4-1-2002

Memorandum and Order

Marilyn Hall Patel

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 **MEMORANDUM AND ORDER**

NuGenEra, Inc., (NuGenEra), a California Corporation, filed this action alleging infringement of Claims 1 and 2 of its Patent F6,635,271 (the '271 patent) against defendants Salvador Dolly (Dolly) and Does I - X. Claims 1 and 2 of the '271 patent encompass Defendant Dolly's entire genome (the Dolly Genome) and ten specific gene combinations isolated from Defendant's genome (the P sequences). Plaintiff seeks injunctive, declaratory and compensatory relief.

Defendant Dolly seeks summary judgment maintaining that (1) Plaintiff failed to state a claim upon which relief may be granted, (2) the '271 patent is invalid, and (3) the '271 patent is unenforceable for public policy reasons.[1] Specifically, Defendant challenges the '271 patent's validity on grounds that it lacks utility and novelty, comprises subject matter that is not patentable, is statutorily barred and is obvious. Defendant challenges the '271 patent's

1. These comprise Defendant's affirmative defenses in his Answer. The pleadings in the case, and other court documents, can be found at http://techlaw.lls.edu/atc3.

enforceability on the theory that it violates his rights to property, privacy, and bodily autonomy.

On cross-motion for summary judgment, Plaintiff NuGenEra argues that Defendant fails to demonstrate invalidity of the '271 patent and that Defendant lacks any proprietary or privacy interest in the tissues removed from his body or in the patented invention.

This action proceeds under a minute order issued by this court on October 15, 2001, limiting argument and testimony at the hearing to Defendant's affirmative defenses.[2] Accordingly, the parties do not argue, nor does this order address, the factual issues of infringement, 35 U.S.C. § 271 (1994), or disclosure, 35 U.S.C. § 112 (1994).

Having considered the parties' arguments and for the reasons set forth below, the court enters the following memorandum and order.

I. BACKGROUND

Defendant Dolly provided a blood sample to Advanced Genetic Testing Co. (AGTC) for routine preconception genetic testing on July 31, 1998. Before providing his sample, Dolly and representatives from AGTC signed a consent form assuring confidentiality and limiting disclosure of test results to a designated physician or genetic counseling service. (*See* Pl.'s Compl. App. A.) The consent form did not discuss disposal of Dolly's blood sample after testing was completed.

NuGenEra purchased Dolly's blood sample from AGTC. At that time, AGTC disclosed Dolly's signed and witnessed consent form to NuGenEra. NuGenEra conducted research on Dolly's cells and found that they are resistant to the human immunodeficiency virus (HIV). (*See* Pl.'s Mem. Supp. Summ. J. at 10.) In vitro and in vivo experiments demonstrated that certain sequences of Dolly's genes (the "P" sequences) code for cell products. (*See* Expert Test. Noriyuki Kasahara, M.D., Ph.D.) Further, the cells expressing the P sequences demonstrated partial HIV resistance both in vitro and in

2. The minute order was contrived to facilitate this academic exercise. As the court advised the parties at the hearing, it would likely have reached the issues of infringement and enablement at the outset had this patent been the subject of an actual dispute. The minute order restricted the parties' arguments and the court's analysis, however, to allow only treatment of patent validity and enforceability.

transgenic mice.[3] Based on these findings, on August 5, 1999, NuGenEra applied for a patent on the Dolly Genome (Claim 1),[4] gene combination P1-P10 (the P sequences) (Claim 2),[5] and an immortalized cell line comprising the Dolly Genome (Claim 3).[6] Because AGTC had not removed identifying information from Defendant's sample prior to its transfer, NuGenEra learned that Defendant was the donor of the HIV-resistant tissues. NuGenEra notified Dolly of his HIV resistance. After learning of his unusual genetic traits, Dolly formed a limited partnership, DollyDeal Limited (DollyDeal). Dolly and DollyDeal sold samples of Dolly's whole blood samples on November 30 and December 12, 2000 to research scientists at the University of California and California State University. On January 28, 2001, Dolly and DollyDeal offered to sell another whole blood sample to Infants' Hospital. Based on these actions, Plaintiff NuGenEra maintains that Defendant infringed Claims 1 and 2 of the '271 patent.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment shall be granted when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *See* FED. R. CIV. P. 56(c). The moving party "bears the initial burden of . . . identifying those portions of . . . [the record that] demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmoving party to "go beyond the pleadings and by her

3. The expert opinions reflect a lack of consensus on the use of transgenic mice as an animal model in HIV research. *Compare* Expert Test. Noriyuki Kasahara, M.D., Ph.D. (some strains of mice may be infected with HIV for research purposes) *with* Expert Test. Richard M. Myers, Ph.D. (mice are not a recognized model for the study of HIV).

4. Claim 1 is an isolated genetic composition comprising forty-six nucleic acid sequences derived from each of Dolly's chromosomes. *See* U.S. Patent No. F6,635,271 (issued May 28, 2000) *at* 971.

5. Claim 2 is "[a] combination of isolated nucleic acid sequences . . . comprising SEQ ID NOS: P1–P10." *Id.* The identity of all nucleotides is disclosed in the written description of the patent application. *See id.* at 3.

6. Claim 3 is "[a]n immortalized human cell line comprising the genetic composition of claim 1." *Id.* It is not a subject of this action.

own affidavits, or by the 'depositions, answers to interrogatories and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324 (quoting FED. R. CIV. P. 56(e)). A "dispute about a material fact is 'genuine' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party discharges its burden by conclusively showing that the nonmoving party has not disclosed the existence of any fact which is susceptible of an interpretation that might give rise to an inference supporting the allegations in the complaint. *Adickes v. S.H. Kness & Co.*, 398 U.S. 144, 160 n.22 (1970). The court does not make credibility determinations in considering a motion for summary judgment. *See Anderson*, 477 U.S. at 249. Rather, it views the inferences drawn from the facts in the light most favorable to the party opposing the motion. *See United States v. Diebold*, 369 U.S. 654, 655 (1962).

The same standard is applied by the Federal Circuit. *See, e.g., Southwall Technologies., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995); *Barmag Barmer Maschinenfabrik AG v. Murata Mach. Ltd.*, 731 F.2d 831, 835-36 (Fed. Cir. 1984). In fact, summary judgment is frequently awarded in patent actions. *See, e.g., Wang Lab. v. Mitsubishi Elec. Am., Inc.*, 103 F.3d 1571 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 818 (1997) (granting summary judgment because prosecution history estoppel precluded finding of infringement); *Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co.*, 66 F.3d 285, 292 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1115 (1996) (granting summary judgment because patentee was estopped by prosecution history and Defendant's method did not infringe patent).

B. Patent Validity

Once issued, patents are presumed to be valid. *See* 35 U.S.C. § 282 (1994); *Carpet Seaming Tape Licensing Corp. v. Best Seam, Inc.*, 694 F.2d 570, 575 (9th Cir. 1982); *Carson Mfg. Co. Inc. v. Carsonite Int'l Corp. Inc.*, 686 F.2d 665, 667 (9th Cir. 1981); *E.I. du Pont de Nemours & Co. v. Berkley & Co. Inc.*, 620 F.2d 1247, 1267 (8th Cir. 1980). A challenging party must offer clear and convincing evidence to overcome this presumption. *See* 35 U.S.C. § 282; *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996) (citing *Transco Prods. Inc. v. Performance*

Contracting, Inc., 38 F.3d 551, 560 (Fed. Cir. 1994)); *Checkpoint Sys. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986). This evidence must demonstrate that the United States Patent and Trademark Office ("PTO") erred in issuing the patent. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). When the movant is the plaintiff-patentee, he must demonstrate validity by a preponderance of the evidence. *See ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576 (Fed. Cir. 1988) (citing *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir. 1988)).

To be valid, at least one claim in a patent must meet the standards of patentability as defined in the Patent Act of 1952, 35 U.S.C. §§100-03, 112. Thus, the claimed invention must have patentable subject matter, (35 U.S.C. § 101 (1994)),[7] have utility (35 U.S.C. § 101),[8] be novel (35 U.S.C. § 102(a)),[9] have a nonobvious nature (35 U.S.C. § 103),[10] and be enabling[11] (35 U.S.C. § 112 (1994)).[12] Furthermore, the patented invention must not be statutorily barred by prior public use or sale. *See* 35 U.S.C. § 102(b).

---

7. Patentable subject matter includes a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. Conversely,

> [t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable. . . . Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting *Funk v. Kalo Inoculant*, 333 U.S. 127, 130 (1948)) (citations omitted).

8. Claimed inventions must have a designated use to establish utility. *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) ("The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit.").

9. Claimed inventions must be novel, i.e., distinct from prior art. Inventions may not be "known or used by others in this . . . country before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a) (1994).

10. A claimed invention must embody a significant, nonobvious advance over prior art to be valid. *See* 35 U.S.C. § 103 (1994).

11. The invention must include a written description that enables others skilled in the relevant art to practice the invention. *See* 35 U.S.C. § 112 (1994).

12. Pursuant to the minute order, the court will not consider issues of enablement except insofar as they relate to the adequacy of prior art.

The testimony of expert witnesses in the relevant field may be admitted by the court to clarify matters of scientific and technological relevance. *See Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998); *Mantech Envtl. Corp. v. Hudson Envtl. Servs. Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998) (stating that extrinsic evidence "always may be admitted by the trial court to educate itself about the patent and the relevant technology"); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980-81 (Fed. Cir. 1995) ("The court may, in its discretion, receive extrinsic evidence . . . for the court's understanding of the patent.") (*aff'd*, 517 U.S. 371 (1996).

III. DISCUSSION

The parties agree that Dolly and DollyDeal sold and offered to sell whole blood samples after the '271 patent issued. The parties raise the following issues: (1) whether the patent is valid; (2) whether the patent is enforceable over Dolly's property and privacy rights; (3) whether NuGenEra had legitimate access to Dolly's initial blood sample from AGTC, and (4) whether the patent was infringed. Based on the limitations imposed by the minute order, two issues are now before the court: the validity of Claims 1 and 2 of the '271 patent and the enforceability of the patent over Defendant's property and privacy rights with respect to his unique genetic make-up as embodied in his nuclear genome and the P sequences.[13]

A. Validity of Patent Claims

Defendant argues the '271 patent is invalid because Claims 1 and 2 lack utility, comprise products of nature that are not patentable subject matter, are not novel, are obvious, and are statutorily barred by prior public use. (*See* Def.'s Mem. Supp. Summ. J. at 7-17.) The court will address these arguments in turn.

1. Utility

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" may apply to obtain a patent on that

13. Pursuant to the minute order, the issue of alleged infringement was not addressed at the hearing or in this order.

invention. 35 U.S.C. § 101 (1994). The monopoly of a patent is thus reserved for those useful inventions that confer a benefit upon society. *See Brenner v. Manson*, 383 U.S. 519, 534 (1966). Accordingly, an invention must demonstrate substantial and specific utility to be patentable. *See id.* at 534-35. The utility need not be commercially viable or wide in application: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not ground for finding lack of utility...." *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed. Cir. 1984). However, potential utility is not enough. *See Brenner*, 383 U.S. at 534-35 (invalidating a patent for a steroid because its asserted utility was speculative, based only on similarity to a compound that showed activity in inhibiting tumors). Furthermore, usefulness for research purposes alone does not satisfy the utility requirement. *See id.* at 536 (stating that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Courts have long debated the appropriate application of *Brenner* to define standards for assessing utility in the areas of biotechnology and genetics. Some lower courts have found the utility requirement met if an invention has practical "real world" utility or "immediate value to the public." *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980). Others have required patent applicants to demonstrate "substantial or practical utility." *Cross v. Iizuka*, 753 F.2d 1040, 1044 (Fed. Cir. 1985) ("It is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered....") (citation omitted).

The PTO's 1999 Revised Interim Utility Guidelines applicable at the time the '271 patent issued required a patent applicant to demonstrate either a "well-established" utility or a "specific, substantial and credible" utility. Revised Interim Utility Guidelines Training Materials 5-8 (1999), *at* http://www.uspto.gov/web/patents/guides.htm [hereinafter Training Materials]. To satisfy this standard, the applicant was required to affirmatively assert utility of the claimed invention in the claims and the supporting written description. *See id.* at 5-8. Notations accompanying the 1999 Training Materials express concern that overly generous interpretations of the utility of gene sequences could hamper

research, leading to patents based on nonsubstantial utility. *See id.* at 29.[14]

In deference to the PTO's expertise in this highly technical area, and in the absence of binding authority to the contrary, this court will apply the PTO's 1999 Training Materials to assess utility of the '271 patent. *See Cross*, 753 F.2d at 1044 n.8 ("[Q]uestions regarding utility are factual in nature . . . and are to be determined in the first instance by the PTO, the agency with the expertise in this regard"); *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("[W]ith regard to questions of fact, we defer to the Agency unless its findings are "clearly erroneous"). Thus, the court will assess the contested claims to determine whether they demonstrate "well-established" or "substantial, specific, and credible" utility. *See* Training Materials *supra.*

a. well-established utility

Well-established utility requires that a person of ordinary skill in the art will immediately be able to appreciate the invention's asserted utility. *See id.*; *see also* Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 Cal. L. Rev. 421, 428 (1999).[15] Courts have found well-

14. The PTO reported comments that highlighted the limited utility of mere DNA base sequence data when viewed in the context of relevant case law, including the following: "Moreover, several comments opined that ESTs [Expressed Sequence Tags that are useful for mapping gene locations even when gene function is unknown] are genomic research tools that should be available for unencumbered research to advance the public good. One comment stated that asserted utilities for ESTs, such as mapping the genome or tissue typing, would probably not satisfy the requirements of 35 U.S.C. § 101 if the length of the attached DNA sequence were greatly extended. Other comments stated that the disclosure of a DNA sequence alone is insufficient to enable scientists to use ESTs for mapping or tissue typing. Some comments suggested that PTO examination procedures would result in granting patents based on nonspecific and insubstantial utilities, contrary to established case law." Revised Utility Examination Guidelines, 64 Fed. Reg. 71,441 (Dec. 21, 1999) (citations omitted); *See Brenner*, 383 U.S. at 534-35 (requiring disclosure of "specific utility" and of "substantial utility" "where specific benefit exists in currently available form"); *In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1996) (requiring that a specific and substantial or practical utility for the invention be disclosed as a condition of meeting the practical utility requirement of section 101).

15. The rule is the same under the current Guidelines. *See* Timothy A.

established utility in devices that were clearly effective in carrying out identifiable functions, including window fasteners and oil-drilling equipment. *See Elliott Core Drilling Co. v. Smith*, 50 F.2d 813, 815-16 (9th Cir. 1931) (finding well-established utility in a commercially successful rotary core drill that did not show sufficient novelty for patent protection); *Edwards v. Dayton Mfg. Co.*, 257 F. 980, 981-84 (6th Cir. 1918) (finding well-established utility for highly successful window holding and fastening devices that lacked new elements). Here, neither Claim 1 nor 2 demonstrates well-established utility.

Claim 1 – The DOLLY Genome

Plaintiff asserts that Claim 1, which comprises the entire DOLLY genome, provides the basis for carrying out an accepted, well-established diagnostic procedure: restriction fragment length polymorphism ("RFLP") comparison. This method compares a subject's genome to the Claim 1 baseline sequence to determine a subject's degree of HIV resistance. Theoretically, as Plaintiff argues, an entire genome may be used as a probe to determine the degree of similarity between two individuals' complete genomes. *See* Charles D. Laird & Brian J. McCarthy, *Magnitude of Interspecific Nucleotide Sequence Variability in Drosophila*, 60 Genetics 303, 314 (1968).

Although the basic methods of RFLP analysis are well-established, comparing two entire genomes would be impractical when viewed by one of ordinary skill in the art at the time of invention. (*See* Expert Test. Richard M. Myers, Ph.D.) Indeed, using RFLP as a diagnostic tool is impractical given the present state of the technology. Whole-genome RFLP comparisons in humans would be extremely laborious, costly, and limited to comparison with only one individual genome whose HIV-resistant properties have not been supported by epidemiological studies. A comparison to DNA profiling as applied to criminal cases is illustrative. In contrast to the enormity of analyzing an entire genome of over 30,000 genes, RFLP for DNA profiling in criminal cases has typically employed a single DNA site (or "locus")[16] to compare individuals' genetic identity. *See*

Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 132 (2001).

16. A "locus" is "[t]he position on a chromosome of a gene or other chromosome marker; also, the DNA at that position. The use of locus is sometimes restricted to mean regions of DNA that are expressed." BIOTECH

Janet C. Hoeffel, *The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*, 42 STAN. L. REV. 465, 472-73 (1990). A single specific site or location on a person's chromosomes has typically been studied for individual variations, or polymorphisms. To achieve a convincing match, lab protocols typically repeat the similarity test on the single selected segment of DNA three or four times. *See id.* at 473. In civil cases, several loci may be compared in a more complex analytical procedure. *See id.* Such a standard forensic DNA profile costs not less than $1,500. *See Frontline: What Jennifer Saw* (PBS television broadcast, Feb. 2, 1997) *at* http://www.pbs.org/wgbh/pages/frontline/shows/dna/etc/faqs.html [hereinafter *Frontline*]. In comparison, whole-genome RFLP would require an effort many orders of magnitude greater. Costs for such a procedure would be both astronomical and untenable for a "well-established" utility.[17] While it is theoretically possible to perform an RFLP analysis on a complete genome, the experience with DNA profiling demonstrates that this use is not viable. Therefore, RFLP analysis for whole-genome comparison is not a well-established utility for the Dolly Genome.

Plaintiff further asserts that the Dolly Genome is useful to maintain a human cell line carrying complete HIV resistance to infection. The means for sustaining a cell line using isolated DNA sequences is not immediately apparent to one skilled in the art. *See* I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810-13 (1997) (describing cloning of a sheep through replacement of an entire nucleus, not insertion of purified, isolated DNA). Because it is not immediately apparent to one skilled in the art, this asserted use is not a well-established utility for the Dolly Genome.

LIFE SCIENCE DICTIONARY *at* http://biotech.icmb.utexas.edu/search/dict-search.mhtml [hereinafter BioTech Life Science Dictionary].

17. Furthermore, in the DNA profiling field, RFLP methods are being abandoned in favor of PCR (polymerase chain reaction) methods that provide effective identifications with smaller fragments of DNA. RFLP methods, even on gene fragments, have been found to be cumbersome and less reliable. *See* Edward J. Imwinkelreid & D. H. Kaye, *DNA Typing: Emerging or Neglected Issues*, 76 WASH. L. REV. 413, 456-60 (2001). The state and direction of the technology thus further detract from Plaintiff's asserted well-established utility for Claim 1.

Defendant argues that Claim 1 lacks utility because its sole usefulness is to conduct human cloning, which is not legal in this jurisdiction. (Def.'s Mem. Supp. Summ. J. at 9-10.) Because such cloning is illegal, it is clearly not a well-established use. Even if it were legal, human cloning is not feasible and could not be the basis of an asserted well-established utility.

Claim 1 thus does not have well-established utility based on its potential application to RFLP comparison, maintenance of an HIV resistant cell line, or human cloning.

Claim 2 - The "P" Sequences

Claim 2 includes DNA sequences that allegedly confer partial HIV resistance in vitro and in vivo. Plaintiff maintains the P sequences are useful diagnostic tools to determine HIV susceptibility employing RFLP.[18] Plaintiff also maintains that the P sequences can yield useful probes for DNA-DNA comparisons. (Pl.'s Mem. Supp. Summ. J. at 21.)[19]

The use of RFLP to compare genetic composition of short sequences is a well-established application of molecular biology, as is the use of DNA probes of moderate length. *See* DAVID F. BETSCH, DNA FINGERPRINTING IN HUMAN HEALTH AND SOCIETY, http://esg-www.mit.edu:8001/esgbio/rdna/fingerprint.html. However, there is no enabling disclosure in the '271 patent as to how the gene sequences are useful for this technique. (Def.'s Mem. Supp. Summ. J. at 15-16.) Although the '271 patent provides examples of DNA-DNA comparisons in its written description, such generic examples are insufficient to demonstrate well-established utility. An invention is not useful if a practitioner of ordinary skill in the art is unable to discern how to practice it. *See Ex parte Deuel*, 27 U.S.P.Q. 2d 1360, 1389 (B.P.A. & Interferences 1993) (finding that a purified growth factor had doubtful utility based on dubious implied utility and a lack of disclosure on how to use the invention); *see also Cross*, 753 F.2d at 1042 n.3 (interpreting the intersection of utility and enablement:

---

18. The P sequences in Claim 2 likely contain fewer than 100,000 base pairs. This is a small fraction of the DNA sequence included in a complete human genome (as in Claim 1), which contains approximately three billion total base pairs. *See* HUMAN GENOME PROJECT INFORMATION *at* http://www.ornl.gov/hgmis/faq/faqs1.html.

19. A gene probe is "a biomolecule that is labeled with radioactive isotopes or with a fluorescent marker that selectively binds to a specific gene so it can be isolated or identified." BIOTECH LIFE SCIENCE DICTIONARY, *supra* note 16.

"It is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious."). Therefore, under the PTO Training Materials, Claim 2 has no well-established utility based on RFLP applications.

Plaintiff further asserts the gene sequences comprising Claim 2 show utility as agents of gene replacement therapy to reduce likelihood or severity of HIV infection. (Pl.'s Mem. Supp. Summ. J. at 20.) Although the techniques of gene replacement therapy are well-established, the success of gene replacement therapy, sometimes called experimental gene transfer, has historically been extremely limited. *See* Vida Foubister, *Intense Scrutiny Confronts Gene Therapy*, Amednews.com, (Feb. 28, 2000), *at* http://www.ama-assn.orgsci-ubs/amnews/pick_00/prl20228.htm (visited Jan. 27, 2002); *Gene Therapy Oversold*, 148 SCI. NEWS 428 (Dec. 23-30, 1995), *at* http://pqasb.pqarchiver.com/sciencenews/ (last visited Feb. 20, 2002); Sally Lehrman, *Virus Treatment Questioned After Gene Therapy Death*, 401 NATURE 517-18 (1999). (*See also* Expert Test. Richard M. Myers, Ph.D.) Unlike RFLP, gene therapy is experimental, not well-established, based on its limited success to date. (*See* Expert Test. Richard M. Myers, Ph.D.) Consequently, Claim 2 cannot be found to have well-established utility based on its potential application to gene therapy.

b. substantial, specific, and credible utility

Because neither claim can be upheld by a well-established utility, the validity of the '271 patent depends upon demonstration of substantial, specific and credible utility. *See* Training Materials *supra*. Claim 1 lacks substantial and specific utility. Claim 1 is therefore invalid for lack of utility. Claim 2 has substantial, specific, and credible utility in the diagnosis and treatment of HIV and AIDS. Claim 2 is therefore not invalid for lack of utility.

i. substantial and specific utility

Substantial and specific utility standards require that the invention has a particular, demonstrated purpose. *See Brenner*, 383 U.S. at 593. "Throwaway," "insubstantial," and "nonspecific" utilities fail this test. *See* Training Materials *supra*. However, if a

compound has credible activity in the treatment of a specific malady, this effect suffices to establish specific utility. *See In re Brana*, 51 F.3d at 1565.

Claim 1 - The DOLLY Genome

Plaintiff argues that use of the genome in Claim 1 includes testing for HIV susceptibility based on the particular type of resistance that Defendant's cells exemplify. (Pl.'s Mem. Supp. Summ. J. at 21.) This diagnostic test is similar to testing for selected genes that indicate increased risk for breast cancer based on specific, known genes. *See* Ralph Scully et al., *In Search of the Tumour-Suppressor Functions of BRCA1 and BRCA2*, 408 NATURE 429-32 (2000).

Results indicating susceptibility to or presence of a disease can be helpful in providing proper medical treatments. *See Institut Pasteur and Genetic Sys. Corp. v. Cambridge Biotech Corp.*, 186 B.R. 9, 20 (Bankr. D. Mass. 1995). Likewise, testing for resistance to or absence of disease can be useful to reassure and diagnose patients. *See id.* at 21 (patent awarded for technique that provided a negative result for HIV infection).

Despite this potential use as a diagnostic tool, as discussed above, whole-genome RFLP comparisons would be extremely laborious and costly. (*See* Expert Test. Richard M. Myers, Ph.D.) Normal forensic DNA profiling using the most simple tests "will not cost less than $1,500." *See Frontline*, *supra*. Whole-genome RFLP would involve comparisons between thousands of DNA fragments and result in prohibitively greater costs than those for ordinary DNA profiling. (*See* Expert Test. Richard M. Myers, Ph.D.) At best, therefore, whole-genome RFLP analysis as the asserted utility for Claim 1 skirts the perimeter of insubstantiality.

Plaintiff's vague assertions of utility for the Dolly Genome are representative of the overly ambitious reach of Claim 1. Plaintiff has patented the entire DOLLY genome without understanding the mechanism or even the specific gene sequence that confers HIV resistance. Plaintiff has thereby monopolized a field that should be open to aggressive research by the biotechnology community. Such monopolization is inconsistent with the policy underlying the grant of a patent:

> Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that

> monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Brenner, 383 U.S. at 534. Having demonstrated only non-specific utility for Claim 1, Plaintiff has failed to satisfy the "substantial and specific" utility standard.

Claim 2 - The P Sequences

The '271 patent asserts in vitro testing has established that the P sequences have utility in diagnosis, treatment, and possible prevention of HIV. Plaintiff relies on *In re Isaacs*, 347 F.2d 887 (C.C.P.A. 1965), for the proposition that in vitro testing is credible and provides satisfactory evidence to establish substantial and specific utility.

Plaintiff's reliance on *Isaacs* is misplaced. The *Isaacs* court determined utility for a known pharmaceutical compound that was a product of cellular metabolism. *Id.* at 890-92. This disputed claim is distinguishable, as it does not involve a known compound. Rather, it involves a coding gene sequence that manifests resistance through unknown products and activities.

Nevertheless, the showing of HIV resistance *in vivo* supports assertion of actual, credible activity by the P sequences, which in turn supports a finding of substantial and specific utility for Claim 2. *See In re Brana*, 51 F.3d at 1567 (finding utility for an anti-tumor compound based on *in vivo* studies and expressing "firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans.") (citing *In re Kimmel*, 292 F.2d 948, 953 (C.C.P.A. 1961)). Plaintiff is not required to prove a specific use of

the claimed invention. *See Nelson*, 626 F.2d at 856. Nor must the plaintiff provide details of the mechanism: "an applicant for patent need not understand the theory of operation of his invention." *In re Storrs*, 245 F.2d 474, 478 (C.C.P.A. 1957); *see Cross*, 753 F.2d at 1042 n.3 ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests"); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565 (Fed. Cir. 1996) ("[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' suffices."); *see also* PTO Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001) (requiring a minimum of "one specific, substantial and credible utility"). Thus, based on the stipulated activity of the P sequences, Plaintiff has met its burden of showing by a preponderance of the evidence that Claim 2 has substantial and specific utility. *See ZMI Corp. v. Cariac Resuscitator Corp.*, 844 F.2d 1576, 1576 (Fed. Cir. 1988).

ii. credible utility

To satisfy the PTO Guidelines, the asserted claims must also have credible utility. *See* Training Materials, *supra*. A claim has credible utility if one of ordinary skill in the art would consider the asserted utility to be reasonable in view of the disclosure and any other evidence of record (e.g., test data, affidavits, or declarations from experts in the art, patents, or printed publications) that is probative of the applicant's assertions. *See id.* at 5.

Claim 1 - The Dolly Genome

Because Claim 1 does not have substantial and specific utility, it cannot satisfy the PTO Guidelines, even if it has credible utility. Therefore, the court need not reach the credibility of Claim 1.

Claim 2 - The P Sequences

Plaintiff argues that the P sequences provide a credible diagnostic utility by determining, through RFLP or other DNA analytical methods, whether other individuals share the claimed sequence. Even if Defendant expresses a unique mutation shared by no one else, determining that a test subject does not carry the claimed sequences would nevertheless provide diagnostic data. While the value of the Claim 2 sequences may presently be useful only to establish absence or presence of HIV resistance in a manner similar to Defendant's, this remains a credible application. Negative results

are therapeutically useful to the medical care system. *See Institut Pasteur*, 186 B.R. at 9 (finding utility in diagnosis that subjects do not have HIV infection). Furthermore, if others are found to carry the assertedly protective sequences, use of Claim 2 for diagnostic tests could lead to the identification of more subjects for future study of HIV resistance.

Plaintiff has further argued that Claim 2 has credible utility if it confers in vitro and in vivo HIV resistance. Plaintiff maintains that the P sequences will be useful for diagnosis and treatment of HIV and AIDS. (*See* Def.'s Reply at 7, 8, 10.)

Defendant counters that the P sequences may consist of "enhancer" genes that do not create cell products but merely regulate other genes. Defendant further argues that other genes may actually be responsible for HIV resistance. These arguments are not persuasive. HIV resistance has been observed based on the presence of the P sequences. The P sequences have demonstrated three known effects: increased HIV resistance in (1) one individual's cells, (2) a hybrid mouse, and (3) in vitro cell culture. Moreover, the parties have stipulated that the P sequences are coding sequences. Therefore, Defendant has not met his burden of proving by clear and convincing evidence that Claim 2 lacks credible utility. Defendant's affirmative defense of invalidity due to lack of utility fails.

2. Product of nature

To be valid, a patent must describe an invention that comprises patentable subject matter. *See* 35 U.S.C. § 101. Patentable subject matter is construed broadly as "'anything under the sun that is made by man.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoted in *Hearings on H.R. 3760 Before Subcommittee No. 3 of the House Comm. on the Judiciary*, 82nd Cong. 37 (1951)). The '271 patent presents the interesting question of whether the Dolly Genome and the P sequences are "made by man" or are products of nature. If the former, they are patentable subject matter. If the latter, they are not.

Products of nature are not patentable subject matter since they are subject to discovery rather than invention. *See Chakrabarty*, 447 U.S. at 309. Human input, however, may transform a product of nature into a human-made product. See *id.* at 309-10. A biological product cannot be patented unless it has been sufficiently

manipulated to cease being "nature's handiwork." *Compare Chakrabarty*, 447 U.S. at 309 (holding that genetically engineered bacterium was patentable subject matter), *with Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (holding that naturally occurring bacteria were not transformed into patentable subject matter when they were merely isolated from nature).

It is well settled that DNA may be patentable subject matter rather than a product of nature. *See In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (upholding patents for isolated human and animal prostaglandins); *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 104 (C.C.S.D.N.Y. 1911) (upholding patents for purified adrenaline isolated from surrounding tissues). In fact, patents have been awarded for sequenced genes that code for proteins that function in detecting or treating diseases, including genes associated with myotonic dystrophy and Machado-Joseph disease. *See* U.S. Patent No. 5,977,333 (DNA Sequence Encoding the Myotonic Dystrophy Gene and Uses Thereof) (issued Nov. 2, 1999), http://patft.uspto.gov/netacgi/nph-Parse; U.S. Patent No. 5,840,491 (DNA Sequence Encoding the Machado-Joseph Disease Gene and Uses Thereof) (issued Nov. 24, 1998), http://patft.uspto.gov/netacgi/nph-Parse; U.S. Patent No. 4,703,008 (DNA Sequences Encoding Erythropoietin) (issued Oct. 27, 1987), http://patft.uspto.gov/netacgi/nph-Parse. By isolating pure cultures and microorganisms, the inventors created a valid claim in a manufacture that did not occur separately and distinctly in nature. *See In re Bergy*, 596 F.2d 952, 975-77 (C.C.P.A. 1979).

Plaintiff argues that Claims 1 and 2 are products of human invention because the genetic sequences have been isolated from nature in a pure form that is altered and useful. Plaintiff further asserts that removal of the genetic fragments from Defendant's tissue created a physically transformed product. Although the presence and character of Defendant's genome is attributable to over three billion years of evolutionary processes, neither this genome nor the P sequences exist in a pure, isolated form in nature. The DNA sequences claimed in the '271 patent derive from nature. However, they were not in exploitable form until acted upon by the inventor who contributed human ingenuity and inventorship. Therefore, in accord with *Chakrabarty*, the Dolly Genome and the P sequences are patentable subject matter.

3. Novelty

A patented invention will not issue unless the invention is novel, that is, newly invented. *See* 35 U.S.C. §§ 102(a), 102(e), and 102(g). The novelty requirement both protects and rewards the original inventors of an innovative device and prevents the grant of a patent to a device that is not innovative. *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.01 (2001) ("An invention must be new at the time of discovery by an original inventor to be patentable.").

Under section 102(a), an invention is not novel if, prior to the date of invention, it was known or used in public in the United States. *See* 35 U.S.C. § 102(a). Defendant argues that providing a blood sample to AGTC was such an anticipating prior public use of his genome (Claim 1) and P sequences (Claim 2). Therefore, Defendant claims as an affirmative defense, that the '271 patent is invalid for lack of novelty.

Defendant's transfer of his blood sample to AGTC did not amount to public use. *See id.* An anticipating prior public use must utilize the complete product or process as enabled in the invention. *See Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001) (holding that anticipating prior art must contain "all of the elements and limitations of the claim . . . arranged as in the claim"). Defendant's sale of whole blood did not anticipate the patented invention—isolated, purified DNA sequences of known composition. Nor were the tests performed by AGTC on Defendant's blood an anticipating prior public use. These tests did not use the Dolly Genome or the P sequences in the isolated forms claimed in the patent. Defendant has not demonstrated an anticipating public use of the complete invention described in the '271 patent. Thus, Defendant has not met his burden of showing by clear and convincing evidence that the '271 patent is not novel.

4. Statutory bar

Even if an inventor meets the § 102(a) novelty requirement, he may lose the right to patent his invention under the statutory bar, § 102(b), if he unduly delays in filing his patent application. *See* 35 U.S.C. § 102(b). Under § 102(b), an invention may not be patented if it is on sale or in public use more than one year prior to the inventor's date of application. The statutory bar prevents monopolization of a useful article that had previously been placed in

the public domain. *See Elizabeth v. Pavement Co.*, 97 U.S. 126, 137 (1877); *Egbert v. Lippmann*, 104 U.S. 333, 337-38 (1881). Therefore, once an invention is for sale or is used in public by the inventor or by any other party, the statutory period begins running. *See* 35 U.S.C. § 102(b). The inventor then relinquishes his right to patent if he fails to apply within one year. *See id.*

Defendant asserts that the July 31, 1998 use of his blood in genetic testing by AGTC triggered the one-year statutory period. Since Plaintiff did not apply for its patent until August 5, 1999, more than one year later, Defendant contends it is invalid as statutorily barred.

Defendant is mistaken. The statutory bar does not apply unless a device was used in substantially identical form as that disclosed in the patent application.

> We conclude, therefore, that the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale.... Second, the invention must be ready for patenting. That condition may be satisfied ... by proof ... that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67-68 (1998); *see Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1572 (Fed. Cir. 1986); *DeLong Corp. v. Raymond Int'l, Inc.*, 622 F.2d 1135, 1141 (3rd Cir. 1980). The use of Defendant's whole blood for genetic testing purposes did not amount to public use of the claimed invention—the genome and isolated gene sequences—and therefore did not trigger the statutory bar. Defendant has thus failed to show by clear and convincing evidence that the '271 patent is invalid as statutorily barred.

5. Nonobviousness

Even if an invention is deemed novel under the § 102 novelty requirement, it may nonetheless be invalid under § 103 because it is not novel enough. Where "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art," the invention is obvious and not patentable. 35 U.S.C. § 103(a) (1994 & Supp. V 2000).

It is not possible to predict the variations in human DNA. *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1207 n.4 (Fed. Cir. 1991). Therefore, based on prior art (i.e., other sequenced genomes), a person having ordinary skill in the art could not have anticipated the unique aspects that render parts of Dolly's genome useful as a diagnostic tool for HIV. Accordingly, obviousness does not invalidate this patent. *See id.* at 1206-09 (finding that the specification of numerous possible DNA segments to code for a protein did not make their creation obvious). Although it may have been obvious for Plaintiff to attempt analysis on human genomes to locate unique activities, this application does not render the '271 patent invalid because research findings are unpredictable. *See In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (finding that although a DNA sequence of gene coding for a monkey protein was disclosed, the sequence of the human gene and protein chain was neither obvious nor predictable, even if the area was an obvious target for research).

Nor is the claimed invention obvious under the "similar compound" test. *See In re Dillon*, 919 F.2d 688, 698 (Fed. Cir. 1990) (holding that claimed new chemical compositions are not obvious when they exhibit unexpected new properties despite structural similarities). Genes differ in their functions based on minor differences in nucleotide sequence. It is unremarkable, therefore, that the gene sequences claimed in the '271 patent have similar structures to previously patented gene sequences. Despite this similarity, the claimed invention demonstrates "unexpected new properties," i.e. resistance to HIV. *See id.* Therefore, the invention claimed in the '271 patent is not obvious.

6. Conclusion as to patent validity

Claim 1 is invalid for lack of utility. Although it is theoretically possible to conduct whole-genome RFLP analyses to compare Defendant's genome to that of other individuals, this process would be impractical, burdensome, and is neither "well-established" nor "substantial and specific" as a medical diagnostic tool. Revised

Utility Examination Guidelines, 64 Fed. Reg. 71,442 (Dec. 21, 1999).

Claim 2 is not invalid as a matter of law. It has substantial, specific, and credible utility. It comprises patentable subject matter. It is novel and is neither obvious nor statutorily barred. Accordingly, the '271 patent is not invalid. *See* 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.").

B. Property and Privacy Rights in Genetic Information

In addition to asserting patent invalidity on statutory grounds, Defendant claims the patent on his genome and sequenced genes infringes his constitutional rights in property and privacy.[20] Courts have addressed the nature and extent of these rights outside the context of patents on human genomes. However, the precise issues raised in this case are matters of first impression. Defendant therefore asks this Court to apply analogous precedent to decide that the '271 patent violates public policy and is therefore unenforceable.

The proper role of the courts in extending public policy into the area of human genetics and patent law bears careful contemplation. With due consideration of judicial constraints, the court turns to an examination of the enforceability of the '271 patent in light of constitutional and legislative protections of Defendant's property and privacy rights.

1. Property rights

Defendant asserts that enforcing Plaintiff's patent would violate his property right in his own body and its biological by-products. He also claims he did not consent to the transfer of his blood sample to Plaintiff and was not given an opportunity to grant or withhold consent.

These claims are familiar to anyone following the ongoing debate over genetic property rights. However, this is not a debate the court can readily join. Defendant's property rights, if any, must be

20. The parties raised additional arguments relating to tort and breach of contract. However, these arguments were not supported by sufficient authority to warrant consideration.

found under California law, since there is no federal statute on point, nor does the Constitution recognize any relevant property interests. *See Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972) ("Property interests . . . are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law."). Accordingly, the court is not free to declare new property interests in genetic material, no matter how inviting the proposition.

a. ownership of Defendant's blood sample and informed consent

The '271 patent is based on research from Defendant's genome, which in turn was isolated from blood samples Defendant supplied to AGTC. Defendant claims he retains a property interest in these samples which is undermined by enforcement of the '271 patent against him. Contrary to Defendant's claims, precedent does not recognize retention of property rights in tissue once it is removed from the body.

The California Supreme Court has held that a patient does not have a continuing property right in excised tissue. *See Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 141, 793 P.2d 479, 492, 271 Cal. Rptr. 146, 159 (Cal. 1990). Moore underwent a splenectomy (removal of his spleen) at UCLA Medical Center. *See id.* After a successful operation, Moore's physician used the excised tissue and other biological samples to develop and patent an immortalized cell line with lucrative medical uses. *See id.*, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49. Moore sued for conversion, claiming ownership of his excised cells. *See id.* at 127, 793 P.2d at 483, 271 Cal. Rptr. at 150. Moore also claimed that his physician breached his fiduciary duty because he failed to inform Moore, prior to the operation, of potential financial interests in Moore's tissue samples. *See id.* at 125, 793 P.2d at 480, 271 Cal. Rptr. at 147.

The California Supreme Court recognized Moore's cause of action for breach of fiduciary duty, but rejected his claim of conversion. *See id.* at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164. It held that finding a property right in excised tissue, and hence requiring informed consent regarding its disposal, would put an undue burden on the medical research community. *See id.* at 146, 793 P.2d at 495-96, 271 Cal. Rptr. at 162-63. The court was hesitant to grant property rights in excised tissue because "the laws governing

such things as human tissues . . . [and] blood . . . deal with human biological materials as objects sui generis, regulating their disposition to achieve policy goals rather than abandoning them to the general law of personal property." *Id.* at 137, 793 P.2d at 489, 271 Cal. Rptr. at 156. Thus, under *Moore*, Defendant has no property rights in his blood sample or in the inventions derived therefrom.

However, current medical and research practices may indicate emerging recognition of genetic property rights. Many medical procedures require patients to sign a consent form. This is particularly common for treatments that result in the excision of tissue. The consensus in the medical community is that patients should be able to determine what happens to their excised tissue. Plaintiff balks at the requirement of consent for its research, yet current medical practice strongly supports such consent.

In fact, several recent legislative initiatives specifically require informed consent. *See, e.g.*, N.M. STAT. ANN. § 24-21-5 (Michie 2001) (requiring informed and written consent for retention of a person's genetic information, gene products, or samples for genetic analysis); Genetic Information Privacy Act, ch. 588, (current version at 2001 Or. Laws 588 (S.B. 114)) (expanding protection against genetic testing without specific informed consent); S.C. CODE ANN. § 38-93-40 (Law. Co-op. 2001); Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 JURIMETRICS 1, 1 (1996).

Nevertheless, Plaintiff argues that required consent would impede medical research both because patients would not give consent and because it would allow donors whose tissues were collected without consent to sue. These arguments are not persuasive. As Defendant's expert witness testified, most people whose consent is requested grant it. (Expert Test. Richard M. Myers, Ph.D.) Therefore, consent is a small obstacle to the collection of tissues needed for medical research. Furthermore, legislation barring actions on tissues collected prior to enactment of a consent requirement would allow the medical community to continue research on samples that already exist, while protecting the interests of future patients. Such legislation is presently being developed in several states. *See, e.g.*, Genetic Privacy Act, ch. 588, sec. 659.700-659.720, § 6(7), 2001 Or. Laws 588 (S.B. 114) (2001).

Thus, the *Moore* court's concern that requiring patient consent would unduly hamper medical research apparently has not been borne out. *Moore*, 793 P.2d at 487-88. However, this court cannot properly re-examine *Moore*. The California Supreme Court is the final arbiter on this state law question. And, the California legislature has yet to adopt legislation protecting personal property rights in genetic material. While Defendant raises property issues that are not without merit, they are not within this court's power to address.

b. right to procreate

Defendant argues that his blood samples deserve special protection as property because they have potential for human life. Relying on California state court precedent, Defendant claims blood samples and other tissues containing DNA should be afforded the same level of protection previously granted to gametic material, such as sperm or fertilized zygotes. *See Hecht v. Superior Court*,[21] 16 Cal. App. 4th 836, 850, 20 Cal. Rptr. 275, 283 (1993) ("[R]eproductive material . . . is a unique form of 'property'"); *see also Johnson v. Calvert*, 5 Cal. 4th 84, 93, 851 P.2d 776, 782, 19 Cal. Rptr. 2d 494, 500 (1993), *cert. denied*, 510 U.S. 874 (1993), *and cert. dismissed*, *Baby Boy J. v. Johnson*, 510 U.S. 938 (1993) (analogizing fertilized ovum to intellectual property).

However, genetic tissue has never been accorded the status of "property" in the usual sense of the term. For instance, in Hecht, "the decedent's interest in his frozen sperm vials, even if not governed by the general law of personal property, occupies 'an interim category that entitles them to special respect because of their potential for human life.'" *Hecht*, 16 Cal.App. 4th at 846, 20 Cal. Rptr. 2d at 281. Similarly, in *Johnson*, the court was confronted with having to resolve parentage as between an egg donor and a host in a

21. The California Supreme Court denied review of this decision and directed the Reporter of Decisions not to publish the court of appeal 1996 opinion in the Official Reports. (Reported at 1997 Cal. LEXIS 131) However, this Court may consider the reasoning in the 1993 opinion as it analyzes the property issues presented in this action. *See McSherry v. Block*, 880 F.2d 1049, 1053 (9th Cir. 1989) (finding that the federal district court should consider the California appellate court's construction of a statute notwithstanding the fact that the analysis was rendered in an unpublished opinion).

surrogate pregnancy. *See Johnson*, 5 Cal. 4th at 93, 851 P.2d at 782, 19 Cal. Rptr. at 500. Property rights per se were not implicated in these cases, and the courts were careful not to imply that they were.

Other courts addressing this question have similarly been hesitant to extend property rights in reproductive tissues. *See, e.g.*, *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992) (frozen embryos are neither property nor persons but rather something in between); *In re Baby M.*, 537 A.2d 1227, 1250 (N.J. 1988) (babies are not property that can be bought and sold). Thus, where courts have considered the allocation of property rights in potential human life, they have consistently and properly deferred to the legislative process.

Furthermore, application of the patented genes to create human life could only be successful through human cloning. This has never been achieved. Cloning a human from an isolated human genome presents a very different "potential for life" than sperm, eggs, and fertilized embryos possess. Moreover, cloning is currently prohibited by CAL. HEALTH & SAFETY CODE §§ 24185-24189 (West Supp. 2001). Defendant thus essentially requests that all human cells containing DNA be protected for their potential for human life, based on an untested and presently illegal method. Therefore, the need for additional judicial protection is minimal.

Defining the particular kinds of cells that may have the potential for human life is a broad task, restricted by our current understanding of science and technology. Due to the frequency with which cells in hair, skin, and other tissues are shed, it would not be practical to label all such cells as the private property of their original owners. This definition "is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot." *Chakrabarty*, 447 U.S. at 317. This court therefore declines to extend the constitutional scope of property to include absolute ownership of DNA material and defers to Congress and the state legislatures.

2. Privacy rights

The right to control private genetic information is central to this action. At present, however, this issue is unsettled by both case law and legislative directive. Defendant makes several arguments that

would construe the constitutional right to privacy to include an individual's right to control the dissemination of his genetic information. Enforcement of the '271 patent against Dolly would be in direct tension with this hypothetical right.

The "right to privacy" encompasses two distinct interests. *See Whalen v. Roe*, 429 U.S. 589, 598-600 (1977). It embraces both a general "individual interest in avoiding disclosure of personal matters" and the "interest in independence in making certain kinds of important decisions." *Id.* at 599-600. The former interest is embodied in the Fourth Amendment,[22] and protects "reasonable expectation[s] of privacy" from governmental snooping. *See Katz v. United States*, 389 U.S. 347, 360-61 (1967) (Harlan, J., concurring). The latter is found in the "penumbras" of the Bill of Rights. *See Griswold v. Connecticut*, 381 U.S. 479, 484-85 (1965). This right, often characterized as the right to "personhood" and "autonomy," has been limited by later cases to family relations and procreational decisions. *See Bowers v. Hardwick*, 478 U.S. 186, 190-91 (1986).

a. right to be free from government snooping

"The constitutionally protected privacy interest in avoiding disclosure of personal matters clearly encompasses medical information and its confidentiality." *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269 (9th Cir. 1998). In *Norman-Bloodsaw*, a routine employee health examination was extended, without the employee's knowledge, to sensitive medical and genetic information, including pregnancy and sickle cell anemia. *See id.* at 1264-65. The district court had held that because the employee knew he was undergoing a medical exam, any undisclosed testing was a de minimus intrusion into his privacy. *See id.* at 1268-69. The court of appeal reversed. *See id.* at 1275. "That one has consented to a general medical examination does not abolish one's privacy right not to be tested for intimate, personal matters involving one's health." *Id.* at 1270 (relying on *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 616 (1989) (finding that while the taking of a bodily fluid

22. U.S. CONST. amend. IV ("The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.").

sample implicates one's privacy interests, "[t]he ensuing chemical analysis of the sample to obtain physiological data is a further invasion of the tested employee's privacy interests").

Assuming Defendant retained such an expectation of privacy in the blood sample he provided to AGTC, he still cannot establish a constitutional violation. Neither AGTC nor Plaintiff are "state actors." *See Mancusi v. DeForte*, 392 U.S. 364, 368 (1968); *Burdeau v. McDowell*, 256 U.S. 465, 467 (1921) (holding that the Fourth Amendment proscribes only governmental action, and does not apply to a search or seizure, even an unreasonable one, effected by a private individual). The only plausible state actor in this case, the United States Patent and Trademark Office (PTO), played no part in acquiring Defendant's genetic information or performing unauthorized tests. Consequently, despite its subsequent publication of Defendant's genome, through the issuance of the '271 patent,[23] the PTO is not implicated in this privacy claim. *Accord Walter v. United States*, 447 U.S. 649, 659 (1980).[24]

b. right to bodily integrity and autonomy

The constitutionally guaranteed right to bodily integrity and autonomy is the right to control one's own body. *See Vacco v. Quill*, 521 U.S. 793, 803 n.7 (1997) (citing *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (1914) (finding that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body"). Integrity refers to the physical integrity of the body. *See Rochin v. California*, 342 U.S. 165, 172 (1952) (pumping a suspect's stomach by force was unlawful). It is the right to be free from unwanted touching, especially in situations where the invasion creates a substantial risk of injury or death. *See Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 287-88 (1990) (O'Connor, J., concurring); *Washington v. Harper*, 494 U.S. 210, 237 (1990)

23. The '271 patent makes public Defendant's genome both by publication of the full DNA sequence and by the preservation of an immortalized cell line containing copies of his genetic material.

24. Nor is Plaintiff an agent of the PTO, such as would make Plaintiff a state actor. In contrast, in *Norman-Bloodsaw*, Lawrence Berkeley Laboratory was operated by state and federal agencies and under contract with the U.S. Department of Energy. *See Norman-Bloodsaw*, 135 F.3d at 1264. It was clearly a state actor bound by the Fourth Amendment.

(Stevens, J., concurring). Autonomy refers to the right to make decisions without outside interference. *See Roe v. Wade*, 410 U.S. 113, 152-54 (1973). Defendant claims both rights are violated by Plaintiff's enforcement of the '271 patent against him.[25]

Plaintiff claims that the right to bodily autonomy is simply a right to be free from physical interference, for example, the right to refuse medical treatment. This is supported by the Court's construction of the right in *Cruzan*. 497 U.S. at 278-79 (recognizing an individual's right to refuse treatment based on bodily autonomy); *see also Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891) ("No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.").

The focus of this right, however, lies in control of one's person and freedom from bodily invasion. *Cruzan*, 497 U.S. at 287-88 (O'Connor, J., concurring). Defendant wishes to extend this right to his tissues after they have been voluntarily removed. Such a construction would go well beyond precedent. Indeed, the Supreme Court has clarified the scope of the right as protecting a person's body. *See Planned Parenthood v. Casey*, 505 U.S. 833, 852 (1992) (stating that a proper analysis of the right to choose an abortion must take notice of physical constraints and pain that only the pregnant woman must bear). The Court has refused, however, to extend the right as unqualified when not being exercised by the actual individual in question. *Cruzan*, 497 U.S. at 282 (upholding Missouri's imposition of a clear and convincing burden of proof when third parties institute proceedings to assert a now incompetent person's wish to refuse treatment). The right to bodily integrity is therefore confined to the scope of one's corporeal body. *See id.* 278-79.

While the forcible excision of tissues would be a clear violation of the right to bodily autonomy, the mere use of materials which are

25. This argument does not suffer from the same state action infirmity as Defendant's Fourth Amendment claim above. Here, it is the enforcement of the '271 patent which Defendant contends causes constitutional injury, not the collection of data by private parties. Enforcement by this court is likely sufficient to satisfy the state action requirement. *See Shelley v. Kraemer*, 334 U.S. 1, 14-18 (1948).

no longer part of a person is not. Such use does not physically impact upon the supplier. Defendant's claim to a violation of bodily autonomy is not supported by constitutional law.

c. right to die

Defendant claims that the patent infringes his right to die. But there is no such right in the abstract. *See Washington v. Glucksberg*, 521 U.S. 702, 735 n.24 (1997) (refusing to apply heightened scrutiny to an asserted constitutional right to die and thereby upholding an anti-doctor assisted suicide law against a facial challenge). Rather, where the right is found, it is in the context of the right to refuse medical treatment, based on either the common-law right to informed consent or the right to resist bodily invasion. *See Cruzan*, 497 U.S. at 278-79; Laurence H. Tribe, *American Constitutional Law* § 15-11, at 1362 (2d ed. 1988). Wherever grounded, the liberty interests implicated in Defendant's case do not rise to a choice between life and death. Defendant's personal right to die is not affected. *See Cruzan*, 497 U.S. at 271. The immortalized cell line in Claim 3 that Defendant claims is artificially extending his life is factually and legally distinct from Defendant's person.[26] Since the cell line is not the Defendant's physical being, his personhood is not affected by its propagation. Nor is Defendant "immortalized" simply because one of his cells is. *See* '271 patent, Claim 3 *supra* note 4. Though cleverly crafted, Defendant's argument extends the right to bodily autonomy to absurd extremes.

d. the genetic privacy act

Defendant argues that, under this Court's equity powers, the '271 patent should be held unenforceable because it violates federal and state public policy on genetic privacy. Defendant seeks a result for which there is scant legal support. Some guidance is provided by the proposed 1996 Genetic Privacy Act (hereinafter the Act). *See* Roche et al., *supra*, at 4.[27] This proposal resulted from a study

26. Moreover, Claim 3 of the '271 patent is not challenged.

27. The text of the Act can be found on the U.S. Dept. of Energy's Human Genome Project Web site. *See* George J. Annas et al., U.S. Dept. of Energy, Pub. No. DE-FG02-93ER-61626, *The Genetic Privacy Act and Commentary*, (Feb. 28, 1995), *at http://www.ornl.gov/hgmis/resource/privacy/privacy1.html.* This Court notes that the Act is merely proposed and that arguments relying on

funded by the Ethical, Legal and Social Implications of the Human Genome Project, Office of Energy Research, United States Department of Energy.[28] As the introduction states:

> The Genetic Privacy Act is a proposal for federal legislation. The Act is based on the premise that genetic information is different from other types of personal information in ways that require special protection.... Genetic information is powerful and personal. As the genetic code is deciphered, genetic analysis of DNA will tell us more and more about a person's likely future, particularly in terms of physical and mental well-being.[29]

The proposed Act seeks to "establish rules for the protection of individual privacy as curiosity about perhaps the most private and sensitive information—genetic information—is driven by the piece-by-piece decoding of the genome." Roche et al., *supra*, at 10. The Act would supplement the thin protections presently afforded by the Privacy Act of 1974[30] by establishing clearer and more uniform national rules for addressing the collection and use of genetic information and materials.[31] *See id.* at 5. The Act lays forth strict requirements for informed consent, detailing the types of research that may allow disclosure of private genetic information, the authority needed to do so and the required procedures for handling genetic material once it is obtained. *See id.* For instance, section 111 would require written authorization for each disclosure:

> Except as provided in section 115 and section 132(b),[32] no person who, in the ordinary course of business, practice of a profession, or rendering of a service, creates, stores,

---

it are not ripe.

28. "Additional support was provided by Boston University School of Public Health." *Id.*

29. *Id.*

30. Privacy Act of 1974, 5 U.S.C. § 552(a) (2000) (concerning disclosure of confidential information about government employees).

31. The proposed Act would further grant a property right in such materials to increase patient participation and consent in medical research. *See* Michael M.J. Lin, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J.L. & MED. 109, 130-32 (1996).

32. The exceptions are for compulsory service of process and limited access for statistical purposes in research.

> receives or furnishes private genetic information may by any means of communication disclose private genetic information except in accordance with a written authorization as provided for in section 112.

Id. This section, if enacted as law, might well be implicated by AGTC's disclosure of information to Plaintiff, or to Plaintiff's patent application itself.

However, as salutary as these rules may be, neither the Genetic Privacy Act, nor any similar federal proposal has yet to be enacted by Congress. In the meantime, genetic privacy remains principally a state concern. Only a handful of states have passed laws regarding genetic privacy. Most states that have addressed the issue are still debating the divergent opinions on these questions, as well as on the propriety of granting privacy and property rights in human tissue. *See* Burk Burnett, *Genetic Discrimination: Litigation Required to Keep Genetic Secrets*, 21 SETON HALL LEGIS. J. 502 (1997). Commentators agree that genetic privacy would be best regulated under federal law, given its national and even global importance. *See* Meredith A. Jagutis, *Insurer's Access to Genetic Information: The Call for Comprehensive Federal Legislation*, 82 MARQ. L. REV. 429, 443-45 (1999).

Pending legislative action, this court cannot apply mere proposals to limit enforcement of an otherwise valid patent. True, Plaintiff failed to safeguard Defendant's identity, in possible contravention of the proposed Act. However, Plaintiff did not violate any obligations currently imposed by law.

Nor do Plaintiff's actions require this court to exercise its equity powers to hold the patent unenforceable under the doctrine of inequitable conduct. As a threshold matter, the doctrine of inequitable conduct is a defense to a patent applicant's actions before the PTO during prosecution of the patent. *See Aptix Corp. v. Quickturn Design Sys. Inc.*, 269 F.3d 1369, 1377 (Fed. Cir. 2001) ("In the absence of any showing of misconduct before the PTO, the . . . patent remains a presumptively valid grant of personal property."). Here, the alleged inequitable action, breach of the confidentiality promised in the signed consent form, was unrelated to any action before the PTO. Moreover, "the doctrine of unclean hands [does not] provide a suitable basis for the trial court's judgment, as this equitable doctrine is not a source of power to

punish." *Id.* at 1378. Whatever the reach of the court's equity powers, they cannot stretch to encompass Defendant's asserted violation of laws that have not yet been enacted.

3. Court's role in patent disputes

As the above analyses demonstrate, enforcement of the '271 patent may well intrude upon Defendant's legitimate property and privacy interests. The extent of the intrusion balanced against the resulting benefit to society is unresolved. Resolution of this issue, and the resulting decision as to enforceability of patents in genetic information, will be instrumental to the progress of medical science and to the protection of our core values. However, the courts are not the proper forum for this resolution.

The Supreme Court faced a similar issue in *Chakrabarty*, where it was asked to deny patentability to new life forms, despite satisfaction of all statutory patent criteria, because of the grave risks posed by genetic research. *See Chakrabarty*, 447 U.S. at 316-17. The Court rejected the plea, stating that it was

> [W]ithout competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

Id. at 317.

Courts have only limited authority to deny enforcement of patents on nonstatutory grounds. Historically, a patent could be invalidated as not useful if it was found to serve an amoral purpose. *See Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568) (holding that a patent had no utility if it was "injurious to the well-being, good policy, or sound morals of society"). However, as the judiciary's self-imposed prudential restraints have evolved, courts have been increasingly unwilling to apply moral judgments to

patent utility. Today a patent's otherwise valid utility will not be challenged on morality grounds unless the invention serves no legitimate purpose. *See Juicy Whip v. Orange Bang*, 185 F.3d 1364, 1368 ("The requirement of 'utility' in patent law is not a directive to the [PTO] or the courts to serve as arbiters of deceptive trade practices."). The Federal Circuit expressly noted in *Juicy Whip* that decisions to make particular types of inventions unpatentable must be made by Congress, and that, until such time as Congress makes that decision, the courts are not free to invalidate patents for lack of utility based on moral policy decisions. *See id.* Courts are no longer in the business of weighing social values to assess a patent's usefulness. *See id.*

Similarly, courts should not deny enforcement of an otherwise valid patent based on judicial weighing of individual rights against societal needs. The parties' arguments on these issues raise legitimate concerns. Nevertheless, these arguments cannot influence the court's analysis of the '271 patent. Deciding the policy issues underlying enforcement of the patent is beyond the scope of the court's authority.

The resolution of the issues raised by this case will have far-reaching implications. The court eagerly adds its voice to the cacophony of pleas for consideration of these issues by a well-informed legislature. However, consistent with the proper role of the judiciary, the court is constrained from doing more. It remains for the legislature to investigate and decide upon the appropriate protections to afford human genetic information.

IV. CONCLUSION

For the foregoing reasons, the court GRANTS Defendant's motion for summary judgment as to Claim 1 of the '271 patent, DENIES Defendant's motion for summary judgment as to Claim 2, and GRANTS Plaintiff's motion for partial summary judgment as to Defendant's affirmative defenses.
IT IS SO ORDERED.

Dated: January 31, 2002

MARILYN HALL PATEL
Chief Judge
United States District Court
Western District of California