RECOMMENDED RESPONSE FOR HUMAN CLONING PATENT APPLICATIONS

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I. INTRODUCTION

The United States Patent and Trademark Office ("USPTO") should not follow the recent decision of the European Union to invalidate patents pertaining to human doning technology. First, human cloning inventions are clearly patentable in the United States; not only do these inventions meet the statutory requirements of proper subject matter and utility, but they are also not precluded from satisfying the other requirements of novelty, nonobviousness, disclosure and enablement.[1] Second, while human cloning technology undoubtedly requires regulation, patent law is not the proper forum or even an adequate one. While patent law is designed to reward inventors of desirable inventions, it is not in the position to regulate or prohibit the undesirable ones.

In addition, the patent infringement immunity given to "medical activit[ies]" by section 616 of the Omnibus Consolidated Appropriations Act of 1996 ("Act") should not be relied upon to prevent enforcement of human cloning patents.[2] First, this legislation has been sharply criticized and should

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1 *See* 35 U.S.C. §§ 102, 103, 112 (1994, Supp. II 1996 & Supp. IV 1998).

2 Omnibus Consolidated Appropriations Act § 616 (1996); 35 U.S.C. 287(c) (1994, Supp. II 1996 & Supp. IV 1998).

be construed very narrowly.[3] Second, an examination of the Act itself suggests that human cloning does not fall within the statutorily defined "medical activity."

Finally, more feasible mechanisms for regulating human cloning exist outside patent law. These mechanisms include future legislation, the Food and Drug Administration's ("FDA") Public Health Services Act,[4] the Federal Food, Drug and Cosmetic Act,[5] and the Department of Health and Human Services's ("DHHS") Fertility Clinic Success Rate and Certification Act of 1992.[6] However, in the event that existing legislation is relied upon, additional provisions are recommended in order to adequately regulate this revolutionary technology.

II. BACKGROUND

A brief review of the science behind human cloning is necessary to ensure that any legal response to this technology is guided by an accurate understanding of its limitations and potential applications.

A. *Definition and Embodiments of Cloning*

A clone is a cell or individual that has been created from, and is genetically identical to, another cell or individual.[7] Currently, there are three

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3 *See* Bradley L. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 3 J. Legis. 265, 276 - 279 (1997); 142 Cong. Rec. S11845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch); 142 Cong. Rec. S11846 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch); 142 Cong. Rec. S11846 (daily ed. Sept. 30, 1996) (letter from John R. Kirk, Jr., chair of the American Bar Association); *see also* 142 Cong. Rec. S11, 843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, general counsel to the office of the United States Trade Representative).

4 *Public Health Services Act*, Pub. L. No. 106-65, 113 Stat. 665 (1999).

5 *Food and Drug Administration Modernization Act of 1997*, Pub. L. No. 105-115, 1111 Stat. 2296 (1997).

6 *Fertility Clinic Success Rate and Certification Act of 1992*, Pub. L. No. 102-493, 106 Stat. 3146 (1992).

7 *See The Concise Oxford Dictionary* 258 (Della Thompson ed., 1995). The Oxford English Dictionary defines a clone as one or more "cells or organisms produced asexually from one stock of ancestors."

known methods for creating clones: (1) somatic cell nuclear transfer ("SCNT");[8] (2) the creation of cell lines;[9] and (3) embryo twinning.[10] While SCNT occurs only in the laboratory, the latter two types of cloning may either take place naturally or be artificially induced.

Contrary to popular perception, cloning is not a new process, even for humans. Many primitive organisms, such as bacteria, replicate primarily through cloning, and have done so for billions of years.[11] Moreover, some invertebrates, such as earthworms, retain the ability to reproduce by cloning throughout their adult lives. Regarding humans, cloning occurs naturally with the fortuitous creation of identical twins and, in the less fortunate, with the development of cancer.[12]

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[8] *See* Gregory E. Pence, *Who's Afraid of Human Cloning* 11 (Rowman & Littlefield Publishers 1998). SCNT literally combines the desired genetic blueprint with the cellular machinery necessary for early embryonic development. Here, an unfertilized egg (ova) has its genetic material removed (through enucleation: elimination of the cell's nucleus, which contains the cell's DNA) and replaced with the genetic material of a properly pretreated donor cell. This combination may be performed through either insertion of the donor cell's nucleus into the enucleated ova or simple fusion of the two cells. The end result is a cell with the cellular constituents necessary for embryonic development, yet with the desired genetic material.

[9] *See* Robert G. Fenton & Dan L. Longo, *Cell Biology of Cancer*, in *Harrison's Principles of Internal Med.* 505 (Anthony S. Fauci et al. eds., 14th ed. McGraw Hill 1998). A cell line is created when a cell is "immortalized" through the loss of normal growth inhibitory factors, causing the cell and its descendants to continue dividing despite signals that would arrest cell division in a normal cell. In the human body, this represents cancer. *See also* Pence, *supra* n. 8, at 11. In the laboratory, cell lines may be created because their virtually unlimited supply of genetically identical cells aids in research.

[10] *See* T. W. Sadler, *Langman's Medical Embryology* 109 (6th ed. Williams & Wilkins 1990). Embryo twinning refers to the process where a single embryo either separates spontaneously or is artificially cleaved into two embryos, which may then develop into identical twins. Naturally, embryo twinning may occur in humans as early as the two-cell stage and as late as the end of the second week of embryonic development. After this point, any separation will be incomplete and result in conjoined twins.

[11] *See* Warren E. Levinson & Ernest Jawetz, *Medical Microbiology and Immunology* 1 (3d ed. Appleton & Lange 1994). Artificially, embryo twinning is occasionally performed in fertility clinics through the introduction of an electric charge in order to increase the supply of embryos available to prospective parents. *See also* Pence, *supra* n. 8, at 11.

[12] *See* Fenton & Longo, *supra* n. 9, at 505. The development of all cancers represents the unregulated and unwanted cloning of an individual cell.

B. *Applications of Human Cloning*

1. Therapeutic and Replicative Cloning and Their Procedures

There are two theorized human applications for cloning technology: (1) the cloning of human cells or tissues for therapeutic purposes ("therapeutic cloning"), and (2) the cloning of a human individual for reproductive purposes ("replicative cloning"). Practically speaking, both procedures would presumably begin with SCNT. In the case of therapeutic cloning, the nucleated ovum after fusion, would be genetically modified or specially treated with cell stimulating/repressing factors to stop development into a human being, and guide its differentiation into a particular cell or tissue type. This process would take place entirely within the laboratory. Although this procedure has not yet been applied to humans and is far from perfected, preliminary research suggests that guided differentiation may be possible in the future.[13]

In the case of replicative cloning, after SCNT has been performed, the nucleated ovum would be inserted into a human uterus (at the proper phase of the menstrual cycle) in a procedure similar to that used with *in vitro* fertilization. A nine month gestation period would ensue, followed by the birth of a human baby that is genetically identical to the person who provided the donor nucleus.

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[13] In October of 1997, the Sunday Times reported the creation of headless tadpoles through manipulation of the frogs developmental pathways. *See* Oliver Morton, *First Dolly, Now Headless Tadpoles; Creation of Headless Tadpoles by Developmental Geneticist Spurs Ethical Debate over Creating Brainless Humans for Medical Use*, 278 Sci. 798 (1997). *See* Andrei Glinka et al., *Dickkopf-1 is a Member of a New Family of Secreted Proteins and Functions in Head Induction*, 391 Nat. 357 (1998) for more detailed discussion of head-inducing factors in frogs and their manipulation. This procedure provides an early example of technology that might one day be used in conjunction with therapeutic cloning, not to create headless humans, but more likely to guide the development of cloned embryos into discrete organs, such as kidneys, or discrete cell types, such as pancreatic β cells for patients with renal failure or diabetes mellitus, respectively. More recently, scientists from the Monash Institute of Reproduction and Development in Melbourne, Australia reported the successful completion of all of the major technical steps involved in the therapeutic cloning of a mouse. *See* James Chapman, *Experts Find How to Clone Embryos for 'Spare Parts'*, Daily Mail (London) 13 (Aug. 16, 2000).

2. Utility of Human Cloning

The application of both therapeutic and replicative cloning to humans would provide significant medical breakthroughs.

a) Therapeutic Cloning

The utility provided by therapeutic cloning is unquestionable: through the creation of a potentially unlimited supply of genetically predetermined tissues, therapeutic cloning is poised to erase the two major constraints to the field of organ and tissue transplantation. First, transplantation is currently severely limited by the inadequate supply of donor organs. For example, in 1999, 3088 people died in the United States while waiting for a kidney transplant and 1767 people died while waiting for a liver transplant.[14] In addition, it is estimated that only 2000 potential cardiac donors become available each year for the pool of over 20,000 candidates awaiting cardiac transplantation.[15] These statistics do not even include the large number of persons who die of organ failure yet were unable to meet the stringent criteria of placement on a transplant list.

Second, the immunosuppressive therapy necessary to prevent the rejection of non-genetically identical organs is expensive and often accompanied by severe and lifestyle-limiting side effects.[16]

By providing a mechanism for the creation of genetically identical organs virtually on demand, therapeutic cloning could solve both of these problems. This ready supply of organs may even foster the development of new transplant techniques to address previously untreated forms of organ and cellular failure such as neural transplants to treat paralysis, Parkinson's Disease, or Alzheimer's Disease, or even T-helper cell transplants to treat Acquired Immuno-Deficiency Syndrome ("AIDS"). However, while cloning

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[14] *See* Norman G. Levinsky, *Organ Donation by Unrelated Donors*, 343 New Eng. J. Med. 430, 430 (2000).

[15] *See* John S. Schroeder, *Cardiac Transplantation*, in *Harrison's Principles of Internal Med.*, *supra* n. 9, at 1298.

[16] *See* Charles B. Carpenter & J. Michael Lazarus, *Dialysis and Transplantation in the Treatment of Renal Failure*, in *Harrison's Principles of Internal Med.*, *supra* n. 9, at 1526-29; Schroeder, *supra* n. 15, at 1299.

appears to be particularly well suited for these tasks, it is by no means the only possible solution.[17]

b) Replicative Cloning

Replicative cloning also represents a tremendous breakthrough in medical science. The procedure provides the first and only known method for both: (1) asexual human reproduction; and (2) the reproduction of an individual who is genetically identical to one already born. With current technology or the lack thereof, humans can only reproduce sexually (through the fertilization of an ovum with a single sperm). In addition, genetically identical individuals can only arise through embryo splitting. While this may either occur naturally, as in the case of twins, or artificially, as may accompany *in vitro* fertilization, embryo splitting is no longer possible after the second week of embryonic development.[18]

By providing a means for human asexual reproduction, replicative cloning would allow those who otherwise could not reproduce (without donated sperm or ova) to have children. This category would include single-would-be parents and couples where one partner is either infertile or possesses a genetic trait that the couple does not wish the risk of passing on.[19] In addition, by providing a method for the reproduction of genetically

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17 *See* Erika Check, *Cloning Pigs for Parts*, Newsweek, Aug. 28, 2000, at 49. In the future, human therapeutic cloning may be unnecessary since other non-cloning procedures might be used instead to produce tissues/organs for transplantation in humans. One such solution may be the harvesting of organs from genetically modified pigs. *See* Sheryl Gay Stolberg, *Breakthrough in Pig Cloning Could Aid Organ Transplants*, N.Y. Times 1 (Jan. 4, 2001). The months of October through December of 2001 witnessed the birth of nine cloned piglets that had previously been genetically modified to prevent their tissues from being rejected by the human body. *See* Diana L. Clarke et al., *Generalized Potential of Adult Neural Stem Cells* 288 Sci. 1660 (2000). Moreover, a recent study suggests that stem cells already present in the adult human body might be used instead of ova for selective differentiation into desired cell and organ types. However, while this procedure is not typically thought of as human cloning, the important similarities between the two procedures may erode any cloning/non-cloning distinction.

18 *See* Sadler, *supra* n. 10, at 109.

19 In the latter situation, however, other potentially more reasonable solutions either exist now or may in the near future. Solutions include pre-term genetic testing possibly accompanied by therapeutic abortion, as well as genetic engineering.

identical individuals, replicative cloning allows for the birth of children with a specific and known bundle of genetic traits.

(1) Limitations Inherent With Replicative Cloning

Two critical and perhaps reassuring factors limit the power of replicative cloning. First, the genes of human clones would not be truly identical to those of the donor, and they would likely be significantly less identical than the genes of identical twins. This is because human DNA is located not only within the human cell's nucleus, which would be transferred from the nuclear donor in SCNT, but also in the mitochondria, which would be passed on by the enucleated ovum. As a result, unless the ova are donated by the same woman who acts as the genetic donor (which is only possible when cloning a premenopausal woman), clones will not possess identical mitochondrial DNA. Considering that the list of medical conditions linked to mitochondrian include disorders of the heart, liver, brain and muscle, the contribution of this genetic material is significant.[20]

Moreover, the DNA passed on to the clone through SCNT will not be identical to the DNA that guided the genetic donor's embryonic development. Mutations constantly occur in the human body's genetic material. In order to create significant genetic differences between identical twins, the necessary mutations must occur within the relatively short period between spontaneous embryo splitting and the completion of critical developmental pathways. In cloning, however, these mutations are given years or even decades to accumulate since they may occur at any time during the donor's life, previous to donating. While these genetic differences may not be widespread, even minor genetic discrepancies may create significant effects.[21]

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[20] *See* Roberto Ferrari, *The Role of Mitochondria in Ischemic Heart Disease*, 28 J. of Cardiovascular Pharmacology (Supp. 1) S1, S1-10 (1996); S. L. Budd & D. G. Nicholls, *Mitochondria in the Life and Death of Neurons*, 33 Essays Biochemistry 43 (1998); D. C. Wallace, *Mitochondrial Defects in Cardiomyopathy and Neuromuscular Disease*, 139 Am. Heart J. 2, S70-S85 (2000); R. J. Sokol & W.R. Treem, *Mitochondria and Childhood Liver Diseases*, 28 J. Pediatric Gastroenterology & Nutrition 1, 4-16 (1999).

[21] *See* M. Goodman et al., *Molecular Phylogeny of the Family of Apes and Humans*, 31 Genome 316, 316 (1989). Only a 0.1% genetic difference separates any two humans, and only a 0.4% difference in active genes separates humans from chimpanzees. *See* Arthur L.

Second, the environment's influential role in human development guarantees that even genetically identical individuals will be neither identical in mind nor body. Minute environmental variations may create significant differences among both physical and psychological traits. For example, identical twins, who despite the above discussion may be presumed genetically identical, may have different fingerprints[22] and have only a 50% convergence for homosexuality.[23] These discrepancies are attributed to subtly different experiences within the same intrauterine environment and usually a strikingly similar extrauterine environment.

In the case of clones and their genetic donors, however, the environmental differentiating effect will be magnified not only by their separate intrauterine environments, but also by presumably different extrauterine environments. Regarding the latter, a clone can be expected to grow up decades after his or her donor, non-identical parenting and significantly different societal pressures and influences. Therefore, while replicative cloning may produce embryos that are nearly identical genetically, it is certain that these embryos will develop into unique and distinct individuals.

C. *Evolution of Cloning*

The modern age of animal cloning began in the late 1960's when Dr. John Gurdon cloned frogs through the SCNT of tadpole nuclei into frog egg cells.[24] Since then, mice, cows, sheep and pigs have been cloned through the techniques of embryo splitting, SCNT from embryonic donors, and SCNT from adult donors.[25] Regarding primates, rhesus monkeys have been

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Beaudet, *Genetics and Disease*, in *Harrison's Principles of Internal Med.*, *supra* n. 9, at 377. Moreover, certain diseases such as sickle cell anemia are due to mutations of only a single base pair.

22 *See* Martin L. Pernoll & Ralph C. Benson, *Multiple Pregnancy*, in *Current Obstetric & Gynecologic Diagnosis & Treatment* 357 (Alan H. DeCherney & Martin L. Pernoll eds., 8th ed. Appleton & Lange 1994).

23 *See* Philip Kitcher, *The Lives to Come* 258-259 (1997).

24 *See id.* at 328.

25 *See id.* at 329. The cloning of mammals began in 1996 when Dr. Ian Wilmut cloned two sheep named Megan and Morag through SCNT from an embryonic donor. *See* Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 Nat. 810, 810 (1997). The next year, Dr. Wilmut cloned Dolly through SCNT from an adult donor.

successfully cloned through embryo splitting[26] and SCNT from an embryonic donor.[27]

However, these clonings have not proceeded without difficulty or complications. To begin with, the survival rate for clones has been shockingly low. For example, Dolly was the only lamb born from 277 cloned embryos -- 29 cloned embryos survived long enough to undergo uterine implantation.[28] Likewise, a recent success in mouse cloning experienced a greater than 97% mortality rate prior to birth.[29]

Moreover, Dolly has been found to be experiencing premature aging.[30] Research suggests this is the result of using a six year old genetic donor, with its attendant degree of age-related damage to the telomeres.[31] However, this problem appears to have been solved, and even reversed, in later clonings.[32] More recent attempts have employed techniques to fortify the genetic donor's telomeres prior to SCNT, resulting in clones that are experiencing delayed aging and are expected to possess extreme longevity.[33]

See T. Wakayama et al., *Full-term Development of Mice from Enucleated Oocytes Injected with Cumulus Cell Nuclei*, 394 Nat. 369, 369 (1998); Yoko Kato et al., *Eight Calves Cloned from Somatic Cells of a Single Adult*, 282 Sci. 2095, 2095 (1998); *See* Check, *supra* n. 17, at 49. These were followed by the SCNT clonings of mice, cows and pigs.

26 *See* A. W. S. Chan et al., *Clonal Propagation of Primate Offspring by Embryo Splitting*, 287 Sci. 317, 317 (2000). In January of 2000, scientists reported the successful cloning of a rhesus monkey through artifical embyro splitting.

27 *See* D. P. Wolf et al., *Nuclear Transfer in the Rhesus Monkey: Practical and Basic Implications*, 60 Biology of Reproduction 199, 199 (1999); L. Meng et al., *Nuclear Transfer in the Rhesus Monkey*, 57 Biology of Reproduction 454, 454 (1997). In March of 1997 researchers from the University of Oregon revealed the first successful cloning of a primate, in this case a rhesus monkey, from an embryonic donor.

28 *See* Wilmut, *supra* n. 25, at 810.

29 *See* Wakayama, *supra* n. 25, at 369.

30 *See In Brief*, 318 British Medical J. 1506, 1506 (1999).

31 *See id.*; *See also* R. P. Lanza et al., *Extension of Cell Life-Span and Telomere Length in Animals Cloned from Senescent Cells*, 288 Sci. 665, 665 (2000).

32 *See id.*

33 *See id.*

Unfortunately for Dolly, these techniques arrived too late for her cloning and she has recently been reported to suffer prematurely from arthritis.[34]

Finally, scientists have believed that SCNT bypasses the protective mechanisms present in germ cells, such as sperm and ova, which correct DNA errors.[35] Although this hypothesis has not yet been tested, this hypothesis suggests that with current techniques, clones are at a higher risk of developing cancers and other mutation-related conditions.

D. *The Birth of Human Cloning*

1. Human Replicative Cloning

Advances in mammalian replicative cloning have not proceeded without the threat or promise of human application. In December of 1997, Richard Seed, a Chicago nuclear physicist with a background in bovine embryo transfer techniques,[36] proclaimed his intent to clone a human being within eighteen months.[37] The announcement quickly gained Dr. Seed public notoriety and ripened popular debate on the ethics and legality of human cloning technology.[38] However, as of thirty-six months past his self-imposed deadline, Dr. Seed has failed to report any successful clonings, and has since been dismissed as a dreamer.[39]

Others have been more successful than Dr. Seed. On December 16, 1998, almost exactly one year after Seed's announcement, a team of researchers from Kyunghee University Hospital in Seoul, South Korea,

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34 *See* Marjorie Miller, *Dolly's Arthritis Raises New Fears About Cloning*, L.A. Times 1 (Jan. 5, 2001).

35 *See* Jonathan Watts & Kelly Morris, *Human Cloning Trial Met with Outrage and Scepticism*, 353 Lancet 43, 43 (1999).

36 *See* Steve Rhodes, *The Weird Science of Richard Seed*, Baltimore Sun 11E (May 17, 1998).

37 *See* Gina Kolata, *Proposal for Human Cloning Draws Dismay and Disbelief*, N.Y. Times A22 (Jan. 8, 2001).

38 *See id.*; *see also* Robert Winston, *Beware of the Charlatans of Cloning*, Daily Mail (London) 8 (Jan. 8, 1998).

39 *See* Rhodes, *supra* n. 36, at 11E.

reported that they had created an embryonic human clone by fusing the nucleus of an adult human cell with an enucleated human ovum.[40] Although the team reportedly destroyed the embryo at the four-cell stage, and their data was later questioned,[41] the researchers suggested that implantation of the embryo would have resulted in a viable pregnancy and the birth of a human clone.[42] Experts remained skeptical about the potential success of the experiment, given the relatively primitive technique employed.[43] Others noted, however, that the experiment signaled the inevitable human application of cloning research.[44]

Forays into the territory of human cloning have even occurred unintentionally. In November of 1998, scientists at the Tokyo University of Agriculture inadvertently applied cloning techniques by intentionally fusing the nuclei of cancerous human white blood cells with bovine egg cells.[45] The University promptly apologized for the experiments and emphasized that the researchers had neither intended to produce human clones nor used human ova.[46]

The next attempt at human replicative cloning appears to be developing among members of the Raelian Religion, whose members believe that life on earth was created scientifically by extraterrestrials. This religious group has established a service called CLONAID® which will provide cloning services for fees as a low as $200,000.[47] Although CLONAID® has yet to

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40 *See* Watts & Morris, *supra* n. 35, at 43.

41 *See* Michael Baker, *Report Casts Doubt on Korean Experiment*, 283 Sci. 617, 617 (1999).

42 *See* Watts & Morris, *supra* n. 35, at 43.

43 *See id.*

44 *See Bioethicists Say Human Cloning is Inevitable*, Med. Indus. Today, Dec. 22, 1998.

45 *See* Jonathan Watts, *Experiment Sparks Cloning Debate in Japan*, 354 Lancet 1801, 1801 (1999).

46 *See id.*

47 *See Clonaid.com – The First Cloning Company* <http://www.clonaid.com> (visited Oct. 5, 2000). "Rael – the founder of a religious organization called the RAELIAN MOVEMENT which claims that life on earth was created scientifically in laboratories by extraterrestrials whose name (Elohim) is found in the Hebrew Bible and was mistranslated by the word 'God', and which also claims that Jesus' resurrection was, in fact, a cloning performed by Elohim – announced today that he and a group of investors have set up a company named VALIANT VENTURE LTD which will offer a service called

announce any success, the corporation was reported to have found customers in the parents of a 10 month old child reportedly lost to medical malpractice in a hospital.[48]

2. Human Therapeutic Cloning

Although still in its naissance, human therapeutic cloning is also undergoing active research. In November of 2001, Advanced Cell Technology, Inc. of Worcester, Massachusetts, published their success in the creation of cloned human embryonic cells.[49] Although the cloned embryos did not progress past the six-cell stage and no attempt was made to guide their eventual differentiation into particular cell lines, the authors stated that the study's specific purpose was to explore the foundations of therapeutic cloning in humans.[50]

III. LEGAL RESPONSE

Developments in animal cloning and the beginnings of human application have quickly inspired reactions from legislative bodies around the world. While these reactions were largely negative, only a small amount of the proposed legislation to regulate or ban human cloning has actually been enacted.

A. *United States*

1. Executive Response to Human Cloning

On March 4, 1997, less than one week after the publication of Dolly's cloning, then - President Clinton announced, "no federal agency may support,

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CLONAID® to provide assistance to would be parents willing to have a child cloned from one of them." *Id*.

48 *See CLONAID Will Soon Start Cloning the First Human Baby Thanks to a Complete Financing*, PR Newswire (Aug. 23, 2000).

49 *See* Jose B. Cibelli *et al*., *Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development*, 2 E-BIOMED: J. of Regenerative Medicine 25 (2001).

50 *See id.* at 26.

fund, or undertake [human cloning research]."[51] President Clinton also petitioned the scientific and medical communities to abide by a voluntary moratorium on private human cloning research until the National Bioethics Advisory Commission ("NBAC") and the entire nation "have had a real chance to understand and debate the profound ethical implications of the latest advances."[52] The NBAC, whose competence to address the issue has been seriously questioned,[53] unanimously condemned the technology three months later and recommended a federal ban on any attempt at replicative cloning.[54]

2. Legislative Response to Human Cloning

a) Federal Legislation

Consistent with the NBAC's recommendation, a flurry of federal legislation was proposed to outlaw human cloning throughout the United States. As of January of 2002, however, none have been enacted. The most recent attempt, the "Human Cloning Prohibition Act of 2001," which would prohibit both replicative and therapeutic cloning, was passed by the House of Representatives in July of 2001 and is expected to be debated in the Senate in February or March of 2002.[55]

b) State Legislation

The various states have been marginally more successful: two of over twenty-five bills to ban cloning introduced at the state level have been

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51 President William J. Clinton, *Announcing the Prohibition on Federal Funding for Cloning of Human Beings, Address Before Reporters*, in Weekly Comp. Pres., Mar. 4, 1997, at 278

52 *See id.*

53 *See* Pence, *supra* n. 8, at 34-35.

54 *See* National Bioethics Advisory Commission, Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission (Rockville, MD, June 1997).

55 *See* H.R. Rpt. 107-2505 (July 31, 2001); Sheryl Gay Stolberg, *The Stem Cell Debate; Controversy Reignites Over Stem Cells and Clones*, N.Y. Times F1 (Dec. 18, 2001).

enacted.[56] In 1997, California became the first state to regulate cloning through the enactment of a "five-year moratorium on the cloning of an entire being in order to evaluate the profound medical, ethical, and social implications that such a possibility raises."[57] The statute provides for fines equivalent to twice the pecuniary benefit of cloning or up to $1,000,000, whichever is greater (for violations by corporations, hospitals, or laboratories) or $250,000 for violations by individuals.[58] Moreover, any such violation will constitute unprofessional conduct.[59] Notably, by addressing only the "cloning of an entire being" this statute regulates replicative cloning, but not therapeutic cloning.

In June of the following year, Michigan became the first state to enact a permanent ban on human cloning.[60] The Michigan statute prohibits both therapeutic cloning and replicative cloning.[61] The statute also provides for fines up to ten million dollars, a possible five-year medical license revocation and up to ten years in prison.[62] Since the enactment of this statute, however, no other anti-cloning legislation has been enacted in the United States.

B. *European Union*

The European Union ("EU") has achieved the greatest success in banning human cloning. The EU's anti-cloning policy was first revealed on May 29, 1997, when the European Council unequivocally condemned this

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56 As of the summer of 1998, twenty-six pieces of state legislation had been proposed to ban human cloning. *See Michigan First State to Enact Permanent Ban on Human Cloning*, Washington Health Week, June 15, 1998, at 2.

57 *See* Cal. Health & Safety Code *prec* § 24815 (Deering 2000).

58 *See* Cal. Health & Safety Code § 24817 (Deering 2000).

59 *See* Cal. Bus. & Prof. Code § 2260.5 (Deering 1997).

60 *See Michigan First State to Enact Permanent Ban on Human Cloning*, *supra* n. 56.

61 *See* Mich. Comp. Laws § 333.16274 (2000). The statute prohibits the use of somatic cell nuclear transfer technology to produce "a human egg cell with a full genetic composition capable of differentiating and maturing into a complete human being." Since this step is necessary for both therapeutic and replicative cloning, both procedures are illegal under the statute.

62 *See id.*

technology.[63] Next, on January 15, 1998, the EU Parliament called on member states to prohibit human cloning through ratification of the supplement to the Council of Europe Human Rights and Biomedicine Convention.[64] Finally, with Directive 98/44, whose deadline for ratification by member states passed on July 30, 2000, the EU precluded the patentability of human cloning inventions by making any process for cloning human beings unpatentable on the grounds that "their commercial exploitation would be contrary to public order or morality."[65]

The directive was released in response to the University of Edinburgh's Patent No. EP 0695351, a European patent issued in December of 1999 by the European Patent Office, for the "[i]solation, selection and propagation of animal transgenic stem cells."[66] The controversial portion of the application, claim 48, describes a method of SCNT that could be applied to humans.[67] Although the University denied any intention to engage in human cloning, critics noted that the patent covers this endeavour through its use of the overly-broad term "animal," without a "non-human" modifier.[68] The University has appealed the invalidation of its patent, but the University is not expected to succeed because of the clear language in the directive.[69]

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63 *See* European Union, Bulletin 6-1997, *European Council Declaration on Banning the Cloning of Human Beings* <http://europa.eu.int/abc/doc/off/bull/en/9706/i1031.htm> (accessed Oct. 11, 2000).

64 *See* European Union, Bulletin 1/2-1998 *Parliament Resolution on Human Cloning* <http://europa.eu.int/abc/doc/off/bull/en/9801/i102001.htm> (accessed Oct. 11, 2000).

65 *See* European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 30/07/1998.

66 *See* European Patent No. 0695351 issued to University of Edinburgh (Dec. 8, 1999).

67 *See id.* Claim No. 48 reads as follows: "A method of preparing a transgenic animal, said animal comprising a source of cells suitable for the isolation and propagation of stem cells including: providing a blastocyst; providing animal cells according to any of Claims 38-39; introducing the animal cells into the blastocyst; transferring the blastocyst to a recipient; and allowing an embryo to develop to a chimaeric animal to enable germline transmission of the selectable marker." [Isolation, Selection and Propagation of Animal Transgenic Stem Cells, WO 94/27274.]

68 *See* Anthony Ramirez, *A Case of Letting the Gene Out of the Bottle*, N.Y. Times, May 14, 2000, § 4, at 5. *See also University Denies Applying for Human Cloning Patent*, Evening Mail (Birmingham) 7 (Feb. 24, 2000).

69 *See id.*

C. *United Kingdom*

The United Kingdom recently became the first nation to specifically authorize human cloning.[70] On November 15, 2001, the High Court ruled that human embryos created through SCNT do not satisfy the statutory definition of "embryo" under Britain's Human Fertility and Embryology Act of 1990, since such embryos do not involve the fertilization of an ovum with a sperm cell.[71] As a result, Mr. Justice Crane concluded that human cloning through SCNT is currently not prohibited.[72] In response, British government officials are said to be planning to appeal the ruling, as well as quickly introduce new legislation in the event that their appeal fails.[73]

D. *Japan*

Although Japan has considered several legislative attempts to ban research on human cloning, no law has been enacted as of yet. The most recent proposal, endorsed by the Japanese Cabinet on October 6, 2000, provides prison terms up to ten years and fines as high as 10 million yen.[74] However, the proposal prohibits only the implantation of a human somatic cell into a uterus, thus it bans replicative, but not therapeutic, cloning.[75]

IV. RECOMMENDATION: PATENTS FOR HUMAN CLONING INVENTIONS SHOULD BE ALLOWED AND ALSO ENFORCED

A critical examination of United States patent law and its application to human cloning inventions leads to the following three conclusions: (1) human cloning inventions are patentable under United States law, (2) patent law is not the proper forum for regulating new technologies, and (3) The

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70 *See* Mark Henderson, Greg Hurst, and Frances Gibb, *Emergency Laws to Ban Human Cloning*, Times (London) 1 (Nov. 16, 2001).

71 *See id.*

72 *See id.*

73 *See id.*

74 *See Anti-Human Cloning Bill to be Submitted to Current Diet*, Japan Econ. Newswire, Sept. 29, 2000

75 *See id.*

Omnibus Consolidated Appropriations Act Of 1996 does not restrict the enforcement of human cloning patents:

A. *Human Cloning Inventions Are Patentable Under United States Law*

The USPTO should not repeat the EU's decision to invalidate patents relating to human cloning inventions. These inventions, such as the one described in European Patent No. 0695351, clearly meet the requirements for patentability in the United States because such technology can satisfy proper subject matter and utility requirements. In addition, these inventions are not precluded in any way from satisfying novelty, nonobviousness, disclosure and enablement.

In support, the USPTO has already issued several patents relating to methods for cloning specifically related to non-human animals, including patents granted to Geron-Biomed and the University of Massachusetts at Amherst.[76] For patenting purposes, the only relevant distinction between human and animal cloning rests on questions of morality, which, as argued in IV.A.2.c., *infra*, should not be relied upon to preclude the patentability of new technologies.

1. Procedures for Human Cloning Are Patentable Subject Matter

The United States Patent Act ("Patent Act") permits the patenting of an invention representing a "process, machine, manufacture, or composition of matter."[77] The United States courts have consistently interpreted this language to include developments in biotechnology, including those claiming processes employing the manipulation of living organisms. For example, in *In re Mancy*,[78] the Court of Customs and Patent Appeals upheld the patentability of a process for creating antibiotics through the provision of specific

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[76] *See* David Pilling, *US Company Awarded on Method that Cloned Dolly*, Fin. Times (London), Jan. 21, 2000, at 2; Lisa Eckelbeckter, *U.S. Issues Cloning Patent for UMass; License Will Benefit Firm Co-founded by Researcher*, Telegram & Gazette E1 (Sept. 1, 1999).

[77] 35 U.S.C. § 101 (1994, Supp. II 1996 & Supp. IV 1998).

[78] *In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. 303 (CCPA 1974).

nutrients to the fungus *Streptomyces bifurcus*.[79] Likewise, in *In re Chakrabarty*,[80] the Court of Customs and Patent Appeals upheld the patentability of a process for transforming bacteria into a strain capable of degrading oil.[81]

In addition, an early policy precluding the patentability of medical and veterinarian therapies does not prevent the patenting of human cloning inventions. This policy, illustrated in the case of *Morton* v. *New York Eye Infirmary*,[82] has since been firmly overturned.[83] In *Ex Parte Scherer*,[84] the Patent Office Board of Appeals held that "[t]here is nothing in the patent statute which categorically excludes [methods of treating the human body], nor has any general rule of exclusion been developed by decisions."[85]

Of note, while the exclusion of medical therapies from patentable subject matter is entirely dead, its spirit has been resurrected through limitations on patent enforcement, as discussed in IV.C., *infra*.

2. Human Cloning Possesses Sufficient Utility for Patenting

The Patent Act also limits patentability to inventions that are "useful."[86] In general, the courts have interpreted "useful" broadly, finding utility wherever the disclosed invention is actually "operable and capable of satisfying some function of benefit to humanity."[87] More specifically, the

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79 *See id.* at 1289, 182 U.S.P.Q. at 303.

80 *In re Chakrabarty*, 571 F.2d 40, 197 U.S.P.Q. 72 (CCPA 1978).

81 *See id.* at 40, 197 U.S.P.Q. at 72.

82 *Morton* v. *N.Y. Eye Infirmary*, 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9,865).

83 *See id.* at 884 (holding that the essential role played by the patient's "natural functions" in the effectiveness of ether as a surgical anesthetic prevents the discovery from being patented).

84 *Ex Parte Scherer*, 103 U.S.P.Q. 107 (Pat. & Tr. Off. Bd. App. 1954)

85 *See id.* at 110 (upholding the patent for a technique of injecting fluids into the human body).

86 35 U.S.C. § 101 (1994).

87 Donald S. Chisum and Michael A. Jacobs, *Understanding Intellectual Property* 2-50 (Bender 1992).

utility requirement can be analyzed by breaking it into its three components: general, specific, and beneficial utility.[88]

a) General Utility

The issue of general utility rests upon "whether [or not] the invention as claimed can really *do* anything."[89] Human cloning inventions described in Part II.B.2 *supra* confirm that these inventions have a utility. Replicative cloning has its utility being a mechanism for human asexual reproduction and in the creation of genetically identical persons.[90] Similarly, therapeutic cloning has utility in providing a method for creating genetically precise human organs for transplantation.[91]

b) Specific Utility

Specific utility is defined as the workability of the invention to fulfill its intended goal.[92] For human cloning inventions, specific utility is the success in creating cloned organs or individuals.[93]

c) Beneficial Utility

The doctrine of beneficial utility has been interpreted to require that "the invention has some minimum social benefit, [and not be] completely harmful or deleterious."[94] However, as Professor Merges astutely notes, applying this doctrine to preclude patentability has been limited to activities that were believed (at least at the time) to be inherently bad.[95] For example, beneficial utility was often invoked in the late nineteenth century to deny patents on gambling devices and fraudulent medicinal products; the public

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88 *See* Robert Patrick Merges, Patent Law and Policy 189 (2d. ed. 1997).

89 *Id.*

90 *See* section II.B.2.b., *supra*.

91 *See* section II.B.2.a., *supra*.

92 Merges, *supra* n. 88, at 189.

93 *See* section II.B.2.b., *supra*.

94 Merges, *supra* n. 88, at 189.

95 *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 Md. L. Rev. 1051, 1062 (1988).

sentiment during this period was that gambling and fraud were inherently bad.[96]

The objectives of human cloning do not meet the "completely harmful or deleterious" standard. On the contrary, not only are the creation of children and the treatment of organ failure not inherently bad, but instead, these practices are highly valued in society.[97]

Moreover, application of the beneficial utility requirement to human cloning inventions is not appropriate. As Professor Merges argues, "patent protection for a new technology normally should not be denied on the basis of speculation about potential negative consequences."[98] Professor Merges supports his argument by illustrating the volatility of moral views on inventions; discoveries such as birth control pills were transformed from illegality to legal and popular usage within the span of a mere several decades.[99] Equally important, the patent system has neither the expertise nor the resources to competently evaluate the often changing morality of these developing technologies. The beneficial utility requirement, therefore, should not serve as a basis to prevent patenting human cloning inventions.

3. Human Cloning Inventions Are Not Precluded from Satisfying the Other Patentability Requirements

Finally, human cloning inventions are not precluded from satisfying the other statutory requirements for patentability. There is nothing specific to human cloning inventions that prevents them from satisfying the novelty requirements of 35 U.S.C. § 102,[100] the nonobvious requirement of 35 U.S.C. § 103,[101] or the disclosure and enablement requirements of 35 U.S.C. § 112.[102]

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96 *See id.* at 1062-64.

97 Without the creation of children, society itself would cease to exist. Regarding organ failure, *see* Norman G. Levinsky, *Organ Donation by Unrelated Donors*, 343 New Eng. J. Med. 430, 430 (2000).

98 *See id.* at 1067.

99 *See id.* at 1064-65.

100 *See* 35 U.S.C. §§ 102(a), (b) (1994).

101 35 U.S.C. § 103 (1994, Supp. II 1996 & Supp. IV 1998).

102 35 U.S.C. § 112 (1994).

B. *Patentability Should Not Be Used As a Means of Regulation*

Patentability should not be used as a means of regulation for human cloning inventions. First, patentability used as a regulation lacks any constitutional basis. The basis for patent law - article I, section 8, Clause 8 of the United States Constitution - provides Congress with the power to "promote the Progress of Science and the useful Arts."[103] This language does not discuss discouraging unwanted science.[104] Instead, the founding fathers presumably envisioned such a regulatory role to rest with the legislature instead.

Second, as discussed in Section IV.A.2.c, *supra*, the United States patent laws were not designed to perform a regulatory role.[105] This is evidenced by the patent system's lack of expertise and resources necessary to engage in regulating outside the PTO's expertise: the PTO is not in the position to hold hearings and weigh societal concerns regarding every new technology it reviews.[106]

Third, patent law is all or none: the only options allowed by the PTO are to either grant a patent or not grant a patent.[107] Therefore, the PTO is not in the position to provide the wide range of options that adequate regulation often requires.

Fourth, the nature of patent law prevents a direct regulation of specific activities. A refusal to grant a patent for a specific technology, does not prevent that technology from being applied. Instead, the PTO merely prevents the inventor from gaining a right to exclude others from making, using, and selling that technology.[108] As a result, by not granting a patent, the PTO actually enables anyone to practice the disputed technology, instead of merely the inventor.

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103 U.S. Const. art. I, § 8, cl. 8.

104 *See* Chisum & Jacobs, *supra* n. 87, at 1-8, stating that: "The patent-copyright clause is unusual among the Article I legislative powers because it . . . specifies both the power's purpose (to promote science and the useful arts) and the means for achieving it (exclusive rights for limited times)." No mention is made of discouraging unwanted science.

105 *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 Md. L. Rev. 1051, 1064 - 66 (1988).

106 *See* Cynthia M. Ho, *International and Comparative Law Issues: Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 Wash. U. J. L & Pol'y 247, 283 (2000).

107 35 U.S.C. § 2(a)(1) (Supp. IV 1999); 35 U.S.C. § 131 (1994 & Supp. IV 1999).

108 35 U.S.C. § 154 (1994).

Fifth, patent protection of a technology is limited to twenty years after the first disclosure, barring any delays in the patent prosecution process.[109] Once the patent expires, the technology is placed in the public domain for anyone to practice.[110]

Finally, the Treaty on Trade-Related Aspects of Intellectual Property Rights ("TRIPs"), to which the United States is a signatory, obligates nations to permit patenting all technologies. Article 27 of section 5 provides, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[111] This article, however, does permit nations to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre[sic] public or morality, including to protect human . . . life or health . . . ."[112] As previously discussed, however, the PTO lacks the resources, qualifications, and mandate to regulate technology on moral grounds.[113]

C. *The Omnibus Consolidated Appropriations Act Of 1996 Should Not Restrict the Enforcement of Human Cloning Patent –*

Section 616 of the Omnibus Consolidated Rescissions and Appropriations Act of 1996 ("Act")[114] should not restrict the enforcement of human

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109 *Id*.

110 *Id*.

111 Treaty on Trade Related Aspects of Intellectual Property Rights, Dec. 13, 1993, § 5, art. 27, 33 I.L.M. 81 (1994).

112 *Id.*; *see also* Cynthia M. Ho, *International and Comparative Law Issues: Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 Wash. U. J. L & Pol'y 247, 266 - 268 (2000). The issues of morality and ordre [sic] public are relevant considerations for patents granted by the European Patent Commission. However, an analysis of decisions by the EPC's Board of Appeals points out that morality and ordre [sic] public are only bars to patentability where the invention has a solely destructive use, or where there is sufficient evidence of actual and substantiated serious prejudice, respectively.

113 *See infra*.

114 Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-208, § 616 (1996) (codified as amended at 35 U.S.C. § 287(c) (Supp. II 1996 & Supp. IV 1998)).

cloning patents. This section amends 35 U.S.C. § 287[115] to prevent the enforcement of medical procedure patents against medical practitioners:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281 [providing a civil remedy for patent infringement], 283 [allowing for injunction in the event of patent infringement], 284 [providing for damages in the event of patent infringement] and 285 [providing for attorneys fees] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.[116]

As a result, if human cloning is deemed a statutory "medical activity,"[117] then a "medical practitioner,"[118] which includes licensed physicians or anyone under their direction, could perform a patented cloning procedure without fear of patent enforcement.[119]

1. The Act Sharply Criticized

An analysis of several factors strongly suggests that the Act should not be relied on to prevent enforcement of human cloning patents. First, the intellectual property legal community and even branches of the United States government have sharply criticized the Act as an unjustified trespass into the field of patent law.[120] The Commerce Department labeled the Act as "drastic" and "premature."[121] Likewise, the PTO suggested the amendment was an unnecessary overreaction with possibly dire consequences, noting that the United States would not have the world's leading medical and pharmaceutical industry if it weren't for the patent system.[122] In addition, the American Intellectual Property Law Association, the American Bar Association Section of Intellectual Property Law, and the United States

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115 35 U.S.C. § 287 (1994, Supp. II 1996 & Supp. IV 1998).

116 35 U.S.C. § 287(c)(1) (Supp. II 1996 & Supp. IV 1998).

117 35 U.S.C § 287(c)(2)(A) (Supp. II 1996 & Supp. IV 1998)

118 35 U.S.C. § 287(c)(2)(B) (Supp. II 1996 & Supp. IV 1998).

119 35 U.S.C. § 287(c)(3) (Supp. II 1996 & Supp. IV 1998).

120 *See* Bradley L. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. Legis. 265, 276 - 279 (1997).

121 *See* 142 CONG. REC. S11845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch); *see also* Bradley L. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. Legis. 265, 275 (1997).

122 *See* 142 Cong. Rec. S11845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch).

Trade Representative have openly criticized the Act's purpose.[123] This profound lack of support, therefore, suggests that the Act should be construed very narrowly, if it all.

2. Human Cloning is Not a "Medical Activity"

In addition, the Act's text suggests that human cloning procedures probably do not satisfy the statutory definition of "medical activity." A "medical activity" is defined as "the performance of a medical or surgical procedure on a body, but shall not include" the practice of a patented machine, manufacture, composition of matter or biotechnology process.[124] Not only does human cloning not involve a "body," but it also satisfies the biotechnology patent exception from immunity.

a) "Body" as Defined in the Statue Does Not Include Human Cloning

The cells manipulated in SCNT, such as the unfertilized ovum (the donor cell) and the fusion product, do not satisfy the statutory definition of "body" under section 287(c)(2)(E). "Body," as defined by the statute, is a "human body, organ, or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans."[125] Although the cellular manipulated product has twenty-three human chromosomes, and is thus undeniably "human," application of the term "body" is doubtful. To begin with, the fusion product is not consistent with the common definition of a human body - a multicellular entity comprised of a well-defined set or organs and tissues.

In addition, the prefusion ovum and the donor cell (such as a skin cell), do not qualify as "organs" or "bodies."[126] Instead, these individual cells are minute portions of organs; the ovum and donor cell are at most "tissues," which is not included in the definition of "body."[127]

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123 *See* 142 Cong. Rec. S11846 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch); *see also* 142 Cong. Rec. S11846 (daily ed. Sept. 30, 1996) (letter from John R. Kirk, Jr., chair of the American Bar Association); *see also* 142 Cong. Rec. S11, 843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, general counsel to the office of the United States Trade Representative).

124 35 U.S.C. § 287(c)(2)(A) (Supp. II 1996 & Supp. IV 1998).

125 35 U.S.C. § 287(c)(2)(E) (Supp. II 1996 & Supp. IV 1998).

126 35 U.S.C. § 287(c)(2)(E).

127 *Id*.

Finally, the ovum and donor cell, as individual cells, do not deserve the rights afforded to an entire human body or organ. The ovum and donor cells are expendable, in contrast with the indispensable life represented by a body and the necessary-for-life physiologic functions represented by an entire organ.

b) Replicative Human Cloning May Not Involve a Statutory "Body" Because It Does Not Relate to the Treatment of Humans

Replicative cloning technology, specifically, may also be excluded from the Act because it fails to satisfy the relevant definition of "body". Under the Act, a "body" means a human body, organ or cadaver used in research "directly relat[ed] to the treatment of humans."[128] In the case of replicative cloning, however, this requirement may not be fulfilled: it is uncertain whether or not the creation of a human being will be considered to directly relate to the "treatment" of that human being. Therapeutic cloning, on the other hand, easily satisfies this aspect of "body's" definition because the purpose of therapeutic cloning is to treat organ failure in the genetic donor through the creation of human tissues.[129]

c) Human Cloning Patents Falls Under The "Biotechnology Patent" Exception

Moreover, patents on replicative and therapeutic cloning inventions fall outside of the Act's jurisdiction since both are "biotechnology patents." The House Conference Report on the Act defines "biotechnology patent" as "a patent on a 'biotechnological process' as defined in 35 U.S.C. § 103(b), as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level."[130] Human cloning patents can reasonably be found to satisfy both of these definitions.[131]

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[128] *See Id*.

[129] *See* section II.B.2.a., *supra*.

[130] H.R. Conf. Rpt. 104-863, at 852-55 (1996).

[131] *See* section II.B.1., *supra*.

Unfortunately, the definition of biotechnological process employed by 35 U.S.C. § 103(b)[132] is ambiguous and confusing. Section 103(b)(3) states that:

> the term 'biotechnological process' means—
>
> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to -
>
> (i) express an exogenous nucleotide sequence,
>
> (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
>
> (iii) express a specific physiological characteristic not naturally associated with said organism;
>
> (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
>
> (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).[133]

It is uncertain whether the "and" connecting (A), (B) and (C) signifies that the definition applies only to processes that satisfy each of the three criteria, or to processes that satisfy only one. While the natural reading suggests processes that satisfy only one criteria listed, the latter leads to a more reasonable definition. Since both (A) and (B) represent separate and parallel methods for achieving the same goal, namely altering cell expression, it follows that the definition intended to require one or the other, and not both. A reading requiring a biotechnological process provide both a mechanism for altering cell expression under (A) and (B) and a mechanism for using the product under (C) is overly strict and redundant.

(1) Both Replicative and Therapeutic Cloning Satisfy the First Condition of a Biotechnological Process

Regardless, human cloning procedures satisfy the literal wording, although possibly not the intended meaning, of (A), (B) and (C). Regarding (A), the nuclear donation inherent in SCNT genetically alters an ovum; which, especially after nuclear donation, can be reasonably considered a discrete

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[132] 35 U.S.C. § 103(b) (1994, Supp. II 1996 & Supp. IV 1998).

[133] *Id*.

organism.[134] Moreover, nuclear donation results in changes in the expression of nucleotide sequences, namely the activation of the genes necessary for embryonic development.[135]

(2) Both Replicative and Therapeutic Cloning Satisfy the Second Condition of a Biotechnological Process

Regarding (B), SCNT involves the fusion of the donor cell and the ovum to create a cell line that expresses specific proteins, namely the proteins responsible for the specific traits seen in that individual.[136] This conclusion requires the creative interpretation of a "cell line" to include the nuclear–ovum fusion product.[137] This interpretation, however, is not entirely inaccurate, because the fusion product will continue to produce new copies of genetically identical cells until the death of that individual or organ.[138]

(3) Both Replicative and Therapeutic Cloning Satisfy the Third Condition of a Biotechnological Process

Regarding (C), human cloning uses a product, namely the cell fusion product, to create a cloned human being through uterine implantation.[139] The monoclonal antibody example cited in (B), however, suggests that section (C) may have meant to cover the creation of conventional biotechnology products

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[134] After nuclear donation, the ovum satisfies all of the commonly accepted conditions of the definition of organism in that it is alive and genetically complete (diploid), it and possesses its own physical identity and at least the potential for self-sufficiency (post-partum).

[135] *See* Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 Nat. 810, 810 (1997).

[136] *See* Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 Nat. 810, 810 (1997).

[137] A cell line is a cell that has been immortalized, allowing it to continue reproducing itself without hindrance by the normal cellular regulatory constraints.

[138] A cell destined to become an organ is similar to a cell line since both will continue to produce copies of the original cell. Even a mature organ continues to produce new cells to replace the death of old ones. However, the cell destined to become an organ will respond to, and be hindered by, normal cellular regulatory constraints while a cell line will ignore them.

[139] *See* section II.B.1., *supra*.

(i.e. drugs, hormones, and growth factors) but possibly nothing as complex or controversial as human beings.[140]

(4) Both Replicative and Therapeutic Cloning Satisfy the Alternate Definition of a Biotechnological Process

Finally, both therapeutic and replicative cloning satisfy the alternate definition of "biotechnological process." Both clearly involve the use of biological materials that are manipulated on the cellular level.[141] Moreover, cellular and nuclear manipulation certainly occurs *ex vivo*, or outside of the body.[142] In fact, the fusion of the ovum and donor cell would most likely occur in a petri dish.[143]

A slight wrinkle, however, is posed by replicative cloning. If the cell fusion product that is destined to become a "body" is interpreted to be a "body" itself, then this manipulation might be viewed as *in vivo* for the fusion product but *ex vivo* for the human donors. As argued above, this interpretation is not justified. In addition, this dilemma is even less likely with therapeutic cloning because a cell destined to become an organ is clearly not a "body," but merely the progenitor of one.

d) Brief Summary: Human Cloning Patents and the Act

A close analysis of the Act reveals that human replicative and therapeutic cloning patents are not exempt from enforcement. Not only do a myriad of arguments demonstrate that human cloning inventions fail to satisfy the statutory definition of "body," but these inventions also clearly fall within the "biotechnology patent" exception to immunity.

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140 35 U.S.C § 103(b)(3)(B), (C) (1994, Supp. II 1996 & Supp. IV 1998).

141 *See* section II.B.1., *supra*.

142 *See id.*

143 *See* Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 Nat. 810, 810 (1997).

V. OTHER MORE APPROPRIATE FORUMS FOR THE REGULATION OF HUMAN CLONING EXIST WITH ADDITIONAL SAFEGUARDS

A. *Regulation of Human Cloning Through the Department of Health and Human Services and Food and Drug Administration Is More Appropriate*

1. Department of Health and Human Services

In the absence of new federal legislation addressing human replicative and therapeutic cloning, both activities could be regulated under the Fertility Clinic Success Rate and Certification Act of 1992 ("Fertility Act").[144] Replicative cloning could be regulated under the Fertility Act as both an "embryo laboratory" and an "assisted reproductive technology" program, while therapeutic cloning could be regulated as an "assisted reproductive technology."[145]

Under section 8 of the Fertility Act, "[t]he term 'embryo laboratory' means a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation."[146] Since uterine implantation of the post-fusion ovum is a necessary step in replicative cloning, this procedure qualifies as an "embryo laboratory."[147]

In addition, section 8 provides that "[t]he term 'assisted reproductive technology' means all treatments which include the handling of human oocytes or embryos, including *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer and such other specific technologies as the Secretary may include in this definition . . . ."[148] Since both replicative and therapeutic cloning necessarily involve the handling of human oocytes, both procedures qualify for regulation under the Fertility Act as "assisted reproductive technology" programs.[149]

The Fertility Act requires clinics performing *in vitro* fertilization, a necessary step in replicative cloning, to provide annual reports to DHHS

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144 *See* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, § 8 (1992) (codified as amended at 42 U.S.C. § 263a-7(1) (1994)).

145 *Id*. at § 1 (codified as amended at 42 U.S.C. §§ 263a-7(1), (2) (1994)).

146 *Id*. at § 8 (codified as amended at 42 U.S.C. § 263a-7(2) (1994)).

147 *See* section II.B.1., *supra*.

148 *See* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, § 8 (1992) (codified as amended at 42 U.S.C. § 263a-7(1) (1994)).

149 *See* section II.B.1., *supra*.

regarding pregnancy success rates.[150] Moreover, DHHS has been directed to establish a model embryo laboratory certification program to assist states in ensuring the quality of fertility services.[151] The outcome of this directive is uncertain.[152] While these requirements are woefully inadequate to address the myriad of issues associated with human cloning, this legislation does demonstrate the DHHS's suitable position to provide any additional necessary regulation.

Unfortunately, the Fertility Act's poor record in monitoring traditional *in vitro* fertilization casts doubt upon whether or not the Fertility Act could provide sufficient supervision of human cloning.[153] A New York State task force on life and law reported, as of 1998, assisted reproductive techniques remained inadequately supervised, with considerable variability in the quality of practice and in compliance with existing standards.[154] For example, while the Fertility Act was signed in 1992, the first report on success rates was not published until December of 1997.[155]

2. Food and Drug Administration

The FDA has also demonstrated its intention to regulate replicative cloning. In a letter directed to the institutional review boards of medical research facilities, the FDA stated on October 26, 1998 that it "has jurisdiction over clinical research using cloning technology to create a human being" under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act.[156] Moreover, this letter provides that "the appropriate mechanism to pursue a clinical investigation using cloning technology is the submission of an investigational new drug application ("IND") to the FDA" as set forth in Title 21 of the Code of Federal Regulations, Part 312.[157]

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150 Fertility Clinic Success Rate and Certification Act of 1992, Publ. L. No. 102-493, § 2 (1992) (codified as amended at 42 U.S.C. § 263a-1(a)(1) (1994)).

151 *See id.* at §§ 3-7 (codified as amended at 42 U.S.C. § 263a-2 – a-6 (1994)).

152 No follow-up study could be found.

153 *See ART into Science: Regulation of Fertility Techniques; Assisted Reproductive Technology*, 281 Sci. 651 (July 31, 1998).

154 *See id.*

155 *See id.*

156 Letter from Stuart L. Nightingale, M.D., Associate Commissioner, Food and Drug Administration, to Institutional Review Boards 1 (October 26, 1998) <http://www.fda.gov/oc/ohrt/irbs/irbletr.html>.

157 *Id*.

According to the FDA, attempts at replicative cloning will be regulated through the same safety and efficacy requirements placed on pharmaceuticals.

B. *Additional Safeguards Are Needed*

Regulation through both the DHHS and FDA, if actually enforced, could adequately address the medical and scientific issues behind human cloning. FDA regulations could supervise the safety of the particular cloning procedures employed, while the DHHS could supervise the manner of cloning procedure employment. However, considering the revolutionary nature of human cloning, additional laws are almost certainly necessary, as discussed below:

1. Who Can Perform Cloning?

The first issue to be determined is who can legally perform human cloning. A recommendation that both human replicative and therapeutic cloning be defined as medical procedures would limit their performance to physicians and those under their direct supervision. A characterization of a "medical procedure" ensures that human cloning is practiced both safely and effectively. This step would set a well defined quality standard for would-be cloners. It also provides additional mechanisms for regulation through specific state medical boards as well as medical malpractice law, since both routes provide the means to sanction those physicians who would engage in human cloning ill-advisedly or incompetently.

2. Protection of a Replicative Clone

A second issue to be resolved involves the legal protections afforded to replicative clones to ensure their healthy embryonic and childhood development. These issues encompass what cloning procedures may be employed, who can donate their DNA, ova, and uterus (as a surrogate mother), and who will be permitted to raise the child.

Considering the difficulties associated with current cloning techniques, deciding which human cloning procedures may and may not be performed is of obvious importance. In addition to regulation through state medical boards, medical malpractice law, and the more cumbersome

legislative determination, protection of human clones may even be sought through application of the "wrongful birth" doctrine.[158]

Meanwhile, the determination of who can donate their DNA, ova, and uterus in replicative cloning is even more controversial. On one hand, a requirement that these donors be healthy benefits the replicative clone by ensuring that he/she is given healthy DNA, healthy cellular organelles, and a safe uterine environment. On the other hand, any such requirement raises the risk of being labeled as eugenics.

Moreover, supervision of who will be permitted to raise the replicative clone is necessary to ensure the healthy post-natal development of the child. At the very least, potential parents should undergo psychological screening to ensure their understanding of the limitations of the procedure and to ensure the potential parents have no illusions about its inability to resurrect the deceased.

3. Rights of Donors

Next, a body of law must be developed to protect the donors involved in human cloning. Some recommendations include assurances of privacy, as well as a requirement that a person's DNA, ova, or uterus may not be used without explicit permission. The law needs to clarify the relative rights of the various donors concerning the replicative clone or to the therapeutically cloned tissues.

In *Moore v. Regents of University of California*,[159] the California Supreme Court held, on the issue of conversion, that a patient does not retain an ownership to excised cells when (1) the excised cells have a similar structure in every human being and (2) the excised cells have been adapted and grown in human tissues and in culture.[160] However, this holding may not be applicable to cells used in therapeutic cloning. First, the *Moore* court stressed that the cells in that case were used to make lymphokines, which are identical in every human and not particular to the plaintiff.[161] Second, the *Moore* court also admittedly feared the effect that granting ownership would

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158 For a recent critique of wrongful birth claims in the non-cloning setting, *see* Mark Strasser, *Misconceptions and Wrongful Births: A Call for a Principled Jurisprudence*, 31 Ariz. St. L.J. 161 (1999).

159 51 Cal. 3d 120, 15 U.S.P.Q.2d 1753 (Cal. 1990).

160 *See id.* at 139, 15 U.S.P.Q.2d at 1762.

161 *See id.*

have on future medical research, which the court viewed as deserving protection.[162]

In therapeutic cloning, however, a person's cells would be chosen because of his/her individual qualities, such as cell surface antigens (which affect rate of organ rejection) and tendency for disease.[163] Moreover, the cells used in therapeutic cloning would presumably not be used in research at all, but simply for therapy. While the *Moore* court also relied on other factors, such as their preference for a legislative resolution and their belief that patients' rights are adequately protected outside of the tort of conversion, the above described disparities demonstrate that the argument against ownership rights is less convincing in therapeutic cloning.[164]

4. Criminal Law

Finally, criminal law should be updated to address transgressions in the field of human cloning. This step is particularly necessary for deterrence purposes, since human cloning cannot be reversed, and is of the utmost importance in the case of replicative cloning, where the result (a child) has rights that cannot be ignored. For example, stiff penalties should be enacted against those who clone a person without the genetic donor's permission.

VI. CONCLUSION

Human cloning technology satisfies the requirements of patentability under the Patent Act. As a result, human cloning technology should be afforded the right to obtain a patent by the PTO. The PTO should not attempt to regulate the safety or the procedures employed through the grant or rejection of a patent.

Although human cloning technology cannot be regulated under the Patent Act, the gravity inherent in the creation of human life and human organs requires significant regulation and supervision. Given the premature and uncertain state of human cloning, regulation may require the effort of multiple agencies, on the federal and state level. State medical boards and medical malpractice law, the DDHS, and the FDA have the mandate and the resources in place to accommodate and regulate this revolutionary step in technology.

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162 *See id.* at 144-45, 15 U.S.P.Q.2d at 1765-66.

163 *See* section II.B.2.a., *supra*.

164 *See* 51 Cal. 3d 120, 142-143, 15 U.S.P.Q.2d 1753, 1764 (Cal. 1990).

However, human cloning is also certain to have novel and profound legal ramifications on many non-medical aspects of society. These include the uncertain rights of cloned individuals, genetic donors, and donors of ova, expansion of the wrongful birth doctrine, as well as the emergence of the new crime and possible tort of "genetic identity theft." These considerations will require legislators and experts in the areas of constitutional law, criminal law, family law, and tort law to re-examine and update their fields accordingly.