

Attack of the Clones... and the Issues of Clones

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Human cloning became a hotly debated topic after Advanced Cell Technology's (ACT) press release of November 25, 2001. ACT announced they had successfully cloned a human embryo—the first step in the process of human reproductive cloning, therapeutic cloning, and the creation of stem cells.¹ ACT's press release caused a worldwide uproar, peaking with President Bush and the Vatican denouncing all types of human cloning within 24 hours of ACT's announcement.²

A shocked and confused populace, finding themselves confronted with new ethical dilemmas, called for legislative reform. A number of foreign legislatures as well as the U.S. House of Representatives acted quickly through November and December in an attempt to outlaw human cloning and aspects of human cloning. The frenetic mood, however, has slowed and legislators, scientists and the general public are trying to analyze the situation to obtain a better understanding of human cloning as well as the related legal, moral and economic issues.

¹ Press Release, *Advanced Cell Technology Reports Publication of Results of Human Somatic Cell Nuclear Transfer and Parthenogenesis* (November 25, 2001), available at http://www.advancedcell.com/pr_11-25-2001.html (last visited April 15, 2002).

² Press Release, *U.S. cloning advance shocks world* (November 27, 2001), available at <http://www.cnn.com/2001/TECH/science/11/26/human.cloning.reax/> (last visited April 15, 2002).

Part I of this article is a hypothetical situation which examples some of the difficult situations which should be addressed by comprehensive human cloning legislation. Part II examines the processes of reproductive and therapeutic human cloning as well as their future markets. Part III discusses the current international and national legislation regulating human cloning. Part IV discusses the future of legislation in the United States as well as a number of factors which need to be considered in order that any legislation that is drafted is comprehensive.

PART I

John Smith Hypothetical Situation

The year is 2007. John Smith, a 67 year-old multimillionaire, has been given only two months to live after a kidney received from a transplant was rejected. John realized well before his operation that the rate of success for kidney transplants was low, and therefore had a back-up plan which could save his life—but in the process, would make him a fugitive.

Over the past year, John had been in covert contact with Dr. Alpha, one of the world leaders in therapeutic cloning—a practice outlawed in 2002 in the United States, but still legal (or at least not illegal) on Dr. Alpha's small Caribbean island. Through this procedure, Dr. Alpha can grow replacement organs for transplant which have close to a 100% success rate because the organs were grown from the recipient's own cells.

Dr. Alpha, an interesting case himself, was one of a growing breed of black market scientists born, raised and educated in the U.S., that left during the 'Brain Drain' which began in 2002 when a number of doctors and molecular biologists fled the U.S.

to other countries with less stringent regulations in the exceedingly lucrative field of therapeutic cloning.

Soon after John's failed U.S. transplant operation, he traveled secretly to Dr. Alpha's Caribbean island (because even conspiring to clone is punishable by ten years in prison and at least one million dollars in fines) where a cloned kidney produced from his own cells was successfully transplanted into his body. After six months of recuperation, John was given a clean bill of health and began his return trip home. Upon arrival in the U.S., John was held in customs for a standard 'cloning materials search' where airport security determined that John had recently received an illegal kidney transplant. John was then arrested for violating the Human Cloning Prohibition Act of 2002 which, among other things, outlawed the importation of cloned products into the U.S.

At trial, John was sentenced to one year in prison and a million dollar fine. John happily accepted his punishment (which was more lenient than the maximum sentence he could have received) because, as he told the reporters, "It's definitely better to be incarcerated than buried or cremated."

After his release, John lived to be 79 years old.

This hypothetical situation of fantastical procedures and black market scientists may sound farfetched, but it is not pure science fiction. Based on recent events such a scenario could happen in the near future. Because of the enormous implications, proposed legislation should address all the potential issues so as to give guidance prior to a judge finding himself attacked by the issues of clones.

PART II

What is Cloning?

Although a large portion of society and a great number of legislatures believes there is only one form of human cloning, the concept of cloning really encompasses three different processes. Each process uses machinery within a living cell to divide, differentiate and eventually produce groups of cells, tissues and organs. The cellular machinery required for a cell to divide and differentiate generally begins with the expression of proteins which are encoded in DNA within the nucleus of a cell. Nuclear DNA determines the sequence of the protein, but does not determine the timing, rate or amount of protein which is expressed in each cell. Each of these processes, can be used to produce an embryo, a fetus and eventually a living organism.

The first type of cloning is *Embryo cloning*, more commonly referred to as “twinning”.³ This process begins by activating an embryo to produce twins and is in essence a duplication of the natural process that produces “identical twins.” Embryo cloning begins with the removal of one or more cells from a fertilized embryo. The removed cells are later encouraged to develop into duplicate embryos. These cloned embryos contain an exact copy of the nuclear DNA as well as copies of the mitochondrial DNA from the original embryo.⁴

Therapeutic cloning is the process with the most foreseeable benefits to mankind. This process uses an unfertilized egg as a host for the nuclear DNA of the

³ This process has commonly been referred to as “twinning” because embryo cloning results in the creation of identical twins.

⁴ The mitochondria is a separate organelle found in every living cell. The mitochondria also contains DNA but generally replicates independently of the nuclear DNA. The mitochondrial DNA is transmitted via the egg’s cytoplasm and hence is not affected by fertilization.

organism being cloned. In essence, the nuclear DNA of the host egg is exchanged for the nuclear DNA of a donor. This process is commonly referred to as “nuclear transfer” or “nuclear replacement.” Therapeutic cloning differs from twinning in that the mitochondrial DNA of the unfertilized egg is retained in the developing clone; the donor’s mitochondrial DNA is not transferred. In therapeutic cloning, the cells produced are not “identical twins,” but have the same potential to develop into organs and tissues having the same outward characteristics, or phenotype, of the donor’s cells.

Therapeutic cloning produces tissue or an entire healthy organ for transplantation into the DNA donor. A therapeutic cloning market will compete with and surpass the current organ transplant market because the risk of rejection of therapeutically cloned organs is very low (likely as low as 0%). In addition, the need for immunosuppressant drugs is eliminated since rejection would be unlikely because a more reliable supply of transplantable, or cloned, organs is provided. Furthermore, therapeutic cloning has the potential to eliminate the long waiting lists which currently exist.

Reproductive cloning is the most controversial form of cloning. Much of the public views this technology as mankind meddling with the natural process of reproduction. In reproductive cloning, the cloned embryo produced by nuclear transfer is implanted into a womb. This implanted embryo could develop into a new human or other organism depending on the origin of the DNA transferred. Reproductive cloning has the potential of producing a “twin” of an existing person, albeit a younger “twin.” This “twin” would have genetically identical nuclear DNA, but would differ physically because of embryological factors including womb placement, nutrient uptake and treatment in the womb. A cloned “twin” could have a different phenotype and would be physically different from the DNA donor because they are not true identical twins. This was recently demonstrated by the birth of “Cc:” the kitten, the first born cloned cat that looks similar to, but not exactly like, her genetic mother.⁵ The differences continue in that the “twin” does not contain the donor’s mitochondrial DNA (approximately 5% of the total DNA in the cell).⁶

As of the date of this article, nobody has successfully completed the process of human therapeutic or reproductive cloning, although Dr. Severino Antinori has indicated that a woman taking part in his human cloning program has been pregnant

⁵ David Braun, *Scientists Successfully Clone Cat*, National Geographic News (February 14, 2002), available at http://news.nationalgeographic.com/news/2002/02/0214_021402copycat.html.

⁶ Additional differences may occur in clones that do not have identical mitochondria including differences in parts of the body that have high demands for energy—such as muscle, heart, eye, and brain—or in body systems that use mitochondrial control over cell death to determine cell numbers.

since February of 2002.⁷ Therefore, it is possible the first human clone could be born as early as October 2002.

Until then, ACT's successful nuclear replacement represents the state-of-the-art. Their accomplishment makes it clear that human therapeutic and reproductive clones will be produced in the near future.

Because human embryos can theoretically be grown to become a new person, some view therapeutic cloning as reprehensible a practice as reproductive cloning.⁸ Although therapeutic cloning shares a number of common elements with reproductive cloning, a vast potential therapeutic cloning market exists because of the potential to treat and cure existing medical problems. Therefore, it is important that society and legislatures should not combine therapeutic cloning and reproductive cloning together as one market because both types of cloning encompass two very different markets.

The Market for Therapeutic Cloning

The potential market for therapeutic cloning is enormous. In 2000, there were 22,953 organs transplanted in the United States; this included 13,372 kidneys, 4,954 livers, 435 pancreases, 911 combination kidney-pancreases, 2,198 hearts, 956 lungs, 48

⁷ Dhabi, Abu and Daniel, Kavitha, *Human cloning project claims progress*, Gulf News, Online Edition (April 3, 2002), available at <http://www.gulf-news.com/Articles/news.asp?ArticleID=46275> (last visited April 15, 2002).

⁸ The produced cloned embryo from both therapeutic cloning and reproductive cloning processes could theoretically be implanted into a womb and develop into a human clone. Because of this, some view therapeutic cloning as controversial as reproductive cloning, even though therapeutic cloning itself does not utilize implantation.

heart and lungs, and 79 intestinal transplants.⁹ Considering that the average cost for an organ transplant is \$214,860¹⁰ and that almost 80,000¹¹ patients were hoping for an organ transplant in 2001, it is apparent that a market of just over \$17 billion dollars exists in the U.S. alone.

The technological advances in the therapeutic cloning market overcome the current problems associated with the existing organ donor market including long waiting lists, uncertainty as to the availability of organs and unpredictability of when the operation will occur. For example, in 1999 there were 3,536 registrants for heart transplants with a median waiting time of 206 days.¹² However, only 2,162 of those registrants received heart transplants in 1999.¹³ More troubling numbers can be seen in kidney transplants for 1997 where 19,022 individuals waited an average of 1,099 days and only 11,536 of those on the waiting list actually received organs.¹⁴ With therapeutic

⁹ See U.N.O.S. Critical Data, U.S. Facts About Transplantation, Table: Number of Transplants Performed in 2000, *available at* http://www.unos.org/frame_Default.asp?Category=Newsdata (last visited May 1, 2002).

¹⁰ New York State Conference of Blue Cross and Blue Shield Plans, values of U.S. average billed charges per transplantation as of July 1, 1999: Calculated by rounding down to the nearest ten the average of the average cost of five transplant operations (heart transplant (\$303,400), kidney transplant (\$111,400), liver transplant (\$244,600), pancreas transplant (\$113,700) and heart/lung transplant (\$301,200)), *available at* <http://acme.webway.com/filecatalogo/1163/ACF1AF3.pdf>.

¹¹ 79,368 patients were waiting for organs. U.N.O.S. Critical Data, U.S. Facts About Transplantation, Table: On April 12, 2002 The UNOS national patient waiting list for organ transplant included the following, *available at* http://www.unos.org/frame_Default.asp?Category=Newsdata (last visited April 30, 2002).

¹² *1999 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network: Transplant Data 1989-1998*. (February 21, 2000), *available at* http://www.unos.org/Data/anrpt_main.htm (last visited December 15, 2001).

¹³ *Id.*

¹⁴ *Id.* Numbers not available for 1998 and 1999 related to kidney transplantation.

cloning, these waiting lists¹⁵ would be limited to the time necessary to grow the organ.¹⁶ This would assure that everyone who needs a transplant could receive one.

Therapeutic cloning is not science fiction. In January of 2002, ACT scientists reported the successful use of cells derived from cloned cow embryos to grow kidney-like organs.¹⁷ These therapeutically cloned organs were not rejected when implanted into cows. Further, these organs functioned by removing toxins and producing urine.¹⁸ This is the first reported successful use of therapeutic cloning technology to grow a specific, transplantable organs. This shows that therapeutic cloning is a viable technology and therefore will produce a viable market.

PART III

Current Legislation on Cloning

A quick summary of the world's laws on human cloning is virtually impossible, especially with the newly revived activity of many international legislatures. The patchwork of legislation worldwide is difficult to untangle and is not uniform. General observations can be made about the current world legislative landscape:

- (1) A trend is developing to outlaw only reproductive cloning while still allowing therapeutic cloning with varying degrees of oversight,

¹⁵ *Id.* Additionally, the median waiting time in days ranged from 439 for livers and 267 for pancreases in 1997. With therapeutic cloning, organs could even be grown well in advance of their actual need (reproductive as well as therapeutic).

¹⁶ With therapeutic cloning, organs could even be grown well in advance of their need.

¹⁷ Rick Weiss, *Scientists Claim an Advance in Therapeutic Cloning*, Washington Post, Page A04 (January 30, 2002), available at <http://www.washingtonpost.com/ac2/wp-dyn/A58739-2002Jan29?language=printer>.

¹⁸ *Id.*

- (2) Very few countries have laws specifically addressing human cloning or aspects of human cloning. Therefore, human cloning is legal in the almost 180 countries worldwide which are silent on the matter, and
- (3) No country has yet come forward and taken the position that human cloning for all purposes is legal.¹⁹

¹⁹ Reproductive as well as therapeutic cloning.

The Western Hemisphere

The American Convention on Human Rights of 1969 is a regulatory provision which developed an Inter-American human rights system.²⁰ Twenty-six countries have ratified this Convention.²¹ Although the Convention does not expressly discuss human cloning, it may inadvertently regulate human cloning in the Americas. The Convention states that “every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception.”²² Arguably, a cloned human embryo could fall within this Convention because it protects life “from the moment of conception” (implying at embryo formation).²³ A more modern view would be that conception would not encompass the term “cloning”, or at least therapeutic cloning, because conception involves a pregnancy.²⁴ Therefore, there is no conception. This Convention then does not appear to regulate or ban all human cloning.

²⁰ See *generally*, American Convention on Human Rights, Pt. 1, Ch. I, Art. 1 and Ch. VIII, Sec. 1.

²¹ Countries which have ratified the American Convention in Human Rights include Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica (Commonwealth), Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Trinidad and Tobago, United States of America, Uruguay and Venezuela.

²² See Pt. 1, Ch. II, Art. 4, Sec. 1, Note 20, *supra*.

²³ *Id.*

²⁴ See, Note 108, *infra*.

The only countries in the Western Hemisphere which explicitly ban or have attempted to ban human cloning are Argentina,²⁵ Brazil,²⁶ Peru,²⁷ Trinidad and Tobago,²⁸ and Bolivia. Cloning is implicitly banned in Mexico,²⁹ Ecuador³⁰, Bolivia³¹ and Costa Rica.³²

In March of 2002, Canada issued guidelines for stem cell research which in essence banned both reproductive and therapeutic cloning, although allowing government funded research on supernumerary embryos.³³ Although these guidelines provide researchers with government funding more freedom in Canada than in the U.S., it places greater restrictions on private research than is currently in place in the U.S.

²⁵ Presidential Decree No. 200/97, Prohibition on Human Cloning Research, Article 1 (July 1997), *available at* <http://infoleg.mecon.gov.ar/txtnorma/42213.htm>.

²⁶ Biosafety Law, Art. 8 and Art. 13, II, Sec. 3, Law No. 8974 (May 1995). (Prohibits production, storage and manipulation of human embryos), *available at* http://www.mct.gov.br/legis/leis/8974_95.htm.

²⁷ General Health Law, Art. 7, Law No. 26842 (1997), *available at* ftp://ftp.minsa.gob.pe/intranet/leyes/L-26842_IGS.doc; Children and Adolescence Code, Article I, Law No. 27337, *available at* <http://www.promudeh.gob.pe/Gpna/Ley27337.html>. (Protects children from the time of conception).

²⁸ *Trinidad and Tobago Gazette*, Vol. 38, No. 18, Legal Supplement Part C (1999). (“An act respecting human reproductive technologies and commercial transactions relating to human reproduction”), *available at* <http://www.ttparliament.org/bills/senate/1999/b1999s04p.pdf>.

²⁹ General Health Law, Art. 330 (1997). (Bans the use of embryonic or fetal tissue from induced abortions for any purposes), *available at* <http://info4.juridicas.unam.mx/ijure/fed/140/343.htm?s=>.

³⁰ ECUADOR CONSTITUTION, Art. 49, Par. 1 (1998). (Indicates that the right to life begins at the moment of conception), *available at* <http://www.georgetown.edu/pdba/Constitutions/Ecuador/ecuador98.html>.

³¹ Law of Boys, Girls and Adolescents, Arts. 1 and 5, Law No. 2026 (October 27, 1999). (Protect adolescents from conception), *available at* <http://www.cajpe.org.pe/RIJ/bases/legisla/bolivia/2026.HTM>.

³² Children’s and Adolescent’s Code, Art. 12, Law No. 7739 (1998). (Recognizes the right to life from the moment of conception), *available at* http://www.cinterfor.org.uy/public/spanish/region/ampro/cinterfor/temas/youth/legisl/c_rica/ii/ii/index.htm.

³³ *Canada Bans Human Embryo Cloning*, Associated Press (March 4, 2002), *available at* <http://www.washingtonpost.com/wp-dyn/articles/A37086-2002Mar4.html>.

Europe

Europe appears to have few supporters of human cloning. Research on human embryos in Europe is either expressly or implicitly prohibited in many countries. A few countries permit human cloning with varying degrees of supervision. Efforts at a uniform European law failed in late November 2001 as the European parliament rejected a move to ban human cloning in Europe.³⁴ If the ban had been approved it would still have been up to each individual state to ratify the uniform law.³⁵

The trend in Europe appears to lean towards banning aspects of human cloning. The Czech Republic, Denmark, Georgia, Greece, Hungary, Portugal, Romania, San Marino, Spain, Slovakia and Slovenia have all ratified the Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings of 1998.³⁶ This protocol outlaws reproductive cloning.³⁷ This protocol has been

³⁴ *Europe rejects human cloning ban*, BBC News (November 29, 2001), *available at* http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1682000/1682591.stm.

³⁵ *See id.*

³⁶ Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, ETS No. 168 (1998), *available at* <http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm>.

³⁷ *Id.* at Art. 1, Sec. 1. (“Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited”).

signed by thirty of the forty-three European states³⁸ although is not effective law until ratified by each signatory state.³⁹

In addition, the majority of European countries have explicitly banned research on human embryos (which, for all intents and purposes, outlaws human cloning) including France,⁴⁰ Germany,⁴¹ Austria,⁴² Hungary,⁴³ Poland,⁴⁴ Norway,⁴⁵ Switzerland,⁴⁶

³⁸ Signatory states include Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Moldova, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the former Yugoslav Republic of Macedonia. For updates of signatories, see <http://conventions.coe.int/Treaty/EN/news.htm> (last visited April 30, 2002).

³⁹ ETS No. 168 at Art. 4. ("This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval"). See Note 36, *supra*.

⁴⁰ Art. L 152-3, Law No. 94-654 (1994), available at <http://www.chu-rouen.fr/uchpg/LOI5.html>. France is also seeking to pass a bioethics bill to outlaw human cloning.

⁴¹ Embryo Protection Law (Dec. 13, 1990), Bundesgesetzblatt, Pt. I, 19 Dec. 1990, pp. 2746-2748. (Criminalizes a variety of acts in reproductive and genetic technologies), available at <http://www.bmgesundheit.de/rechts/genfpm/embryo/embryo.htm>.

⁴² Reproductive Medicine Law, Serial No. 275 (1992) (Regulating Medically Assisted Procreation); The Marriage Law, and the Rules of Jurisdiction, General Civil Code, 44 (2) *IDHL* 247 (1993).

⁴³ Public Education Act LXXIX, *Magyar Közlöny*, No. 2000/65, p. 3978 (1993).

⁴⁴ Act Concerning Family Planning, Protection of the Human Fetus and Conditions of Permissibility of Abortion (1993) (amended 1996).

⁴⁵ Medical Use of Biotechnology, Act No. 56 of 5 August 1994 ("The Act relating to the application of biotechnology in medicine").

⁴⁶ SWITZ. CONST. Art.119, §(2)(c) (amended 1999) (Prohibiting the use of medically assisted reproduction for research purposes as well as for the fertilization of more ova than are capable of being immediately implanted).

Ireland⁴⁷ and Italy.⁴⁸ Denmark⁴⁹ and Greece⁵⁰ have enacted legislation outlawing human cloning either explicitly or implicitly. Cloning of human beings is also illegal in Spain,⁵¹ although in June of 1999, the Spanish Committee of Experts on Cloning indicated it would be beneficial to lift the existing ban on cloning for some therapeutic procedures.⁵²

European countries which have approved various aspects of human cloning include the United Kingdom, which has legalized therapeutic cloning, as well as

⁴⁷ IR. CONST. art. 40, §3 (amended 1983) (Implying that research on the embryos are prohibited by equating the right to life of the “unborn child” to that of the mother).

⁴⁸ For a discussion of Italian law, *see generally* <http://www.cnn.com/2001/WORLD/europe/08/07/clone.legislation/>. (“Italian law forbids “all form of experimentation or intervention whose objective, even indirectly, is the cloning of humans or animals.””)

⁴⁹ Medically Assisted Procreation, Art. 25, Act No. 460 (1997). (Implicitly prohibiting the creation of human clones, chimeras and hybrids and prohibits the reimplantation of genetically modified embryos as well as embryos that might have been harmed by research activities). *See also Cloning - Statement from the Danish Council of Ethics* (2001), *available at* http://www.etiskraad.dk/publikationer/Kloning_UK/app1.htm.

⁵⁰ The General Council of Health issued a statement in 1988 implicitly prohibiting the practice of cloning. *See Embryos, scientific research and European legislation*, European Parliament Directorate General for Research – Directorate A, Briefing Note No. 14/2001 (May 2001), *available at* http://www.europarl.eu.int/stoa/publi/pdf/briefings/14_en.pdf.

⁵¹ Law No. 35 of 22 (November 1988). (On techniques of assisted reproduction). *See generally* <http://www.pcb.ub.es/inauguration/OBiDangl.html>.

⁵² *Id.* The Spanish Committee of Experts on Cloning published a report in June 1999 supporting legislation to lift the existing ban on cloning in order to allow the creation of tissue to cure certain diseases. However, the report continued to support outlawing legalization of the reproductive cloning of human beings.

Sweden⁵³ and Finland⁵⁴ which allow the use of supernumerary embryos⁵⁵ for research purposes, with a few prohibitions⁵⁶ on research. A bill is being prepared in the Netherlands tracking the laws of Sweden and Finland.⁵⁷

The United Kingdom appears to be the most open to therapeutic cloning. The U.K. allows the creation of embryos for research purposes under the 1990 Human Fertilisation and Embryology Act with approval of the Human Fertilisation and Embryology Authority (HFEA).⁵⁸ This organization controls the use and creation of human embryos in the U.K. On January 22, 2001, the House of Lords passed a law previously approved by the House of Commons, which, among other things, made it legal to create embryos for stem cell research by nuclear replacement.⁵⁹ This law was challenged in court by the Pro-Life Alliance prompting the HFEA not to grant any

⁵³ Concerning Measures for the Purposes of Research or Treatment in Connection with Fertilized Human Oocytes, Law No. 115, Sec. 2 (1991). (“The purpose of experimentation shall not be to develop methods aimed at causing heritable genetic effects”).

⁵⁴ Medical Research Act, Law No. 488 (1999). (Explicitly prohibiting research which modifies the germ line, but makes an exception for research done for the purposes of curing or preventing serious hereditary disease), *available at* <http://www.finlex.net>. *See also* Statement of Embryo and Stem Cell Research in Finland, Forum of Embryo and Stem Cell Researchers (November 2, 2001), *available at* <http://life2000.helsinki.fi/english/results/statement021101.PDF>.

⁵⁵ *See id.*, Medical Research Act, Sec. 15, Law No. 488 (1999). (Embryos donated by persons following treatment against sterility and not intended for implantation).

⁵⁶ *Id.* at Sec. 14. Research cannot continue after the 14th day of existence of the embryo and consent must be granted by the couple supplying the embryo.

⁵⁷ Embryo Bill (2000). (Bill containing rules relating to the use of gametes and embryos), *available at* <http://www.minvws.nl/document.html?folder=393&page=16897>.

⁵⁸ Human Fertilisation and Embryology Act, Sec. 3 (1990), *available at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv3.

⁵⁹ Human Fertilisation and Embryology (Research Purposes) Regulations (2001). (“Explanatory Notes Referring to the Human Reproductive Cloning Bill as brought from the House of Lords on 26th November 2001 [Bill 57]”), *available at* <http://www.parliament.the-stationery-office.co.uk/pa/cm200102/cmbills/057/en/02057x-.htm>.

licenses for research involving nuclear replacement until judicial review of the Pro-Life Alliance's application.⁶⁰ In November 2001, a High Court judge ruled in favor of the Pro-Life Alliance indicating that embryos not created by fertilization (union of sperm and egg) were not covered by the 1990 Act or any additions to it.⁶¹ This judgment, contrary to the intent of the Pro-Life alliance, left human cloning unregulated in the U.K.⁶² The U.K. government was granted permission to challenge this ruling in January of 2002 and has, in the interim, approved emergency legislation on November 23, 2001 to explicitly ban human reproductive cloning.⁶³ This legislation has met with disapproval by opponents who point out that the current law, as worded, would allow human clones to be born by other methods (such as through embryos being placed in animals). Further, a House of Lords Select Committee reviewed the issues surrounding human cloning and stem cell research and in February of 2002 ruled that embryo cloning should be allowed to proceed in the U.K.⁶⁴ Therefore, although the U.K. appears to be more open to at least therapeutic cloning, their laws are still in flux.

⁶⁰ *R v. Secretary of State for Health, ex parte Bruno Quintavalle* (on behalf of Pro-Life Alliance) (Fam. 2001).

⁶¹ Justice Crane on November 15, 2001 held that human embryos created by cell nuclear replacement do not constitute embryos as defined under the U.K. Human Fertilisation and Embryology Act (1990).

⁶² Roger Moorgate, *Human Cloning Legal in United Kingdom*, The Reproductive Cloning Network, available at <http://www.reproductivecloning.net/hosting/news/news7.html> (last visited January 24, 2002). (The British Medical Association says it is extremely concerned by the court's judgement: "Ironically, this 'victory' for the Pro-Life Alliance means that there currently exists no legal prohibition to human cloning... It is extremely important to remember that it was the clear intention of Parliament that research using (cloned) embryos should be permitted with the strict controls set out in the HFE Act of 1990.... This was because embryonic stem cell research offers huge potential to patients suffering very debilitating diseases," the association said).

⁶³ *New round in UK human clone battle*, CNN.com (January 18, 2002), available at <http://www.cnn.com/2002/WORLD/europe/01/18/uk.clone/index.html>.

⁶⁴ *UK backs human embryo cloning*, CNN.com (February 27, 2002), available at <http://www.cnn.com/2002/WORLD/europe/02/27/cloning/index.html>.

The Non-Western World

Legislation in the Eastern Hemisphere differs from the patchwork of Europe in that there is not much legislation dealing with human cloning. Existing legislation tends to be more lenient than laws in Europe by allowing therapeutic cloning while outlawing reproductive cloning. In December of 2001, China announced its official support for therapeutic cloning while declaring its opposition to reproductive cloning. Japan⁶⁵, Australia⁶⁶ and India⁶⁷ allow varying degrees of use of stem cells for therapeutic cloning but have banned all aspects of reproductive cloning. Korea does not have any law addressing cloning, although in 1999 the National Assembly discussed revising the Biotechnology Promotion Act to add regulations concerning bioethics and biosafety.⁶⁸ New Zealand is currently attempting to ban all cloning for two years, although their law would allow a minister to authorize exemptions.

Other countries addressing human cloning include Russia and Israel. On December 20, 2001, the Russian Duma (lower house of parliament) voted to place a five

⁶⁵ The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques (2000). (Japan adopted a law prohibiting reproductive cloning and prescribing the adoption of guidelines to allow the use of stem cells derived from supernumerary embryos and therapeutic cloning), *available at* <http://www.biol.tsukuba.ac.jp/~macer/eclone.pdf>.

⁶⁶ Australia, in early 2002, changed from allowing their states to decide on how to legislate cloning (which resulted in cloning being banned in three of the six Australian states), to uniform national legislation banning reproductive human cloning, while still allowing stem cell research and therapeutic cloning. *See* Communique of the Council of Australian Governments' meeting, 11th, Canberra (April 5, 2002), *available at* <http://search.aph.gov.au/search/>.

⁶⁷ India also has banned reproductive cloning but allows therapeutic cloning in limited circumstances. *See* Guidance for International Collaboration for Research in Biomedical Sciences, Pharmacology 1999; 31: 383-384 (reprint of ICMR Bulletin, Vol. 29, Pages 73-74), *available at* <http://www.ijp-online.com/archives/1999/031/05/r0383-0384fi.pdf>.

⁶⁸ Yang Sung-jin, *Cloning of human embryos to be strictly banned: draft*, The Korea Herald (May 19, 2001). (In May 2001, the Korean government indicated that it is drafting a law which would strictly ban artificial cloning of human embryos as well as research on embryos in principle), *available at* http://www.koreaherald.co.kr/SITE/data/html_dir/2001/05/19/200105190024.asp.

year ban on human cloning. If approved at a third reading, this ban will apply to human cloning as well as to the import or export of cloned human embryos. In 1998, Israel passed a law to ban human cloning for five years, but allows therapeutic cloning if a showing can be made to an advisory committee that the research does not violate the ban.⁶⁹ In 2003, the Israeli parliament will decide whether to renew this ban.⁷⁰

The United Nations (“UN”) on February 25, 2002 began an initial round of talks concerning an international treaty to ban the cloning of human beings.⁷¹ Quick action from the UN however is not likely as the treaty drafting process typically takes years because all 189 member-nations are free to participate in the deliberations.⁷²

This review of international law provides support for the Hypothetical Situation of Part I, because regardless of U.S. action, cloning will be legal in other countries. Therefore, if the U.S. would ban all aspects of human cloning, this situation could easily arise.

⁶⁹ Human Beings and Genetic Modifications for Reproductive Cells, Law No. 5759 (1998). *See generally* Report of the Bioethics Advisory Committee of The Israel Academy of Sciences and Humanities on the Use of Embryonic Stem Cells for Therapeutic Research (August 2001), *available at*: <http://www.academy.ac.il/bioethics.html>.

⁷⁰ *See generally* Report of the Bioethics Advisory Committee of The Israel Academy of Sciences and Humanities on the Use of Embryonic Stem Cells for Therapeutic Research, Note 69, *supra*.

⁷¹ Irwin Arieff, *UN Panel Begins Drafting Global Ban on Cloning*, Reuters (February 26, 2002), *available at* http://story.news.yahoo.com/news?tmpl=story&cid=594&u=/nm/20020226/hl_nm/clone_2.

⁷² *Id.*

The United States

In the U.S., federal financing of human cloning activities is prohibited via President Bush's 2001 order.⁷³ Authorization to conduct research on human embryos has been left to the discretion of the states themselves, subject to the approval of the U.S. Food and Drug Administration⁷⁴ (FDA) (although the FDA's self-assertion of jurisdiction over an entire human being would likely be held in question).⁷⁵ Like the rest of the world, most states do not have legislation addressing human cloning and provide no control over private research. Only California,⁷⁶ Louisiana,⁷⁷ Rhode Island,⁷⁸ Virginia,⁷⁹ Missouri⁸⁰ and Michigan⁸¹ have laws addressing human cloning, with the

⁷³ Remarks by the President on Stem Cell Research, Office of the Press Secretary (August 9, 2001). (President Bush indicated that the federal government would only finance stem cell research from stem cells produced before August 9, 2001), *available at* <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

⁷⁴ The FDA indicated in 1998 that it had regulatory 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 (FFDCA). *See* Department of Health and Human Services Protection of Human Subjects, 45 C.F.R. §46 (2000), *available at* http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html.

⁷⁵ Because the FDA has asserted its jurisdiction, FDA approval is now required for products of human cloning until a court states that the FDA does not have jurisdiction. *See* 30 SETON HALL L.REV. 464 (2000); and Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?* 11 HARV. J.L & TECH. 619 (1998).

⁷⁶ CAL. BUS & PROF. CODE §2260.5, §16004, §16105: "Medical Practices Act" (1997), CAL. HEALTH AND SAFETY CODE, ANN. §24185, §24187, §24189 (1997).

⁷⁷ LA. REV'D STAT. ANN., Title 40, §§1299.36 through 1299.36.6 and Title 37, §1285(A)(31) (1999).

⁷⁸ R. IS. GEN. LAWS §§23-16.4-1 - 23-16.4-4 (Supp. 1998).

⁷⁹ VA. CODE ANN. §§32.1-162.21 - 32.1-162.22 (2001).

⁸⁰ MO. ANN. STAT., Title 1, Chapter 1, §1.217 (1998).

⁸¹ MICH. STAT. ANN., §§333.16274-333.16275, §333.20197, §§333.26401-333.26406, §750.430a (1999).

majority of these states allowing specific exceptions for scientific research as well as for cell-based therapies. Fines for violating these statutes in some states reach as high as \$10 million. Criminal sanctions exist only in Michigan, however, where human cloning is punishable by imprisonment for up to 10 years.

A number of other states have pending legislation addressing human cloning.⁸² Recently, the California Advisory Committee on Human Cloning (CACHC), a committee assembled to evaluate “medical, ethical and social implications, review public policy and advise the Legislature and the Governor in this Area”⁸³ released a report recommending that California modify its laws to allow therapeutic cloning, while continuing to ban reproductive cloning.⁸⁴ The CACHC also proposed legislation which if enacted would prohibit reproductive cloning while allowing therapeutic cloning.

The states’ autonomy in this field may soon end as the federal government has taken up the issue of human cloning. In July of 2001, the House of Representatives passed the Human Cloning Prohibition Act of 2001.⁸⁵ This Act bans all human cloning, making it punishable by up to 10 years in prison with a fine of at least \$1 million. The Senate is expected to debate and vote on a cloning bill in the spring of 2002. Already, Senator Sam Brownback has introduced Senate bill S.1899, which is very similar to H.R. 2505.⁸⁶ If enacted into law, S.1899 would ban therapeutic cloning, reproductive

⁸² New York, Massachusetts, Indiana, Illinois, Kentucky and Texas.

⁸³ Final Report of the California Advisory Committee on Human Cloning, pp. 17 and 38, *citing* Senate Concurrent Resolution 39.

⁸⁴ CACHC (2002).

⁸⁵ Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. 1st Sess. (2001).

⁸⁶ Human Cloning Prohibition Act of 2001, S.1899, 107th Cong. 2nd Sess. (2002).

cloning and the importation of products produced by such processes into the U.S. with penalties of up to ten years in jail and fines of at least \$1 million. Two bills which only outlaw reproductive cloning were introduced by Senator Tom Harkin as S.1893 and Senator Dianne Feinstein as S. 1758.⁸⁷ These bills prohibit reproductive cloning while allowing therapeutic cloning by outlawing the implantation of products of human cloning.⁸⁸ Both bills also penalize violators with fines of at least \$1 million and not more than 10 years in prison.⁸⁹

At this time, the Senate appears more open to allowing some aspects of human cloning; they did not approve a December 3, 2001 bid to place a six-month moratorium on human cloning in order to have more time to further discuss the issues involved. Support is growing in the U.S. for a ban on reproductive cloning while allowing therapeutic cloning. The National Academy of Sciences released a report in 2002⁹⁰ recommending banning reproductive cloning in the U.S. by legislation.⁹¹ The Council indicated that a ban criminalizing implanting a cloned embryo should be sufficient to stop reproductive cloning.⁹²

⁸⁷ Human Cloning Prohibition Act of 2001, S.1893, 107th Cong. 2nd Sess. (2002) and Human Cloning Prohibition Act of 2001, S. 1758, 107th Cong. 1st Sess. (2001).

⁸⁸ S.1893 at (c)(1); S. 1758 at 301(a)(1).

⁸⁹ S. 1893 at (b)(1)-(2); S. 1758 at (d)(2)-(3).

⁹⁰ SCIENTIFIC AND MEDICAL ASPECTS OF HUMAN REPRODUCTIVE CLONING, COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY, NATIONAL RESEARCH COUNCIL, National Academy Press (2002).

⁹¹ *Id.* at ES-1 (“The panel therefore unanimously supports the proposal that there should be a legally enforceable ban on the practice of human reproductive cloning”).

⁹² *Id.* at ES-11 (“But a legally enforceable ban that criminalizes the implantation step should be sufficient to prevent such proscribed activity”).

Although the exact language of the legislation is still uncertain, it appears that Congress will pass federal legislation on human cloning within the coming year. Federal legislation would most likely make legislation by the states unnecessary or will preempt state enacted legislation under the Supremacy Clause.⁹³ Any bill passed by Congress that does not completely ban human cloning likely will run into a Presidential veto as President Bush has announced his opposition to any type of human cloning.⁹⁴ A Presidential veto or congressional inaction would relegate the responsibility to enact comprehensive legislation to the states. However, the states are incapable of regulating international trade, patents and immigration issues.

In this current climate, Part I's hypothetical situation becomes rather probable. The House of Representatives has already passed a complete ban on human cloning. Although the Senate has not proposed a bill yet, it is clear there is heavy pressure from President Bush to completely ban all aspects of human cloning. If the Senate would approve a complete ban on human cloning, the John Smith hypothetical situation could easily occur.

PART IV

Factors to Consider for Future U.S. Legislation

⁹³ U.S. CONST., Art. VI, cl. 2 ("This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding").

⁹⁴ Alan Bjerga, *Abortion foes cheer Bush on cloning - Activists Add Human Cloning To Political Agenda*, San Jose Mercury News (Jan. 23, 2002). ("I urge the United States Senate to support a comprehensive and effective ban on human cloning"), available at 2002 WL 6718280.

The House-approved anti-cloning bill outlaws both therapeutic and reproductive cloning and makes it unlawful to perform or attempt to perform human cloning, participate in an attempt to perform human cloning or ship or receive the product of human cloning for any purpose.⁹⁵ This bill penalizes the performers and participants⁹⁶ in human cloning with fines of at least \$1 million (plus up to double any profits) and up to 10 years in prison. The bill also makes it illegal to receive or to attempt to receive an organ produced by therapeutic cloning.

The current proposed legislation does not consider (1) a separated analysis of the economic effects of therapeutic cloning and reproductive cloning on the United States (including loss of revenue and relocation of biotechnology companies, as well as medical and scientific professionals), (2) the inadequacy and unique nature of the House approved penalties, (3) the potential unconstitutionality of any legislation banning all forms of human cloning, (4) the uncertain impact U.S. and foreign patents could play and (5) the reversal of somatic cells to an embryological state for use in human cloning.⁹⁷ The Senate should also consider that cloning will be legal in some part of the world regardless of U.S. actions. Therefore a cloning industry will appear with or without U.S. participation. Therefore, the Senate needs to consider the possibility of approving and allowing aspects of human cloning in the U.S. in order to stay involved in worldwide regulation of this industry during its formative stage. If the

⁹⁵ H.R. 2505, Note 85, *supra*.

⁹⁶ As used, performers means those who actually perform the operation or produce a twin and participants are defined as the DNA donor and host.

⁹⁷ Although the reality of somatic cell reversal to an embryological state has been discounted, the future of technology is unpredictable. Therefore, legislation should address all potential violators to be fully comprehensive.

U.S. completely outlaws human cloning, it relinquishes any control over the future direction of this industry to other countries. Therefore, additional issues need to be examined in order to ensure that comprehensive human cloning legislation is passed.

Economic Impact on the U.S.

If the U.S. completely bans human cloning (therapeutic and reproductive), the U.S. would be at an economic disadvantage with respect to other countries. From the above discussion, it is apparent that a multi-billion-dollar per year market potentially exists for therapeutic cloning (transplants). A market of this size will develop regardless of U.S. involvement. Already, major world powers including China, Japan, Russia and the U.K. have indicated they will allow aspects of therapeutic cloning thereby keeping open the opportunity to capitalize on this fledgling market as well as collecting the taxable proceeds which accompany it. Major world powers with definitive, but less stringent legislation clearly provide more promising locations for a start-up industry than countries which continue to ban human cloning or which are uncertain about the future direction of legislation.

A complete U.S. ban on human cloning carries with it the danger of losing startup biotechnology companies and hindering large U.S.-based pharmaceutical conglomerates by restricting them from entering newly developed peripheral markets. This exodus will also include a "brain drain" as scientists and doctors involved in this industry leave the U.S. for less restrictive environments. The individuals leaving would include not only scientists who are directly involved in cloning, but also individuals in peripheral industries. These adjunct companies could incidentally find themselves in violation of the Human Cloning Prohibition Act through their day-to-day business and

subject to massive fines and prison time for simply conducting research or engaging in scientific activity. The attractiveness of other countries with more lenient laws could potentially harm the U.S. biotech market, currently the strongest in the world.

A total U.S. ban or even a moratorium on human cloning would result in the loss of start-up companies and the loss of pioneering inventions which could be patented elsewhere, thereby preempting this U.S. industry. These pioneering inventions need not fall in the areas of cloning. There are peripheral markets for discoveries relating to pharmaceuticals, treatments and biologics made during therapeutic and reproductive cloning which have implications outside human cloning. Although patents in the U.S. may not be enforceable if they involve outlawed technologies, it is still apparent that inventions outside the area of human cloning would be patentable. Former Commissioner of Patents and Trademarks Q. Todd Dickinson recently stated that human stem cells are patentable.⁹⁸ This peripheral market could be stunted by a U.S. ban on human cloning (or on the ability to work with human embryos).⁹⁹ Future patents on drug treatments or of human cloning techniques outside the U.S. would preempt pharmaceutical companies from using these technologies.

Currently, the number of companies leaving the U.S. for other locations is small and limited to relatively obscure companies such as Clonaid (a company founded by a

⁹⁸ Statement of Q. Todd Dickinson Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee (January 12, 1999). (“Accordingly, it is the present position of the Patent and Trademark Office that purified and isolated stem cell lines are patentable subject matter under 35 U.S.C. §101”), *available at* <http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf>.

⁹⁹ The human stem cell market is envisioned as a pharmaceutical market built on manipulative gene expression to reprogram one cell type to be converted into another cell type.

religious group called the Raelians).¹⁰⁰ However, with such a large potential worldwide market, it is probable that the numbers will increase over time in the event of a complete legislative ban on all forms of cloning in the U.S.

A New Class of Violators and Penalties that Are Not Deterrents

Anti-cloning laws, such as the House passed bill, could create unique fugitive classes in the United States. Initially, only researchers would be subject to criminal penalties under such an anti-cloning act. This is a new concept in the U.S. where researchers are not generally viewed as criminals in our society, especially when the U.S. prides itself on its researchers' ingenuity. The fines and penalties will be an effective deterrent because researchers have little incentive to violate such a statute, especially when it makes good economic sense to simply leave the U.S. or to redefine their career to avoid any contact with human embryos.

As shown in Part I's hypothetical situation, with the development of an international therapeutic cloning industry, a second round of criminals will develop – terminally ill individuals looking to increase their lifespan by finding organs for transplant. Because this would be a unique class of felons (those who want to extend their lives), penalties will need to be examined to see if they are in fact deterrents. It should be apparent that fines and prison sentences will not deter this second round of potential violators because when it comes to a choice between life (subject to a huge fine and potential jail time) or death, the punishment would be viewed simply as an

¹⁰⁰ After investigation by the FDA, Clonaid announced they would be relocating their reproductive cloning activities outside the U.S. See *'Raelian' biochemist insists she will clone human*, CNN.com, (June 30, 2001), available at <http://www.cnn.com/2001/HEALTH/06/30/clone.lab.txt/> (last visited January 24, 2002).

additional cost of the life-saving procedure. If legislation seeks to fine recipients of illegal transplants, it will only deter poor individuals who cannot afford the operations and the additional fines incurred.

A separate issue which should be addressed (if therapeutic cloning is banned) is how to treat foreign citizens who have had organs replaced using therapeutic cloning techniques where it is legal in their country. Under the House's bill, they would violate the proposed legislation while vacationing in the U.S.!

Finally, if only therapeutic cloning is allowed by statute, a potential international industry which may develop is recreational cloning. This industry would involve replacing organs grown through therapeutic cloning when the organs do not need to be replaced. Currently, transplants are only available in the U.S. once organs have failed or are close to failure. However, if therapeutic cloning were legalized, organs could be replaced at will. This could lead to a new industry similar to plastic surgery where individuals could replace their organs on demand (because it worked better two years ago) rather than only when necessary (at failure).

Constitutional Challenges

Despite Congress's best intentions, any bill drafted will certainly be a target for a challenge on Constitutional grounds. Any statute that bans human cloning appears to violate the Due Process Clauses of both the Fifth and Fourteenth Amendments which prohibit state and federal governments from depriving an individual's "life, liberty or

property without due process of law.”¹⁰¹ ¹⁰² The Supreme Court in *Skinner v. Oklahoma* indicated that one of the fundamental rights of man was the right to procreate.¹⁰³ In *Skinner*, the Court struck¹⁰⁴ down a sentence of sterilization for a chronic thief stating that procreation was “one of the basic civil rights of man ... fundamental to the very existence and survival of the race.”¹⁰⁵ The Court citing *Stanley v. Illinois*¹⁰⁶ stated that *Skinner* set forth a right to “conceive and to raise one’s children” which is a right “far more precious ... than property rights.”¹⁰⁷ Therefore, conception is more precious than even property rights. Further, the Court’s use of the term “conceive” does not exclude the implantation of cloned embryos.¹⁰⁸

The Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey* also recognized that procreation is included among the liberties protected by the Due Process clauses of the Fifth and Fourteenth Amendments.¹⁰⁹ In striking down a Pennsylvania abortion law, the Court stated that:

¹⁰¹ U.S. CONST. amend. V (“No person shall be...deprived of life, liberty, or property, without due process of law”).

¹⁰² U.S. CONST. amend. XIV, § 1 (“nor shall any state deprive any person of life, liberty, or property, without due process of law”).

¹⁰³ 316 U.S. 535 (1942).

¹⁰⁴ Although *Skinner* utilized and Equal Protection Clause argument, the fact that the Court found procreation to be a fundamental right applies equally to the Due Process Clause.

¹⁰⁵ 316 U.S. at 541.

¹⁰⁶ 405 U.S. 645 (1972).

¹⁰⁷ *Id.* at 651.

¹⁰⁸ Webster’s dictionary defines “conceive” as “to become pregnant.” See *Merriam-Webster OnLine: Collegiate Dictionary* (2000), available at <http://www.merriam-webster.com/dictionary.htm> (8 Oct. 2000) (last visited January 24, 2002).

¹⁰⁹ 505 U.S. 833 (1992).

Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education. . . . These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.¹¹⁰

Therefore, an individual's fundamental right to procreation is protected. This fundamental right also applies to unmarried persons as indicated by *Eisenstadt v. Baird* where the Court stated that "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹¹¹ Although these cases discussed coital relations, the Court's use of language such as "bear[ing] or beget[ting] a child" is broad enough to encompass other forms of procreation including human cloning.¹¹²

A constitutional challenge to a complete ban on human cloning appears valid in that an infertile individual may have the only opportunity to "bear" a child containing his/her own genetic material through the process of reproductive cloning. Therefore, reproductive human cloning most likely is included in, "the right of the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹¹³

¹¹⁰ *Id.* at 851.

¹¹¹ 405 U.S. 438, 453 (1972).

¹¹² Webster's dictionary defines "bear" (v.) as "to give birth". See *Merriam-Webster OnLine: Collegiate Dictionary* (2000), available at <http://www.merriam-webster.com/dictionary.htm> (8 Oct. 2000) (last visited January 24, 2002).

¹¹³ 405 U.S. at 453.

Any statute would appear to eviscerate this right and would likely result in a successful constitutional challenge. One prime candidate for a challenge (if enacted) would be a recently submitted bill into the Senate proposing to outlaw the use of somatic cell nuclear transfer to initiate human pregnancies.¹¹⁴ The plain language of this bill appears very close to intruding on the fundamental right of procreation.

A completely unexpected and counterintuitive result could also occur under the current House bill (which bans both therapeutic and reproductive cloning). If only the ban on reproductive cloning were found to be unconstitutional¹¹⁵, the worst of both worlds would exist because individuals would be free to practice reproductive cloning but would be prohibited from practicing therapeutic cloning.¹¹⁶

The Role of Patents in Human Cloning

The patentability of human cloning as well as the products of human cloning in the U.S. is similarly murky. There are no statutory or judicial restrictions against issuing patents claiming human clones. Several bills have been introduced addressing the issuance of patents on humans including the Transgenic Animal Patent Reform Act.¹¹⁷ The bill was approved by the House and would have prohibited the patenting of human

¹¹⁴ Human Cloning Prohibition Act, S.2076, 107th Cong. 2nd Sess. (2002).

¹¹⁵ Because therapeutic cloning may of itself not implicate these constitutional considerations.

¹¹⁶ It should also be noted that if reproductive cloning falls within constitutionally proscribed fundamental rights, then its protection likely only extends to those individuals who either bear or beget a child and thus would be available only to the mother of the child (bearer) as well as the DNA donor (begetter).

¹¹⁷ Transgenic Animal Patent Reform Act, H.R. 4970, 100th Cong. (1988).

beings.¹¹⁸ However, the Senate did not approve the bill and it never became law. In 1987, then Assistant Secretary and Commissioner of Patents and Trademarks Donald J. Quigg stated in a public letter that “the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution” while indicating that the Patent and Trademark Office (PTO) would consider non-human animals as patentable subject matter.¹¹⁹ This PTO ban on patents however may not actually be valid because case law suggests that human clones are indeed patentable.

A human clone is a man-made invention. The Supreme Court in their landmark decision *Diamond v. Chakrabarty*¹²⁰, held that the subject matter of patents “include[s] anything under the sun that is made by man.”¹²¹ The Supreme Court recently reiterated this broad interpretation of what is patentable in *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int’l., Inc.*, by stating, “As this Court held in *Chakrabarty*, ‘the relevant distinction’ for purposes of §101 is not ‘between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.’”¹²² Because a cloned human being is a human-made invention, they are patentable.

If Congress passes a law outlawing reproductive cloning or completely banning human cloning, then patents or patent applications claiming processes of cloning or products of human cloning could violate 35 U.S.C. § 101. Section 101, provides that

¹¹⁸ See 134 CONG. REC. H.R. 7436-02 (1988).

¹¹⁹ 1077 Off. Gaz. Pat. Office 24 (Apr. 21, 1987). See *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 923 (Fed. Cir. 1991).

¹²⁰ 447 U.S. 303 (1980).

¹²¹ *Id.* at 309.

¹²² ___ U.S. ___, 122 S.Ct. 593, 598 (2001) citing 447 U.S. at 313.

“whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” may obtain a patent on that invention or discovery. The Supreme Court in *Brenner v. Manson*¹²³ indicated that an invention lacks utility if that invention is “injurious to the morals, health, or good order of society, or frivolous and insignificant.”¹²⁴ The commonly cited examples of inventions injurious to the morals, health or good order of society are found in *In re Nelson*¹²⁵, where the United States Court of Customs and Patent Appeals stated that, “[A] new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.”¹²⁶ Human cloning does not fall within this standard because unlike the listed examples, it does not cause immediate physical harm. More recently, the Federal Circuit indicated in *Juicy Whip, Inc. v. Orange Bang, Inc.*, that “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.”¹²⁷ The Court held that although the patent at issue claimed an invention that could defraud customers, “we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the

¹²³ 383 U.S. 519 (1966).

¹²⁴ *Id.* at 533.

¹²⁵ 280 F.2d 172, 178 (C.C.P.A. 1960).

¹²⁶ *Id.* at 179.

¹²⁷ 185 F.3d 1364, 1367-68 (Fed. Cir. 1999).

capacity to fool some members of the public.”^{128, 129} The Court reasoned, “The requirement of “utility” in patent law is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices” and that “Other agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products.”¹³⁰ The court found support in *Webber v. Virginia* in that, “Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted.”¹³¹

The court also indicated that if the invention at issue was unlawful, then it would most likely lack utility under Section 101.¹³² Therefore, if all human cloning were outlawed by federal legislation, then any form of human cloning would lack the requisite utility of Section 101 and therefore would not be patentable. The Court of Appeals for the Federal Circuit however has stated the better way to limit the scope of patentable subject matter would be through explicit legislation such as 42 U.S.C. §

¹²⁸ 185 F.3d at 1368.

¹²⁹ For example, courts had invalidated patents on gambling devices on the ground that they were immoral. See, e.g., *Brewer v. Lichtenstein*, 278 F. 512 (7th Cir. 1922); *Schultze v. Holtz*, 82 F. 448 (N.D. Cal. 1897); *National Automatic Device Co. v. Lloyd*, 40 F. 89 (N.D. Ill. 1889). That is no longer the law. See *In re Murphy*, 200 U.S.P.Q. (BNA) 801 (PTO Bd. App. 1977).

¹³⁰ 185 F.3d at 1368.

¹³¹ *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880).

¹³² 185 F.3d at 1367-8 (“Orange Bang has not argued that it is unlawful to display a representation of the beverage in the manner that fluid is displayed in the reservoir of the invention” and did not reach this issue. Therefore, the court left this issue open).

2181(a).¹³³ However, until Congress outlaws human cloning or specifically removes human cloning from patentable subject matter (the more preferred route), it does appear patentable.

Also, although the Thirteenth Amendment prohibition on slavery would appear to be ban patents on human clones themselves, it may not preempt a patent claiming a clone as a product of cloning.¹³⁴ A patent does not grant ownership to the product claimed therein; rather, it grants to the patent owner the right to exclude others from making, using, offering to sell, selling or importing into the United States the product of that patent.¹³⁵ Therefore, arguably, because there is no ‘ownership right’ or grant of slavery, it appears that the Thirteenth Amendment would not be violated by a grant of a patent claiming a human clone.

If Congress bans human cloning or explicitly remove human cloning from patentable subject matter, then patent applications to those outlawed processes and products would be rejected.¹³⁶ Similarly, any issued patents claiming products or processes of human cloning would also be unenforceable in court. These rejections and bans to enforceability however would only apply to the outlawed human cloning and not to inventions related to discoveries made during the development of a cloning

¹³³ This section exempts inventions useful only in connection with special nuclear material or atomic weapons from patent protection.

¹³⁴ U.S. CONSTITUTION, amend. 13, Sec. 1 (“Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction”).

¹³⁵ 35 U.S.C. § 271(a).

¹³⁶ These inventions would be rejected for lacking utility under 35 U.S.C. § 101 or for specifically being removed from patentable subject matter.

industry (such as pharmaceuticals which control cell differentiation, etc.) unless they too were specifically outlawed.

Although Europe is one of the most active regions in the human cloning industry, an interesting situation will arise if the U.S. bans all forms of human cloning. The European Patent Office (EPO) issued a patent claiming a process of human cloning to the Roslin Group.¹³⁷ This patent is licensed to a U.S. company, Geron Corporation. This patent issued in direct violation to a 1998 European directive on biotechnical inventions stating that human cloning is unpatentable.¹³⁸ The EPO immediately admitted that issuance of this patent had been “a mistake” because the patent did not disclaim cloning of humans.¹³⁹ This disclaimer was required before the patent was allowed to issue.¹⁴⁰ Because the EPO could not act by itself, it asked third parties to file a notice of opposition so that it could revoke the patent.¹⁴¹ Although this patent was mistakenly issued, it is still a valid patent claiming aspects of human cloning.¹⁴² By licensing this patent, Geron Corporation is liable if Congress passes legislation

¹³⁷ EPO Patent No. 1,005,789, published June 7, 2000 (entitled Quiescent cell populations for nuclear transfer). Claim 1 of EP 1005789 recites, “A method of nuclear transfer, the method comprising the transfer of the nucleus of a quiescent diploid donor cell into a suitable recipient cell” and is clearly broad enough to claim human cloning.

¹³⁸ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, Ch. I, Art. 5. (“The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the partial sequence of a gene, cannot constitute patentable inventions”).

¹³⁹ See *Patently Human, European Patent Appears to Cover Clones of People*, Reuters, Feb. 22, 2000, available at <http://abcnews.go.com/sections/science/DailyNews/cloningpatent000222.html#top>. (last visited April 24, 2002).

¹⁴⁰ Directive 98/44/EC at Chapter I, Article 5.

¹⁴¹ See *id.*

¹⁴² See EP 1,005,789, claim 1.

prohibiting human cloning.¹⁴³ This problem awaits other unwitting U.S. companies who similarly license or own technologies related to human cloning. This will be especially troubling because the penalties for human cloning or even attempting to clone humans would be calculated based on the unrealized profits derived from human cloning.¹⁴⁴

The Reproductive Cloning Industry

Another issue likely to arise is how the U.S. should deal with an international reproductive cloning industry specifically banned by the U.S. As discussed above, a sterile individual has the best and perhaps only chance to have genetically-related offspring through reproductive cloning. Because many people share an instinctive desire to sire their own genetically-related progeny, a reproductive cloning market will materialize. This market currently includes at least one member—Clonaid, which has predicted they will successfully produce the first human clone by February 2004.^{145, 146} This market, even if outlawed in the U.S. could still be legalized in other countries hoping to cash in on the tax revenue and other economic advantages which would arise from this profitable industry. Therefore, some biotech companies will leave along with the corresponding brain drain should reproductive cloning be outlawed.

¹⁴³ Until EP 1005789 is amended with the required disclaimer.

¹⁴⁴ H.R. 2505, Note 85, *supra*.

¹⁴⁵ The self-proclaimed “First Human Cloning Company” See <http://www.clonaid.com>.

¹⁴⁶ *Canadian Cult Head Predicts Human Clone in 2 Years*, Reuters, London (February 14, 2002), available at <http://ca.news.yahoo.com/020214/5/j8ib.html>.

More importantly, new issues and advances in technology arising from reproductive cloning should be addressed by Congress legislatively. This is preferable to having litigable arguments open to judicial interpretation, especially because Congress is in a much better position to determine the full extent and scope of issues and to have full and complete hearings including input from all sides.

Issues which should be addressed include:

- (1) What happens if a cloned individual applies for American citizenship?
- (2) Should a ban be placed on citizenship status of one group of people? Or would that in itself be a Constitutional violation?
- (3) Would denying a human clone citizenship in effect be punishing the innocent?
- (4) If citizenship would be granted, what would happen when the parents of the clone would visit the clone in the U.S.? Should they be arrested?
- (5) How would international tourists be treated? Should foreign tourists who are clones be denied access to the country?
- (6) Are technological advances such as artificial wombs also outlawed by legislation banning reproductive cloning?¹⁴⁷

CONCLUSION

Although most of society has to wait until May of 2002 to see *Attack of the Clones*, the world has been given a preview of an assault of human cloning issues. Unlike the George Lucas film, these issues will not be resolved after two hours. The

¹⁴⁷ See Robin McKie, *Men redundant? Now we don't need women either*, The Observer International (Feb. 10, 2002), available at <http://www.observer.co.uk/international/story/0,6903,648024,00.html>. (last visited April 24, 2002).

U.S. Senate is now preparing to debate the merits of human cloning. Within this debate a number of unaddressed issues should be discussed including the economic impact of a therapeutic cloning industry as well as of a reproductive cloning industry.

To be comprehensive, any enacted legislation should address the creation of a new class of criminals and the possible non-deterrent nature of monetary penalties. Further, to ensure that congressional time is not wasted, any proposed legislation needs to be evaluated to ensure its constitutionality. Congress should also address peripheral issues such as the economic impact of international patents on U.S. pharmaceutical and biotechnology corporations, the loss of U.S. patent rights and potential nationalization problems with expatriate human clones.

In light of recent events, it is clear that a multi-billion-dollar per year market will soon appear. Therefore, well thought out legislation needs to be enacted. Internationally, therapeutic human cloning has been legalized in a few economic super powers. 180 other countries do not even address human cloning. Therefore, the chance exists that the U.S. could be excluded from the financial and technological gains of this international marketplace.

Furthermore, because of the desire of some to have genetically related offspring, a reproductive cloning industry will appear, and most likely without the U.S. as an active participant. Therefore, U.S. legislation needs to address all of these issues to ensure that the U.S. and its biotechnology industry are not lost in a galaxy far, far, away...