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Plaintiff's Motion for Summary Judgment: Memorandum of Points and Authorities in Support Thereof

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NUGENERA, INC.

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF CALIFORNIA

NUGENERA, INC., a California corporation,	)	Case No. MHP-01-9999
	)	
	)	**PLAINTIFF'S MOTION FOR**
Plaintiff,	)	**SUMMARY JUDGMENT:**
	)	**MEMORANDUM OF POINTS**
vs.	)	**AND AUTHORITIES IN**
	)	**SUPPORT THEREOF**
SALVADOR DOLLY and DOES I-X,	)	
	)	
	)	Date: Nov. 9, 2001
Defendants.	)	Time: 2:30 pm
	)	Courtroom: Ramo Auditorium

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: *Page(s)*

Statutes:

House and Senate Reports:

Court Documents:

Miscellaneous:

I. INTRODUCTION

This Brief addresses an infringement suit brought against Defendants for violating Plaintiff's patent under 35 U.S.C. § 271. Plaintiff asserts that Defendant Salvador 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. Plaintiff argues that the patent withstands all challenges of patentability, including §§ 101-103 subject matter, utility, novelty, and obviousness. Finally, because the ownership rights in question have the potential to drastically affect the future of scientific and medical research, principles of public policy require that Plaintiff's patent and ensuing rights be affirmed and enforced.

II. STATEMENT OF FACTS

On July 31, 1998, Defendant Salvador Dolly (Dolly) provided Advanced Genetic Testing Company (AGTC) with a whole-blood sample. Dolly signed a consent form that allowed AGTC to carry out genetic testing on his blood sample. A true and correct copy of this form appears as Appendix A of the Complaint.[1]

A short time after AGTC completed Dolly's genetic testing, Plaintiff NuGenEra, Inc. (NuGenEra) purchased many tissue samples that were no longer needed. This service by AGTC included the tissue submitted by Dolly. NuGenEra used these tissue samples for medical research purposes. After performing a significant amount of labor, NuGenEra determined that Dolly's tissue sample is completely resistant to Human Immunodeficiency Virus (HIV). At this point, NuGenEra embarked on a program to sequence the genome corresponding to this HIV immune tissue. The sequencing revealed a unique combination of alleles (gene variants), designated P1-P10.

NuGenEra filed a patent application on the full "Dolly Genome" and a combination of genes (P or P1-P10) suggested by the sequence comparison. U.S. Patent Number F6,635,271 ('271 patent) was

1. The *Loyola of Los Angeles Law Review* will not be publishing the Complaint or Appendix A referenced in Plaintiff's Points and Authorities. Appendix A contains NuGenEra's Consent Form at issue in this case. To obtain a copy of the Complaint and Appendix A, 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.

issued to Plaintiff on May 28, 2000. NuGenEra notified Dolly of his immunity to HIV.

NuGenEra's '271 patent contains three independent claims. Independent Claim 1 comprises the entire Dolly Genome. Independent Claim 2 comprises the ten genes of the P locus (P1-P10). Claim 3 covers an immortalized human cell line comprising the genetic composition of Claim 1.

On November 30, 2000, Dolly and a limited partnership initiated by Dolly, DollyDeal Ltd. (DollyDeal), sold a whole-blood sample to Dr. William Morgan of the University of California.

On December 12, 2000, Dolly and DollyDeal sold a whole-blood sample to Dr. Paul Hu of California State University.

On January 20, 2001, Dolly and DollyDeal attempted to negotiate the sale of a whole-blood sample to Dr. Antoinette Avazian of Infants' Hospital. Dr. Avazian did not accept Dolly's offer.

III. ARGUMENT

A. Dolly Retains No Rights to His Excised Tissue

Plaintiff contends that it committed no wrongdoing in obtaining a sample of Dolly's blood. 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.

1. Dolly has no ownership rights to the blood sample

a. AGTC fulfilled any fiduciary duty it had to Dolly and made a legal transaction in providing the sample to Plaintiff

At the time AGTC received Dolly's blood sample, it had no intention of selling or profiting from Dolly's blood in any way. Since AGTC performed the tests on Dolly's blood in good faith and in agreement with the signed form (*see* Pl.'s Compl., App. A), AGTC fulfilled its fiduciary duty to Dolly. Therefore, AGTC was the legal owner of the blood sample.

b. Dolly retains no legal ownership or control over the blood sample by contract or statute

The consent form signed by Dolly makes no mention of how the blood is to be disposed. Dolly had no expectation of control over the blood sample. At no point did Dolly attempt to exercise control of the blood sample once it was removed.

Dolly is also limited in the amount of control he can exercise over the blood sample by California statute. "California statutory law drastically limits any continuing interest of a patient in excised cells." *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 137, 793 P.2d 479, 489, 271 Cal. Rptr. 146, 156 (1990). California's limitation on the rights of patients to maintain control of excised cells stems from such statutes as section 7054.4 of the California Health and Safety Code, which states: "Notwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste 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). Clearly, the right to dispose of excised cells is not reserved to the patient. Therefore, AGTC had the right to dispose of its blood samples by transferring them to NuGenEra, and no liability was transferred to Plaintiff by doing so.

2. Legal ownership of the blood sample rightfully belongs to NuGenEra

a. recognizing a patient's inherent ownership in excised cells would impose great hardship to medical research and defeat public policy

Granting ownership of the blood sample to Dolly would present enormous logistical problems to companies such as AGTC. Such a policy would place a colossal burden on the part of AGTC by forcing it to find out how each patient wants his or her blood sample to be disposed. It would also severely hinder the ability of companies, such as NuGenEra, to perform needed research by drastically reducing their access to blood samples. Absent specific requests from individuals, the most practical method for dealing with legally obtained blood samples would be to default ownership to the current holder of the sample.

Courts now recognize that an "important policy consideration is that we not threaten with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is, or may be, against a donor's wishes." *Moore*, 51 Cal. 3d at 143, 793 P.2d at 493, 271 Cal. Rptr. at 160. Further, "[l]iability based upon existing disclosure obligations, rather than an unprecedented extension of the conversion theory, protects patients' rights of privacy and autonomy without unnecessarily hindering research." *Id.* at 144, 793 P.2d at 494, 271 Cal. Rptr. at 161. In this way, Plaintiff would still have obtained legal ownership of the sample even if AGTC had violated its fiduciary duties. NuGenEra had no reason to question the valid ownership of the cells they obtained from AGTC. It would be time consuming, costly, irrational, and outside the legal duties of NuGenEra to require it to gain further consent before performing its research. The current policy prevents the unnecessary hindrance of research.

Having obtained Dolly's tissue sample legally and with legitimate purpose, NuGenEra thus owns the rights to its use and disposition, which includes the right to perform tests on the blood sample obtained from Dolly.

B. Plaintiff's '271 Patent Is Valid

Plaintiff's patent meets each element of patentability that Defendant Dolly challenges under 35 U.S.C. §§ 101-103. Section 101 of the statute provides that: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1994).

1. The patent satisfies the statutory subject matter requirement under § 101

a. Congress intended for patent laws to be construed broadly, and courts have repeatedly upheld the patentability of gene sequences as a manufacture or composition of matter so long as utility is disclosed

Congress contemplated that patent laws be construed broadly in scope as indicated by its expansive use of terminology. The four

patentable categories specified under § 101 as statutory subject matter are those of process, machine, manufacture, and composition of matter. In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Court held that living things could also be considered nonnatural, human-made inventions. Indeed, the Supreme Court warned in *Diamond* that we "'should not read into the patent laws limitations and conditions which the legislature has not expressed,'" *id.* at 308 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)). The court based this warning on its examination of legislative history, which shows that Congress intended statutory subject matter "to include anything under the sun that is made by man." *Id.* at 309 (quoting S. Rep. No. 82-1979, at 5 (1952)). Courts have thus included nonnaturally occurring, living inventions "'having a distinctive name, character [and] use'" within that scope. *Id.* at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)) (alteration in original). When considering this question of patentable subject matter, the Supreme Court has surmised that only such concepts as physical phenomena, laws of nature, and abstract ideas may not qualify, but these are intangible categories to which the claims of Plaintiff's patent do not belong. *See Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Genomic sequences and combinations have therefore been, and are increasingly now, recognized as compositions of matter due to their existence as isolated and purified chemical compounds that have resulted from laborious time and research.

Claim 1 and Claim 2 of Plaintiff's patent are respectively comprised of an isolated composition and a combination of nucleic acid sequences, both of which fall into the category of "composition of matter" within the meaning of 35 U.S.C. § 101, due to their isolated and purified states. It is a well-established principle that an invention is not per se unpatentable simply because the composition is isolated from nature. The court in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911) affirmed the patentability of adrenaline and the idea that isolated compounds from nature are eligible subject matter, opining that "even if it were merely an extracted product without change, there is no rule that such products are not patentable." *Id.* at 103. Likewise, sixty years later the court in *In re Bergstrom*, 427 F.2d 1394 (1970) held

extracted human and animal prostaglandin to be patentable because those compounds "do not exist in nature in pure form." *Id.* at 1401. In the twenty years since the Supreme Court made its landmark ruling in *Diamond* that a microorganism could be the "result of human ingenuity and research," *Diamond*, 447 U.S. at 313, patents have been increasingly awarded to sequenced genes that code for proteins found to be useful in detecting and treating diseases in which they play a significant role. Such genes include ones that contribute to the occurrence of myotonic dystrophy and Machado-Joseph disease or help alleviate low blood pressure.[2]

Defendant Dolly's contention that an isolated genome sequence and gene combination is unpatentable subject matter, solely because it was extracted from Dolly's donated tissue sample, is not consistent with the current practice of U.S. patent law. The patented product exists in an altered and useful form, physically different from its precursor tissue, as a direct result of Plaintiff's work. It satisfies the broad, nonrestrictive reading of composition of matter that courts have agreed Congress had in mind when writing the law. After Plaintiff's discovery of the gene and the subsequent research it conducted to isolate and purify its beneficial properties, the invention became a physically transformed product, separate from Dolly's tissue, and certainly qualified as a nonnatural product of human ingenuity.

A nucleic acid that has been removed from the body and isolated in vitro by separating it from other biological compounds is thus a chemical composition of matter, as it cannot normally be found existing in nature in its altered form. Inventiveness of the discovery thus lies in the extraction of a previously unknown Deoxyribonucleic Acid (DNA) sequence. Likewise, the combination of genes P1–P10, isolated from Dolly's cells, could be considered a "manufacture" due to its ultimately nonnatural, man-made isolated state, separate from the rest of the tissue. It may also qualify as a "composition of matter" based on its selective, nonnatural combination. Plaintiff's

2. *See generally* U.S. Patent No. 5,977,333 (issued Nov. 2, 1999) ("DNA sequence encoding the myotonic dystrophy gene and uses thereof[.]"); U.S. Patent No. 5,840,491 (issued Nov. 24, 1998) ("DNA sequence encoding the Machado-Joseph disease gene and uses thereof[.]"); U.S. Patent No. 4,703,008, (issued Oct. 27, 1987) ("DNA sequences encoding erythropoietin[.]").

claims thus satisfy the conceptions of statutory subject matter that courts have always understood and continually affirmed.

Claim 3, which covers an immortalized human cell line comprising the genetic composition of Claim 1, is likewise patentable subject matter under § 101 as an invention wholly created from the purified invention claimed in Claim 1. The court in *Moore* directly addressed the patentability of human cell lines when it affirmed that human "cell lines are patentable because '[l]ong-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art . . .,' and the probability of success is low." *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 142, 793 P.2d 479, 492-93, 271 Cal. Rptr. 146, 159-60 (1990) (quoting OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 33 (1987)) (alteration in original). Although Plaintiff's claimed cell line was derived from Dolly's precursor cell, the cell's subsequent isolation, purification, and immortalization in vitro represent the "inventive effort" rather than the mere "discovery of naturally occurring raw materials" that *Moore* distinguishes as that which patent law rewards. *See id.*

Isolating a gene sequence, creating nonnaturally occurring gene combinations, and propagating an immortalized cell line are all products of time, external effort, ingenuity and creativity. The *Bergy* court held "biologically pure cultures" to be patentable subject matter (manufacture) under § 101 based on the "discovery and skills" of the scientist used to extract the patented product from a "complex jungle of microorganisms" which, on its own, could not be used to produce the invention's desired product of fermentation. *See In re Bergy*, 596 F.2d 952, 972 (C.C.P.A. 1979), *aff'd*, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Similarly, Dolly's original tissue source, occurring untouched in nature, could not, in its existing state, provide the valuable research resource that may be used to combat HIV infection, a use for which Plaintiff's invention is targeted. Plaintiff's invention, in its physically improved form, withstands Dolly's attempt to analogize it to a "claim to his heart as an organ" since his heart has not been transformed in any way. The research that created this purified form of the Dolly Genome gave rise to a "manufacture" or "composition of matter" structurally improved

from its precursor material that thus qualifies as man-made, patentable subject matter under § 101.

2. The patent satisfies the § 101 utility requirement

a. the current standard of pharmacological utility under Brenner v. Manson *merely requires that the invention confer a benefit to society, which is easily met by its potential uses at present and in the future*

The traditional requirement of utility under *In re Nelson*, 280 F.2d 172 (C.C.P.A. 1960), that an invention simply avoids being "frivolous" or "injurious" to society, has since been relaxed to a standard that appreciates an invention's utility by the general benefit conferred to the public. *See id.* at 178-79. Specifically, courts now cite the principle laid down in *Brenner v. Manson*, 383 U.S. 519 (1966) to evaluate the utility of a pharmacological invention by examining "the benefit derived by the public from an invention with substantial utility." *Id.* at 534.

The current standard is easily met by Plaintiff's claims. Plaintiff's discovery of the Dolly Genome's heightened resistance to HIV, as well as its subsequent isolation in Claim 1 and Claim 2 of the specific gene combination responsible for this effect, provide tremendous opportunity for scientific research. The most notable use for these cells is as a valuable source of anti-HIV compounds, which can be used to develop anti-HIV drugs. The specific gene combination may also act as a diagnostic tool for HIV susceptibility. Plaintiff's immortalized cell line in Claim 3 further provides a perpetual source of the isolated product of Claim 1, with which the comparison may be conducted and its methodology improved. The invention thus greatly benefits the public by providing a model comparison for present-day HIV diagnosis, as well as future opportunities for research to advance developing treatments or possible cures of this disease. Plaintiff's invention thereby meets the standard of substantial utility, and certainly that of nonfrivolous and noninjurious, to satisfy patentablity under § 101.

b. the utility in Plaintiff's invention lies in its diagnostic properties and propagating conditions that permit further, advanced research, rather than on a separate, "immunity-boosting mechanism"

Dolly asserts that utility in Plaintiff's patent is insufficient because its claims do not identify specific factors that confer immunity, and assumes that the patent must necessarily claim an "immunity-boosting mechanism within either the body or host cell." These contentions misunderstand judicial interpretation of "the statutory term 'useful[,]' . . . [which] require[s] disclosure of at least one available practical benefit to the public." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001). As of January 2001, the United States Patent and Trademark Office (PTO) revised its guidelines to incorporate these judicial determinations "by requiring the disclosure of at least one specific, substantial, and credible utility." *Id.* Plaintiff's diagnostic utility alone satisfies this updated standard, and is similar in utility to that which the court found in *Institut Pasteur v. Cambridge Biotech Corp. (In re Cambridge Biotech Corp.)*, 186 B.R. 9 (Bankr. D. Mass. 1995). That court upheld the use of a diagnostic method for HIV antibody detection that was useful in determining if a candidate did not have the disease. *See id.* at 21. As Plaintiff's expert has indicated, the current techniques in gene therapy make the Dolly Genome a potentially valuable tool in the treatment of Acquired Immune Deficiency Syndrome (AIDS). (*See* Expert Test. Noriyuki Kasahara, M.D., Ph.D.)[3] This patent thus meets all current court and PTO-established standards of substance and benefit.

3. The patent meets the novelty requirement under 35 U.S.C. § 102

The Dolly Genome and the P sequences represent novel contributions to the art of human genetics. The genome is an isolated, previously unknown variant of the human genome sequence. Likewise, there is no evidence of prior use or sale of the genome as described in the claim.

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3. The *Loyola of Los Angeles Law Review* will not be publishing the Expert Testimony of Noriyuki Kasahara referenced in Plaintiff's Points and Authorities. 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.

a. the Dolly Genome sequence is novel under 35 U.S.C. § 102(a)

The invention is novel unless it was "known or used by others in this country, . . . before the invention thereof by the applicant." 35 U.S.C. § 102(a) (1994). The isolated Dolly Genome was neither used nor known prior to its discovery by NuGenEra.

i. the published human genome sequence does not anticipate the Dolly Genome under § 102(a)

Direct anticipation requires identity of the prior art and the claimed invention. The prior art has to contain "all of the elements and limitations of the claim . . . in a single prior reference, arranged as in the claim." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). No prior art reference contains the Dolly DNA sequence described in the claims. While the human genomes are similar, the numerous differences between the published human genome and the Dolly variant rule out direct anticipation.

ii. the use by Dolly does not anticipate the invention under § 102(a)

The alleged prior use by Dolly has no bearing on patentability, as he never possessed the invention. Dolly's DNA has certainly been in use in every one of his trillions of cells from the day he was conceived. However, the courts have upheld numerous patents for various compounds isolated from human bodies. Purified hormones and other human tissue products have been awarded patents despite the "use" of such compounds by every living human being. Human adrenalin and human prostaglandins have been patented. Likewise, isolated fragments of human DNA are patentable.

Anticipation under § 102(a) requires preexisting knowledge that makes the subsequent invention redundant. Dolly possessed no knowledge of the sequence or the unique properties of his DNA. NuGenEra obtained this knowledge when it isolated and sequenced the Dolly Genome. The result is a valuable tool for biomedical science.

A new property or use does not make a known composition of matter patentable. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). In this case, however, the composition of the Dolly DNA was

unknown. NuGenEra discovered both the new composition and the unique properties of the Dolly Genome.

b. actions by AGTC do not anticipate or invalidate the invention

Likewise, AGTC has not possessed a complete invention. The genetic testing of DNA and limited studies AGTC performed fall short of the statutory requirements for a bar to patentability.

i. the genetic testing of Dolly's DNA by AGTC does not anticipate the isolation and sequencing by NuGenEra under § 102(a)

AGTC withdrew Dolly's blood for genetic testing. However, AGTC was neither aware of, nor interested in, the properties of the entire genome. The testing was limited to a few genes that concerned Dolly at the time. The tests verified a few nucleotides as being nonmutant. The bulk of the DNA was a mere byproduct of testing. AGTC abandoned the sample and later sold it as an unneeded byproduct. The Supreme Court has long held that where the substances "were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention," such production does not anticipate a future discovery of the same substance. *Tilghman v. Proctor*, 102 U.S. 707, 711-12 (1880). Accordingly, the unused Dolly DNA stored in AGTC's test tubes does not anticipate the future discoveries by NuGenEra.

ii. the tests conducted by AGTC do not anticipate the sequencing of the entire Dolly Genome under § 102(a)

The exact procedures employed by AGTC are absent from the record. However, one thing is certain: AGTC did not sequence the entire six billion base pairs of the Dolly Genome. Thus, the composition of matter determined by AGTC is only a small part of the one contained in the claim. These limited tests carried out by AGTC do not rise to the level of anticipating knowledge or use under 35 U.S.C. § 102(a). The Federal Circuit repeatedly noted that an anticipating prior art must contain the entire invention.

iii. the sale of blood by AGTC is not anticipating under § 102(b)

As AGTC did not possess the invention, it could not have engaged in a sale that would invoke a statutory bar under 35 U.S.C. § 102(b). The Dolly blood sold to NuGenEra was only a first step in the inventive process. A sale of an incomplete invention can create a § 102(b) bar. The seller would have needed to have gone beyond a mere conception. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 825 F. Supp. 65, 69 (D. Del. 1993), *aff'd*, 72 F.3d 1577 (Fed. Cir. 1996). Furthermore, the terms of the sale must reflect the value of the invention if it works as expected. In this case, AGTC had no idea of the unique features of the Dolly Genome or its potential value. The circumstances of the sale and the bulk transfer of the unused samples suggest that Dolly's blood was sold for "scrap value."

c. the alleged use by Dolly and AGTC was private and not disqualifying under § 102(b)

Patent laws reward an inventor not only for the creative effort but also for delivering the invention to the public. Therefore, secret, nondisclosing use does not preclude patentability.

Dolly "used" his DNA within the context of his own bodily functions that are unquestionably private. Such functions are in fact protected from the public by the United States Constitution. The Supreme Court recognizes the fundamental right of personal privacy founded in the Fourteenth Amendment. *See Roe v. Wade*, 410 U.S. 113 (1973). At the same time, one's tissue can be used by the public once it leaves the body. *See Moore*, 51 Cal. at 143-48, 793 P.2d at 494-97, 271 Cal. Rptr. at 161-64. This distinction further underscores the fact that what happens within the body has no bearing on the future fate of human biological material.

The use of DNA by AGTC was likewise private. Whatever limited testing it performed was protected by the confidentiality agreement. (*See* Pl.'s Compl., App. A.) The Supreme Court looks at such explicit agreements as "injunction[s] of secrecy" when determining whether the use was public. *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

Whatever the use by Dolly and AGTC may have been, the public could not benefit from it. Implied or express privacy considerations kept the information from the public domain. Such

secret use cannot bar NuGenEra from being rewarded for giving the public access to a valuable medical research tool.

4. The patent meets the nonobviousness requirement under 35 U.S.C. § 103

The prior art is limited to genomes of persons other than Dolly. A multitude of important sequence differences distinguish the Dolly Genome from the prior art. Some of these variations confer a resistance to HIV. The level of ordinary skill in molecular biology does not allow one to predict sequence variations that will result in a particular phenotype. Extensive efforts are being undertaken to identify genetic variations similar to Dolly's.

The isolated Dolly Genome as a whole and the isolated Dolly P1-P10 locus are nonobvious under the test set out in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which courts use to determine obviousness as a question of law. As discussed in turn below, the following factors are considered: (1) the scope and content of the prior art; (2) the differences between the prior art and the patent claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, such as commercial success, unfilled need, and the failure of others to solve the problem. *See id.* at 17-18.

a. the state of prior art is limited to gene sequences of other individuals and cannot anticipate the Dolly Genome sequence because every individual's genome is unique

The prior art cited by Defendant Dolly is the published "human genome." *See* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304 (2001). The "genome" consists of the DNA sequence of all the twenty-four human chromosomes (twenty-two autosomes, and the X and the Y chromosomes). The definition of "human" is far less precise because no two individuals (with the exception of identical twins) have exactly the same sequence. The mere fact that DNA is used for personal identification is proof that each individual has a unique genome. The sequenced human genome is derived from several donors but not Dolly. The scope of the prior art is therefore limited to the DNA of those individuals whose DNA has been used for sequencing.

b. estimated differences between the prior art and the invention are great

The second prong of the *Deere* test inquires whether there are differences between the prior art and the claimed invention. Plaintiff NuGenEra needs merely to state the facts. Independent Claim 1 comprises the entire Dolly Genome. A direct comparison of the claimed sequence to the prior art human genome sequence is estimated to reveal millions of differences. Independent Claim 2 comprises the ten genes of the P1-P10 sequences. Each gene differs by one or more nucleotides from the prior art genome.

c. level of ordinary skill in the art is not yet sophisticated enough to have predicted the sequence of the Dolly Genome

The third inquiry deals with the level of the ordinary skill in the art at the time of the invention. Many sophisticated techniques in molecular biology have become standard practice. However, no method exists (chemical, biological or computer based) capable of predicting specific useful variations in human DNA.

The Federal Circuit has established that for a novel DNA sequence to be obvious, the actual sequence of As, Cs, Gs and Ts must be obvious to a practitioner looking at prior art sequences. *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-09 (Fed. Cir. 1991). In the present case, by looking at three billion base pairs of the prior art human genome, one must be able to suggest every one of thousands of specific substitutions that would create the Dolly Genome—the blueprint for all of Dolly's unique characteristics. In the case of Claim 2, one must envision the substitutions in the published sequence that will convert the P1-P10 genes into their HIV resistant variants.

i. obvious methods do not render the result obvious

Defendant Dolly argues that the inventors isolated the Dolly Genome using standard methods (i.e., the entire procedure would have been obvious to a person of ordinary skill in the art of molecular biology). However, the Federal Circuit has long held that the mere availability of the technology and the incentive to apply it do not make the result obvious. *See In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995). Similarly, a conceived method of preparation of

some undefined DNA does not define it with precision sufficient to render it obvious. *See Amgen*, 927 F.2d at 1208-09. The inventors' interest in Dolly's HIV resistance provided the "incentive to apply the technology" and suggested an obvious direction of research. This "obvious to try" standard was explicitly rejected by the Federal Circuit in *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

ii. the Dolly Genome is nonobvious under the "similar compound" test

A novel chemical may be obvious if its structure and properties are similar to a prior art chemical. *See In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990). It is nonobvious if a similar structure possesses unexpected new properties. *See id.* at 693. Arguably, the Dolly Genome is very similar to other sequenced human genomes. However, multiple nucleotide substitutions distinguish Dolly from the prior art DNA sequence. In addition, at least one property is remarkable and unexpected; complete HIV resistance. Under the *Dillon* standard the prima facie case of obviousness is easily rebutted.

d. objective evidence from the medical research community supports the nonobviousness of this invention

Finally, the Federal Circuit looks at the objective evidence of nonobviousness. These "secondary considerations" include commercial success of the invention, unfilled need, and failure by others to arrive at the same result.

As the scientific expert has indicated, a major effort is currently under way to identify genetic variations such as Dolly's. The Dolly Genome holds significant promise for researchers in the field. NuGenEra chose to make a large investment in labor and capital in order to develop the CL100 cell line. Commercial success is further manifested by Dolly's sale of his blood to at least two scientists. The testimony of Plaintiff's expert clearly points to the need for such material in the medical research community.

C. As a Matter of Public Policy, Plaintiff Should Be Granted Ownership of Its Research and the Right to Exclude Others from the Profits Generated from It

1. NuGenEra has the right to own and profit from the results of its research

Should courts permit people to sell their DNA in violation of a patent, they would severely limit incentives for genetic research. Prior to testing and/or sequencing, companies have no concept as to the value of the DNA in their possession. Companies have to invest their own resources for a chance to find a useful sequence among hundreds and thousands of genomes. What company would expend limited resources of time and money if it had no chance of profiting from its labor? If courts granted this right to profit to individuals who happen to have a favorable genome, rather than to the company that expended its resources to find the genome, its utility and sequence, no company would conduct genetic research under such uncertain conditions.

If one individual could patent his genome, what is to stop everybody from doing so? For the most part, everybody is unique. It could be argued that everybody possesses unique qualities that are beneficial. Would one identical twin have the right to profit over the other? The obvious result would be a disaster to both ongoing research and future research. Gene patents already awarded to biological and chemical companies would be invalidated, and the entire Human Genome Project could become the property of people whose DNA has already been sequenced. This would most certainly hinder future research by removing necessary incentives for companies to perform genetic research.

2. NuGenEra is the owner of the results from its research

In this case, NuGenEra should have the right to profit from its research. NuGenEra exerted time and money to find a genome that contains HIV resistance. It bore the cost of sequencing the genome, finding the genes that code for resistance, and created a cell line with the genome. It is NuGenEra that made the investment to find a useful genome and turn that genome into something usable. Thus, NuGenEra should be able to profit from it.

3. Dolly is not an inventor or contributor to NuGenEra's results

Dolly should not be able to profit from his unusual genome because all he holds is a product of nature. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980). He could no more patent his DNA than he could patent his body or his organs. As the source of the blood sample, he has made no discovery and produced no invention from which to profit. *See Brown v. Regents of the Univ. of Cal.*, 866 F. Supp. 439, 442, 445 (N.D. Cal. 1994). The blood in his veins and the DNA in the nuclei of his cells are "products of nature—the manifest results of over three billion years of reproduction, natural selection, and evolutionary processes unbroken in Dolly's unique phylogenetic line since the origin of life on this planet." (Def.'s Answer at 3.)[4] Dolly would not have even known he was immune to HIV had it not been for NuGenEra's research. Because Dolly played no part in the discovery of his HIV immunity, the sequencing of his genome, the identification of the genes that cause HIV resistance, or the creation of the cell line containing his genome, he is in no way the discoverer or the inventor of the claims held in NuGenEra's patent. His existence does not entitle him to profit.

4. Dolly does not have the right to sell his genome

Dolly was able to sell his genome, in the form of blood, by offering it as HIV resistant. Dolly learned of his immunity from NuGenEra. Without this information obtained from NuGenEra, Dolly would not have been able to sell his blood for any more money than anyone else. The knowledge he gained from NuGenEra should not give him the right to cheat NuGenEra out of profits from its research.

As the PTO stated, "[t]he patent system promotes progress by securing a complete disclosure of an . . . inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing the composition for a limited time." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093-94 (Jan. 5, 2001).

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4. The *Loyola of Los Angeles Law Review* will not be publishing the Answer referenced in Plaintiff's Points and Authorities. 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.

Therefore, NuGenEra should be able to profit from its useful invention, the Dolly Genome.

Society stands to gain in many ways by allowing companies to profit from genetic research. Genetic research may lead to treatment for diseases, or even cures. However, the most that could be gained by allowing individuals the right to sell their genome is a profit for that individual. And even that profit is unlikely, as companies would be unwilling to pay for materials from which they could never profit.

IV. CONCLUSION

For the foregoing reasons, Defendant Dolly retains no inherent genomic rights to his excised tissue. Moreover, public policy allows the grant of this patent as it promotes valuable research opportunities. Finally, the '271 patent is valid and Plaintiff states a valid infringement claim. Thus, Plaintiff's Motion for Summary Judgment should be granted.

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