several genes to have the same effect separately or in combination. Each gene confers resistance by itself (as verified by the experiments), but it is possible to have more than one as Dolly has all ten.[4]

The required presumption of validity limits the interpretation of claims to those that will not be invalidating. Therefore, the interpretation that suggests that billions of experiments were not done is not likely to be adopted.

In conclusion, it is apparent that in the case of the P1-P10 sequences (Claim 2) the "target disease" demanded by Defendant Dolly is AIDS. The "real world use" for the P1-P10 sequences and the entire genome is diagnosis and treatment of AIDS. NuGenEra's '271 patent is justly awarded and well deserved. It is true that the genome and the genes therein may have more uses than was

4. The reality of the laboratory practice suggests that the genes were tested separately. The introduction of genes into cells is significantly less efficient as the sequences get longer. It is preposterous to think that a researcher would overcome the tremendous difficulties of introducing ten genes at once prior to testing them one-by-one (the latter being an ordinary experiment done with relative ease).

envisioned by NuGenEra at the time of application. However, the multitude of future uses neither discredits nor contradicts the presently available uses. The recent PTO examination guidelines state: "Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001).

Finally, it has been argued that insufficient proof of utility is a counter-productive reason for denying the patent protection. The purpose of the patent system is to create incentives that stimulate discovery and disclosure to the public. If the inventors are forced to hold back the disclosure (in order to gather more and more convincing evidence of utility), both the inventor and the public lose and the legislative purpose is frustrated. On the other hand, if the patent is granted but the utility is not as hoped for, the result is in line with the legislative intent. The new information is disclosed to the public. At the same time the patentee does not gain more than he deserves if the invention is disfavored by the market because of insufficient utility. *See* Eric P. Mirabel, *"Practical Utility" Is a Useless Concept*, 36 AM. U. L. REV. 811, 823 (1987).

III. NO INDIVIDUAL RIGHTS OF DEFENDANT DOLLY ARE VIOLATED BY THE ENFORCEMENT OF THE PATENT

A. No Issues of Privacy or Fiduciary Duty Are Raised by Defendant Dolly's Original Consent Form

Defendant Dolly has attempted to show at length how the existence of the consent form signed by Dolly leads to legal and ethical concerns for NuGenEra. Upon closer examination it becomes clear that NuGenEra obtained the sample in a legally valid and morally acceptable way. It should be recognized that NuGenEra was not one of the original parties involved in obtaining the consent. The form represents an agreement solely between AGTC and Dolly. When NuGenEra purchased the sample from AGTC, a copy of the consent form was supplied to NuGenEra for reasons that have not been made clear.

Furthermore, AGTC fulfilled all fiduciary duties to Dolly because AGTC had no economic or personal interests in his genetic material. *See Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120,

129, 793 P.2d 479, 483, 271 Cal. Rptr. 146, 150 (1990) (explaining that a physician must disclose personal interests in research and that failure to do so raises a cause of action based on informed consent and breach of fiduciary duty). Whereas AGTC fulfilled its duty towards Dolly, NuGenEra never had any such duty. Defendant Dolly would make it seem that some action of NuGenEra violates the genetic privacy of Dolly. This is simply not true. NuGenEra has not disclosed any information tying the identity of Dolly to his genomic sequence.

B. There Exists No Inherent Right to Profit from Productive Use of One's Tissue Samples

NuGenEra's patent does not limit any rights of profit that belong to Dolly. This is because such a right never existed in regard to blood or human parts. Neither courts nor statutes recognize a right to profit from human parts. Further, any added value of Dolly's blood, above the value of the blood of a normal human being, is a result of NuGenEra's research and the property of NuGenEra.

1. Courts do not recognize a constitutional right to profit from research conducted on excised tissue

Defendant Dolly seeks to assert common law and constitutional property rights to use and sell his genetic material by claiming property rights to be inherent in one's removed blood. In doing so, he relies on the authority of a decision in which the factual premise and legal issues considered are greatly distinguishable. The court in *Green v. Commissioner*, 74 T.C. 1229 (1980) simply held that for tax-related purposes, blood sold could be classified as a product, not a service, and that the deterioration over time of certain factors within the blood could not be translated into depreciation value. *See id.* at 1238. The tax court compared a person's blood to "hen's eggs, bee's honey, cow's milk, or sheep's wool." *Id.* at 1234. This analogy led the court to consider the donation of blood to be the sale of a product. *See id.* However, the court never stated that blood is property.

What is important to note is that in reaching this conclusion, the court did not discuss what kind of products may actually constitute property. Further, blood is not universally regarded as a product. A New York court ruled in *Perlmutter v. Beth David Hospital*, 123

N.E.2d 792, 794-96 (N.Y. 1954), that the transfer of blood is a service, and not a product. A California Court of Appeal affirmed that decision in *Shepard v. Alexian Bros. Hospital, Inc.*, 33 Cal. App. 3d 606, 610-12, 109 Cal. Rptr. 132, 134-35 (1973).

The difference between human blood and the milk of a cow or the eggs of a hen is impossible to ignore. Humans need blood, whereas a cow does not need its milk. One cannot regulate how often a hen lays an egg, but there are restrictions on how often a person can donate blood. Cutting a sheep's wool will not adversely affect the sheep's ability to grow wool. However, taking blood can adversely affect humans. Repeatedly losing blood eventually causes a person to lose the ability to generate plasma. *See Green*, 74 T.C. at 1232. Clearly, blood cannot be treated in the same manner as a hen's egg.

Along the same lines, Defendant Dolly's reliance on a conclusion in *Hecht v. Superior Court*, 16 Cal. App. 4th 836, 850, 20 Cal. Rptr. 2d 275, 283 (1993), classifying isolated sperm as property due to its potential to create a child after fertilization, is broadly overstated because the court made this recognition only as factually applied to the case. The court found the decedent sperm donor had an interest "in the nature of ownership, to the extent that he had decision making authority as to the [use of his] sperm [for reproduction]," *id.* at 846, 20 Cal Rptr. 2d at 281, and found that the sperm qualified as property under section 62 of the California Probate Code in order to grant the Probate Court jurisdiction over the vials. *See id.* It is worthwhile to note that the court did not reach a conclusion as to property rights in the human body, and specifically declined to extend to the sperm general laws relating to personal property. This case is thus distinguishable on the ground that accordance of property rights was granted only to determine the disposition of gametic material and respective reproductive rights of a decedent-donor and his widow.

Due to the factual distinction and pertinent questions that these prior decisions did not reach, authority on this subject of property rights lies in *Moore*. Because Defendant Dolly likewise did not arrange to retain possession of his blood sample, he retained no constitutional protection to profit from any productive use of those samples, as he claims. Therefore, reliance on the narrow holdings of *Green*, *Hecht*, and the Uniform Anatomical Gift Act (UAGA) to

demonstrate a continuing right to profit from donated or sold blood is erroneous.

2. Legislative statutes do not recognize a constitutional right to profit from research conducted on excised tissue

Defendant Dolly argues the genome "is inviolably one's own property, as much as a heart, or brain, or blood is one's own property." (Def.'s Mem. Supp. Summ. J. at 1020.) Further, Defendant Dolly argues that the classification of blood and DNA as "property" gives a person the right to profit from them. (*See* Def.'s Mem. Supp. Summ. J. at 1023-26.) If that were true, then Dolly would have the right to sell his brain. However, the State of California does prevent people from profiting from the sale of their body parts. Under section 367f(a) of the California Penal Code, "it shall be unlawful for any person to knowingly acquire, receive, sell, promote the transfer of, or otherwise transfer any human organ, for purposes of transplantation, for valuable consideration." CAL. PENAL CODE § 367f(a) (West 1999). This law strongly suggests California's aversion to the sale of human products. Even nonessential organs, such as a person's kidney, are not exempt from this prohibition. This indicates there is no implicit right to sell one's blood for profit. Without such a right, Dolly lost no potential for profiting from his blood or his genes when the Office of Trademarks and Patents granted NuGenEra's patent.

Defendant Dolly also claims that the UAGA implicitly categorizes body parts as property solely because donations refer to the giving of "something," a single term, which Defendant Dolly, without inquiry into legislative intent, concludes must equate to property and its bundle of implied rights. The inapplicability of this statute as an authority to Defendant Dolly's right to profit claim is addressed in *Moore*, which states that the Act "does not, however, permit the donor to receive 'valuable consideration' for the transfer." *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 137 n.22, 793 P.2d 479, 489 n.22, 271 Cal. Rptr. 146, 156 n.22 (1990) (quoting CAL. HEALTH & SAFETY CODE § 7155 (West 1970 & Supp. 2001)). Defendant Dolly's attempt to characterize his blood samples as donations for which he may claim a constitutional right to profit thus fails.

C. *Defendant Dolly Does Not Have an Inherent Right to Profit from His Genome*

As there is no natural right to profit from the sale of one's blood, there exists no right to profit from one's genome. Defendant Dolly's argument that his genome sequence belongs to him and that he has a right to sell it does not hold. He has no more right to sell his DNA than he does his brain. Therefore, NuGenEra's patent does not infringe on Dolly's right to profit.

D. *Profitability of the Dolly Genome Currently Belongs to NuGenEra*

If the Court finds that Dolly can sell his genome, what would be its value? AGTC sold Dolly's blood sample to NuGenEra for a minimal price. Then, the value of his blood was the same as anybody else's. Had Dolly gone directly to NuGenEra to sell his blood at that time, it could be inferred that NuGenEra would not have paid Dolly any more money than they paid AGTC. Dolly would not have expected a higher price, as he would not have known any reason for a higher price.

After NuGenEra discovered Dolly's HIV immunity and filed its patent, the monetary value of Dolly's blood rose. Dolly did nothing to increase the value of his genome. The value of Dolly's blood rose because of the knowledge that it contained HIV resistant genes. NuGenEra discovered this information, and it is the intellectual property of NuGenEra. Dolly's profit from selling his genome is profit he stole from NuGenEra, not the profit from his genome alone. Dolly's genome was no more marketable than a normal human genome before NuGenEra's discovery. Therefore, the patent does not impose new limitations on Dolly's ability to profit, nor should it increase Dolly's ability to profit.

E. *NuGenEra's Patent Does Not Limit Defendant Dolly's General Right to Profit*

NuGenEra does not object to Dolly donating blood. Nor does NuGenEra object to Dolly participating in research. These were rights he had before NuGenEra ever made its discovery and invention. What Plaintiff does object to is Dolly attempting to profit from research NuGenEra performed. The patent does not limit

Dolly's natural rights; it merely prevents him from trampling over NuGenEra's.

F. Patents Are Exclusionary Rights and Cannot Be Considered an Invasion of Defendant Dolly's Right to Bodily Autonomy

Defendant Dolly argues that NuGenEra's patent should be invalidated for fundamental reasons of public policy, so far as it prevents Defendant Dolly from being able to use his genetic material. He claims that the existence of the NuGenEra patent reflects the severe consequences of a legislative failure and argues that the patent threatens each citizen's "life, liberty, and the pursuit of happiness," (Def.'s Mem. Supp. Summ. J. at 1018), equating the enforcement of the patent to an invasion of his bodily autonomy. Such dramatic language might strongly suggest that Dolly has been harshly mistreated or that he at the very least, faces a serious threat to his liberty or quality of life. Upon closer examination, however, it is apparent that no such mistreatment has occurred and no such threat exists. Bodily autonomy implicates a freedom from physical harm and does not apply to excised tissue that a patient has willingly donated. *See Moore*, 51 Cal. 3d at 147, 793 P.2d at 494, 271 Cal. Rptr. at 161. The right to bodily autonomy, as tort law understands it, addresses physical invasions or restraints of an individual's corporeal body or person. The patent's authority is an exclusionary right, and one that invades no actual bodily boundaries. It certainly does not violate, as Defendant Dolly insists, the "right to use, and control the use of, their own person." (Def.'s Mem. Supp. Summ. J. at 1020.)

Moreover, the right to bodily autonomy is a protected liberty, but no right is absolute if there exist laws that restrict them. Incarceration, which curtails bodily autonomy, is an available punishment for criminals who violate the law. In the same way, under U.S. patent law, others are prohibited for twenty years from the manufacture, use, sale or offer of sale of patented inventions. Defendant Dolly's exclusion from selling his tissues cannot, therefore, be considered an affront to his absolute rights.

NuGenEra's patent is purely a matter of intellectual property. Just as NuGenEra's possession of this intellectual property places no claim upon the physical body of Dolly, it is likewise reasonable that Dolly's physical body gives no inherent claim upon the patent.

These distinct entities need not interfere with each other. Notwithstanding the patent, Dolly keeps his right to donate blood, sell blood plasma, or even offer his tissue to those interested in general academic research. In short, he maintains the same personal rights he had before he learned about the NuGenEra patent. He is limited only in that he cannot supply his blood for the sole purpose of infringing the NuGenEra patent. But this is profit that Dolly would never have been able to gain before the research and subsequent patent by NuGenEra. It would seem then that Dolly is not interested in maintaining his rights, so much as he would like to expand them in a particularly profitable way.

1. Grant of the patent is not an invasion of Defendant Dolly's genetic privacy

Defendant Dolly alleges that NuGenEra's patent violates his genetic privacy. This argument holds very little merit given the circumstances that led to the present suit. Although NuGenEra received enough information to notify Defendant Dolly of his natural resistance to HIV once they discovered this trait, Plaintiff never attributed the patented sequence to any particular source. In fact, Defendant Dolly's role as the original tissue source was unknown to the public until he infringed the patent. He argues that in patenting his nucleotide sequence under Claim 1, NuGenEra violated the policy of the proposed Genetic Privacy Act, which guards against genetic discrimination based on dissemination of "'information about an identifiable individual.'" (Def.'s Mem. Supp. Summ. J. at 1022 (quoting Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 JURIMETRICS J. 1, 7 (1996)).) However, this argument seems tangential considering that NuGenEra never allowed any genetic information to be identifiable to Dolly. As we recall, Dolly has been responsible for this himself. NuGenEra never thwarted the Genetic Privacy Act's policy goals through its work on the tissue sample. Defendant Dolly claims that the information held within the Dolly Genome contains "power to greatly harm the very individual from which it is derived." (Def.'s Mem. Supp. Summ. J. at 1020.) Danger exists only to the extent that the genetic information can be tied to an individual owner. It is ironic that Dolly is personally responsible for any public knowledge that ties him to the genome in the NuGenEra patent. For this reason,

Dolly was the only individual NuGenEra informed about the source of the genetic sequences involved in the patent and this as a courtesy.

2. Defendant Dolly's constitutional rights to procreate or die are not affected

Defendant Dolly contends that the enforcement of NuGenEra's patent further violates two other privacy rights: the right to die (personal privacy) and the right to make decisions regarding whether or not to bear children (relational privacy). The Supreme Court has indeed found these rights to be fundamental, but these liberty rights are as inapplicable to Defendant Dolly's reproductive rights as they were to his alleged right to profit from his tissue. The factual settings and legal issues upon which those constitutional law decisions were predicated bear little resemblance to Defendant Dolly's situation. In *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 269, 284-87 (1990), the Court upheld the right of a terminally ill patient to refuse medical treatment, so long as the decision is made of sound mind. NuGenEra's patent does not preclude Defendant Dolly from his right to die or ability to execute his wish that medical treatment be withheld should he ever find himself in this situation. He is also not prevented from deciding not to procreate, which was ruled a fundamental right in *Eisenstadt v. Baird*, 405 U.S. 438 (1972). In *Troxel v. Granville*, 530 U.S. 57, 74-75 (2000), the Court held that parents have the right to control the upbringing of their children, but this decision also does not pertain to Defendant Dolly's complaints. These decisions affirmed the fundamental rights to life and control of family decision making, as society has traditionally understood them. Defendant Dolly's contention, however, that these rights should extend to protect his infringement of NuGenEra's patent misapplies the Court's understanding of the fundamental right of liberty.

NuGenEra's patent does not prevent Defendant Dolly from making fundamental life decisions regarding his own body. His assertion that NuGenEra's immortalized cell line (described in Claim 3) of the patent could cause him to be "kept alive" is scientifically unfounded in principle and practice. The patented cell line is physically distinguishable from Defendant Dolly's original tissue source due to its purified state.

Defendant Dolly's speculation that he could be reproduced against his will through the technology of cloning is not a viable argument to invalidate an otherwise valid gene patent. There are statutory safeguards, including the one in effect in California, which have placed a moratorium on human cloning until its ramifications can be fully ascertained. Defendant Dolly's allegations of perceived constitutional injury and unsubstantiated fears regarding the enforcement of Plaintiff's patent thus do not amount to legitimate public policy concerns. For this reason, Defendant Dolly's affirmative defenses fail to meet the clear and convincing standard of evidence needed to invalidate the '271 patent.

IV. CONCLUSION

For the reasons stated above and in Plaintiff's Points and Authorities, NuGenEra's patent is valid, the patent's enforcement does not violate any of Defendant Dolly's rights, and the social benefits of this type of patent greatly outweigh risks of potential harm. Even if the Court should find Plaintiff's arguments unconvincing, sufficient evidence has been presented to allow Plaintiff to continue with discovery in order to identify the remaining (but currently unknown) Defendants and make more specific statements regarding policy concerns and actual infringement of this patent.

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Respectfully Submitted,

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