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ETHICAL AND LEGAL ISSUES IN SINGAPORE BIOMEDICAL RESEARCH

Taiwo A. Oriola[†]

Abstract: In 2000, Singapore established the national "Bioethics Advisory Committee" to examine the ethical, moral, social, and legal implications of life sciences and biotechnology. The Committee will examine numerous topics, including genetic discrimination, cloning, and stem cell research. The Committee is expected to release its first set of recommendations concerning stem cell research in the first half of 2002. This paper proposes that leveraging Singapore into a world-class biomedical research center will entail synchronizing the relevant areas of its legal ethics infrastructure and culture with that of the major players in the global biotechnology industry. Conversely, adhering to prevailing local ethical views will undermine its competitiveness in a field in which the market is truly global. This hypothesis is predicated on the transient and imprecise nature of ethics and the relative certainty of biotechnology's commercial promise in light of post-Chakrabarty intellectual property law.¹

I. INTRODUCTION

Singapore is poised to become a beehive for biomedical research.² This reflects a deliberate economic policy to diversify the electronics dominated manufacturing sector. The Singapore government has earmarked three billion dollars (USD 1.6 billion) to promote research and development in life sciences.³ The Economic Development Board of Singapore already

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¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). A bacterium was bioengineered to consume oil by Ananda Chakrabarty, a biochemist with the General Electric Company. *Id.* The U.S. Patent Office denied patents on the ground that no patent could be issued on a living organism, being a product of nature. *Id.* On June 16, 1980, the Supreme Court held by the slim margin of five to four, inter alia, that Chakrabarty's bacterium was not a product of nature, but a new composition of matter, the product of his ingenuity, not of nature's. As such it was patentable under the existing law. *Id.*

² Researchers at the Department of Obstetrics and Gynaecology, National University of Singapore published the world's first report in 1994. See A. Bongso et al., *Isolation and Culture of Inner Cell Mass Cells from Human Blastocysts*, 9 HUMAN REPRODUCTION 2110 (1994). The research was carried out on twenty one donated human embryos. *Id.* See also Gwen Lee, *Tissue Engineering: Creating and Growing Body Parts*, 2 INNOVATION 14, 15 (2001).

³ *Singapore Research Centres Merge to Boost Biomedical Drive*, AFP, Sept. 19, 2001, 2001 WL 25016529.

views the budding biotech industry as a potentially crucial manufacturing sector.⁴ According to the Board's joint Press Release of February 6, 2002, the biomedical sciences industry's "manufacturing output for 2001 grew by 3.2% to SGD 6.6 billion," while "its value added grew by 3.6% to SGD 4.0 billion." Employment in the industry also grew "by 5.7% and reached 6,000," the projected manufacturing output for the sector is expected to be SGD 12 billion by 2005.⁵ Today, Singapore is a biotech haven with a variety of international players actively engaged in both research and applied biotechnology.⁶

⁴ See Kwek Mean Luck, *The Biotechnology Era: Ramifications of Genelabs Diagnostics v Institut Pasteur*, 13 SINGAPORE ACADEMY OF LAW J. 89 (2001).

⁵ "The pharmaceutical sector's output of SGD 5 billion accounted for seventy-six percent of the total Biomedical Sciences manufacturing output and enjoyed a growth in employment of 7.6%." See Press Release, Economic Development Board ("EDB"), Biomedical Sciences Group ("BMS Group") and Biomedical Research Council ("BMRC") Industry Briefing (Feb. 6, 2002) [hereinafter Feb. 6 Press Release], http://www.a-star.gov.sg/astar/upload/mid1/type14/cat63/444_312_06Feb02_BMS_Briefing_2002.doc. Medical technology grew by 3.4% in manufacturing output, and crept to SGD 1.6 billion, with 4.7% employment growth. *Id.*

⁶ For example, researchers from the National University of Singapore, the Monash Institute of Reproduction and Development, the Hadassah Medical Center of Israel, and the Hubrecht Laboratory of the Netherlands Institute of Developmental Biology teamed up to form a biotechnology company called ES Cell International (ESCI) in July 2000. The Economic Development Board of Singapore and a private investment company in Australia jointly fund ESCI. See generally Lee, *supra* note 2.

Furthermore, there are industry-to-industry collaborations within Singapore and across frontiers. For instance, Gleneagles Clinical Research Center offered its services of site management and clinical monitoring to fifty clinical trial sites in the region. Similarly, Quintiles, a local biotech company, supplies clinical trial test kits and materials to companies conducting trials in Asia. Moreover, some foreign biotech companies have set up shop in Singapore through their subsidiaries. These include Surromed, a US-based company focusing on the R&D of proprietary nanotechnology-based biomedical research tools and S*Bio, a drug company which is a joint venture between a local investment company and Chiron, a U.S. biotechnology company. Another category includes companies that directly set up R&D centers in Singapore. Recent examples are Eli Lilly and Novartis, two of the world's leading pharmaceutical companies. Their research projects are expected to commence in 2002 with projected expenditures of SGD 260 million on research over five years for Eli Lilly, and SGD 220 million on research over five to ten years for Novartis. Other biomedical companies with investments are: GlaxoSmithKline U.K., with SGD 80 million worth of a new manufacturing facilities, and Merk Sharp & Dohme, which plans to construct a new pharmaceutical formulation facility, bringing the company's total capital investments in Singapore to SGD 900 million. Schering-Plough (United States) is constructing a SGD 225 million lyophilisation plant for the production of hepatitis C drug called Interferon, and an anti-inflammatory agent for rheumatoid arthritis called Remicade. Others are Baxter (United States) with SGD 120 million projected fixed assets investment, and BD (United States) with SGD 25 million planned fixed assets investment. See Feb. 6 Press Release, *supra* note 5.

Also, the Biomedical Research Council was established in October 2000 by the government of Singapore. The main objectives are to support, sustain and stimulate excellent research for maintaining and improving human health to train people in high quality research skills to meet Singapore's health needs, quality of life and global economic competitiveness; and to promote societal awareness of biomedical research. The Council oversees and provides support to public sector biomedical research and development activities in Singapore. It also aims to strengthen collaborative public research in biomedical sciences. *Id.* For other related materials, see Agency for Science, Technology, and Research, <http://www.a-star.gov.sg/astar/index.jsp>.

Biotechnology's main resource is living organisms. It involves intervening in nature through varied scientific techniques to achieve a desired result. In this respect, it is markedly different from automobile and electronic technologies and, consequently, far more controversial. The term "biotechnology" came into wide usage in early the 1970s, but it is not an entirely new concept. In fact, biotechnology has been applied in cheese making, wine fermentation, plant breeding, and animal husbandry for centuries.⁷

The use of microscopes by early scientists⁸ led to the discovery of cells in both plants and animals.⁹ Cells are the factories of life that encode the vital reproductive information of plants and animals. "Chromosomes"¹⁰ were identified as the likely carriers of this reproductive information. They are "threadlike" in nature and reside in the nucleus of the cell. Scientists soon discovered that "genes" were actually located on chromosomes, and are made from deoxyribonucleic acid ("DNA").¹¹ It subsequently became clear that DNA is the carrier of hereditary information in plants and animals.¹² In 1953 two Cambridge University scientists, James Watson and Francis Crick, finally deciphered the structure of DNA. They described the structure as having "two helical chains each coiled round the same axis"¹³ and observed that each DNA molecule comprised two sugar-phosphate backbones that entwined one another. This shape is known as the "double helix."¹⁴ This discovery of the structure of DNA facilitated useful insights into how DNA

⁷ It is said, however, that none of these techniques would qualify as "biotechnology" in the modern sense. See ERIC S. GRACE, *BIOTECHNOLOGY UNZIPPED: PROMISES & REALITIES* 2 (1997). For further readings, see *BIOTECHNOLOGY, PATENTS AND MORALITY* (Sigrid Sterckx ed., 2000); *BIOTECHNOLOGY: SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY* (Frederick B. Rudolph & Larry V. McIntire eds., 1996); *BIOTECHNOLOGY: A HOPE OR A THREAT?* (Ifikhar Ahmed ed., 1992); LISA YOUNT, *BIOTECHNOLOGY AND GENETIC ENGINEERING* (2000).

⁸ In 1665, an English scientist, Robert Hooke, while examining plant tissue with the aid of microscope, discovered tiny spaces surrounded by wall-like structures. GRACE, *supra* note 7, at 3. These he called "cells" in his published observations. *Id.* He assumed that their function was to transport substances through the plant. *Id.* The subsequent development and use of more powerful microscopes by "a Dutch draper and skillful lens grinder" called Anton Van Leeuwenhoek, led to the discovery of microorganisms, which he called "very little animalcules." *Id.*

⁹ *Id.*

¹⁰ Every living organism has a specific number of chromosomes comprising a set of almost identical pairs (one from each parent). *Id.* at 10. For example, humans have twenty-three pairs of chromosomes, or forty six in total. *Id.*

¹¹ DNA comprises sugar, phosphate, and four different nitrogen-containing bases named guanine, cytosine, thymine and adenine. *Id.* at 17. They are frequently expressed by the acronym: G, C, T, and A. *Id.*

¹² *Id.* at 14.

¹³ See J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids*, 171 *NATURE* 737 (1953) available at <http://www.nature.com/genomics/human/watson-crick/>.

¹⁴ See GRACE, *supra* note 7, at 15.

reproduces itself when a cell divides, and in that process, passes on a complete copy of hereditary information to both "daughter" cells.

Scientists soon revealed the process by which hereditary information in the DNA code was converted to proteins, the complex chemicals that do most of the work of the cell.¹⁵ This process involves copying DNA into ribonucleic acid ("RNA"), a related chemical slightly different in composition.¹⁶ Unlike DNA, RNA is mobile and moves from the cell nucleus to the rest of the cell.¹⁷ There, the RNA shepherds the assembly of amino acids into a protein molecule in accordance with the original DNA specifications and instructions.¹⁸ In other words, genes are instructions for making various proteins.¹⁹ According to Eric S. Grace,²⁰ "every process and product in living cells depends on proteins. They do everything from activating essential chemical reactions, to carrying messages between cells, to fighting infections, to making cell membranes, tendons, muscles, blood, bone, and other structural materials."²¹

A defective or missing protein molecule is known as "genetic mutation."²² Genetic mutations may be rectified by "gene therapy."²³ The ultimate genetic technology is "genetic engineering." Genetic engineering may be used to introduce a desirable trait into plants²⁴ or animals,²⁵ to cure a

¹⁵ *Id.* at 18.

¹⁶ The difference between DNA and RNA lies in the presence of uracil rather than thymine as one of the four RNA bases. See YOUNT, *supra* note 7.

¹⁷ This is known as "cytoplasm". See YOUNT, *supra* note 7.

¹⁸ All living things are built and run by the same types of molecules, and are fundamentally the same at the molecular level of life where "there is no difference from a person and a bacterium." GRACE, *supra* note 7, at 1.

¹⁹ Proteins are of structural and functional importance. GRACE, *supra* note 7, at 21. Examples are: collagen (found in bone and skin), keratin (makes hair and nail), fibrin (helps blood clot), elastin (major parts of ligaments), hormones (control body functions), antibodies (fight infection), enzymes (help speed up chemical reactions in the body), and hemoglobin (carries oxygen in the blood). *Id.*

²⁰ *Id.* See also George Wei, *Inventions, Genes And Napoleonic Victories*, 9 SINGAPORE ACADEMY OF LAW J. 1, 59 (1997).

²¹ GRACE, *supra* note 7, at 21.

²² See Savio L.C. Woo, *Gene Therapy: Beyond Genetic Diseases*, in BIOTECHNOLOGY: SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY, *supra* note 7, at 72.

²³ *Id.* at 74-76.

²⁴ Such desirable traits, which are meant to increase crop yields or to accomplish a specific task, range from resistance to drought, insect pests, diseases, or frost to herbicide tolerance. For example, scientists at Cornell University in the United States have created bananas that contain a vaccine for hepatitis B. See *Feeding The Five Billion: New Agricultural Techniques Can Keep Hunger At Bay*, ECONOMIST.COM (Nov. 8, 2001), available at http://www.economist.com/PrinterFriendly.cfm?Story_ID=841826&CFID=2134030&12/6/2001.

China also has made considerable advancements in genetically modified ("GM") plants that are second only to the United States. See Tom Clarke, *China Leads GM Revolution*, NATURE ONLINE (Jan. 25, 2002), at <http://www.nature.com/nsu/020121/020121-13.html> (reporting that China is developing the largest plant biotechnology capacity outside North America and that poor farmers in China are cultivating more areas of genetically modified plants than small farmers in any other developing country). About 141

particular genetic disease in a person,²⁶ or for experimental purposes in animals.²⁷

Today, the technology is ubiquitous. It is worth billions of dollars in global investment capital.²⁸ It has raised as much promise as fear,²⁹ and has

GM plants have been developed. *Id.* See also Jikun Huang et al., *Plant Biotechnology In China*, 295 SCIENCE 674, (2002).

²⁵ For example, Aqua Bounty Farms, based in Massachusetts, has applied for Food and Drug Administration (FDA) approval of a genetically engineered salmon that is six times the size of the normal fish. See Sharon Tisher, *Frankenfish and the FDA*, BANGOR DAILY NEWS (Feb. 15, 2002), available at <http://www.bangornews.com/editorialnews/article.html?ID=51024>. In the 1980s, the gene responsible for bovine growth hormone (somatotropin or "BST") production was successfully isolated and transferred into bacterial cells to produce large quantities of BST. See JOHN E. SMITH, BIOTECHNOLOGY 175-76 (3d ed. 1996). When cows were injected with about thirty milligrams of BST there was significant increase in milk production. *Id.*

²⁶ For example, in a collaborative research effort, the National University of Singapore's Department of Pediatrics, using genetic engineering, has implanted a new strand of DNA into the genetic blueprint of a patient suffering from Duchenne Muscular Dystrophy ("DMD"), a fatal muscle wasting disease. See National University of Singapore, *Altering Genes to Save Lives*, <http://www.nus.edu.sg/corporate/research/gallery/research5.htm>. The new DNA stopped the production of the defective gene, and induced the production of a partially functional dystrophin, leading to a considerable improvement that was less life threatening to the patient. *Id.*

Similarly, on September 26, 2000, the cells from the cord blood of a new born baby, Adam Nash, was transplanted into Molly his sister, who was suffering from fanconi's anemia, a fatal genetic disease. See Rick Weiss, *Test Tube Baby Born to Save Ill Sister*, WASH. POST, Oct. 3, 2000. In February 2002, the Fertilization and Embryology Authority in the United Kingdom ruled that a couple could use this technique to create a designer baby. See "Designer Baby" Row Couple Defend Decision, ANANOV, Feb. 24, 2002, at http://www.ananova.com/yournews/story/sm_528603.html. Embryos will be screened to ensure that the next baby is genetically identical to the couple's son. *Id.* The baby's umbilical cord cells will be transplanted into the bone marrow of their son, who suffers from a potentially fatal disease called "thalassaemia." *Id.* This decision has drawn much criticisms in and from outside the United Kingdom. *Id.*

²⁷ An example is the "Harvard Oncomouse," a mouse genetically engineered to be susceptible to cancer by researchers at Harvard Medical School. See *Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (1987). The feat was accomplished by exploiting transgenic technology to insert the myc oncogene tied to a mammary-specific promoter into the new embryo of a normal mouse. *Id.* Also, scientists at the Roslin Institute, Edinburgh, Scotland, successfully cloned a sheep, "Dolly," by a nuclear transfer from a cultured cell line of adult and fetal mammalian cells. See K.H.S. Campbell et al., *Sheep Cloned By Transfer From A Cultured Cell Line*, 380 NATURE, 64 (1996). The feat took the world by surprise, raising speculation that human cloning was afoot. *Id.* See also I. Wilmut et al., *Viable Offspring Derived From Fetal And Adult Mammalian Cells*, 385 NATURE, 810 (1997).

²⁸ For instance, the world market for pharmaceutical biotechnology by 2004 will be an anticipated EUR 506 billion, while the global market for industrial biotechnology (only partly biotech) will be an anticipated EUR 1.5 trillion by 2010. See BJÖRN THEGEY, LIFE SCIENCES AND BIOTECHNOLOGY—A STRATEGY FOR EUROPE, COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE ECONOMIC AND SOCIAL COMMITTEE OF THE REGIONS, 7 (2002), http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf. Also the market capitalization of Europe's public biotechnology companies is estimated at EUR 75 billion, while that of the United States is EUR 376 billion. See J. SENKER ET AL., FINAL REPORT: EUROPEAN BIOTECHNOLOGY INNOVATION SYSTEMS, 54 (2001), <http://www.sussex.ac.uk/spru/biotechnology/ebis/ebisfinalreport.pdf>.

²⁹ The promise is of tackling incurable and intractable diseases, such as diabetes and Parkinson's, and boosting global food production, while the ethical, moral and environmental fears are of human cloning, life and gene patenting, gene pollution, and safety concerns. See GRACE, supra note 7; see also Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 47-59 (2001).

sparked a global ethical, moral, and political debate on issues ranging from genetically engineered crops to stem cell research and human cloning.³⁰

Perhaps the most hotly contested spheres of modern biotechnology are biomedical and biopharmaceutical research and applications, which depend primarily on plant, animal, and human genetic materials.³¹ First there is the problem of plant and animal genetic resource control and access, which predominates the trade and political discourse.³² Second, biomedical

³⁰ For instance, the European Union's continual ban on GM food imports on safety grounds from the United States and Canada, despite the World Trade Organization ("WTO") ruling on its impropriety could escalate to the biggest trade dispute ever, and would surely dwarf the banana wars in its full ramifications. See *GMO Update: EU Labeling of GMOs; Brazil; Thailand*, BRIDGES WEEKLY TRADE NEWS DIG. (July 31, 2001), <http://www.ictsd.org/html/weekly/31-07-01/story5.htm>. The European Union's ban has been in place since 1998 and is likely to remain for another two years, while the EU member states continue to debate proposed labeling and traceability regulations, according to EC Environment Commissioner, Margot Wallstrom. *Id.* The U.S. Trade Representative (USTR) Robert Zoellick had described the EU approach as founded on "fears and lack of a scientific basis or knowledge." See BRIDGES WEEKLY TRADE NEWS DIG. (Jan. 24, 2002).

³¹ Accessing genetic resources goes to the heart of the North/South dispute on fashioning a concrete agenda for the preservation of the biodiversity. Developing countries feared that transgenic plants and animals would eventually deplete biodiversity and create an unprecedented corporate control over transgenic beings mainly through the instrumentality of patent laws. The specter of poor farmers paying royalties for transgenic seeds has been deprecated as a regime designed to make "bioserfs" out of the farmers. This problem is by no means peculiar to farmers from developing countries. For example, in March 2001, Monsanto, a multinational agro-biotechnology company, successfully sued an elderly Saskatchewan farmer in Canada, Percy Schmeiser, for patent infringement. See *Monsanto Canada, Inc. v. Schmeiser*, [2001] F.C. 256, available at <http://decisions.fct-cf.gc.ca/fct/2001/2001fct256.html>. The company contended that the farmer had illegally planted and sold harvested seed containing the gene and cells covered by Monsanto's patent on Roundup Ready Canola. *Id.* There have been increasing calls for the harmonization of the principles of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS" agreement) with that of the Rio Biodiversity Convention in the context of acknowledgement of the source, and compensation for the use of genetic resources in biotechnology inventions. See generally VANDANA SHIVA, *PROTECT OR PLUNDER: UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS* (2001).

³² See *supra* note 31 and accompanying text. See also Philippe Cullet, *Property Rights Over Biological Resources: India's Proposed Legislative Framework*, 4 J. WORLD INTELL. PROP. 211, (2001); Ehsan Masood, *Social Equity Versus Property: Striking The Right Balance*, 392 NATURE, 537 (1998). For instance, India, China, Brazil and nine other of the world's most biodiverse countries signed an alliance on February 18, 2002 to fight biopiracy and ensure the preservation of their peoples' right to their genetic resources. See Virginia Gewin, *Poor Nations Seek New Biodiversity Deal*, 415 NATURE, 949 (2002). The twelve nations, which also include Indonesia, Costa Rica, Colombia, Ecuador, Kenya, Peru, Venezuela, and South Africa, comprise 70% of the world's biodiversity. *Id.* Dubbed the "Group of Allied Mega-Biodiverse Nations," the alliance is bent on promoting its cause at the U.N. World Summit on Sustainable Development to be held in Johannesburg, South Africa in August 2002. *Id.* See also Mark Stevenson, *China, Brazil, India, 9 Other Nations Form Alliance Against Biopiracy*, ASSOCIATED PRESS, Feb. 19, 2002, http://www.enn.com/news/wire-stories/2002/02/02192002/ap_46427.asp. See also Anne Marie Ruff, *Guarding the Region's Riches*, FAR E. ECON. REV., Jan. 31, 2002, available at 2002, WL-FEER 5169463. It is based on the interview granted by a Thai lawyer, on the best way to protect Thai local traditional knowledge and products, especially the "jasmine rice" on which researchers from the United States have allegedly been preying. See also Susan Young, *The Patentability of Maori Traditional Medicine And The Morality Exclusion In The Patents Act 1953*, 32 VICTORIA U. WELLINGTON L.R. 255 (2001) (making the case for the protection of Maori traditional medicine and exploring the suitability of the New Zealand patents law for this purpose).

research and clinical applications raise ethical, moral, and legal issues posed by gene patenting, human genetic sourcing,³³ ownership and theft of genetic materials or body parts, genetic discrimination, genetic screening and confidentiality, stem cell research, and human cloning.³⁴ Of particular concern is embryonic stem cell research, which has brought the concept of "personhood" to the forefront of bioethics discourse in countries around the world.³⁵

Using a comparative analysis, this Article will explore the hypothesis that ethical views on biomedical research in Singapore are bound to be disparate as in other countries. Also, this Article proposes that Singapore must align its ethical and legal views with that of the other leading biotechnology nations in order to maintain its competitive standing.

At its conclusion, this Article examines the driving force behind biotechnology inventions, intellectual property law, and the relative weakness of countervailing trends in bioethics. From *Chakrabarty*³⁶ to *Harvard Oncomouse*,³⁷ the tilt in favor of modern biotechnology is palpable. Consequently, the fortune and future of biomedical research in Singapore depends more on intellectual property than on the vagaries of ethics.

II. SETTING THE STAGE FOR ETHICAL AND LEGAL ISSUES IN SINGAPORE BIOMEDICAL RESEARCH

The "Bioethics Advisory Committee" ("Committee") was established by Singapore in December 2000 to address the ethical and social issues

³³ Central to the issue of human genetic sourcing for biomedical research are the prohibition against commercialization of human body parts and the necessity for patients' informed consent in pre- and post-operative body parts excision. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, (Cal. 1990). The Supreme Court of California held that there was a breach of fiduciary duty or lack of informed consent based on allegations that a physician concealed his economic interest in postsplenectomy takings of blood and other samples for use in research when the physician failed to disclose that he had begun to investigate and initiate procedures for obtaining a patent on cell line developed from the patient's cells. *Id.* The court however held that Moore had no part in the proceeds of the patented cell line, since he could not, in law, own the excised body parts from which the cell line was isolated. *Id.* This was essentially a policy decision—ostensibly to facilitate unhindered medical research. *Id.*

³⁴ See Kaan Terry Sheung-Hung, *Rights, Ethics And The Commercialization Of The Human Body*, SING. J. LEGAL STUDIES 483, (2001); LORI ANDREW & DOROTHY NELKIN., *BODY BAZAAR: THE MARKET FOR THE HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* (2001); Catherine Keller, *Playing God*, in BORN NOT MADE: THE TROUBLING WORLD OF BIOTECHNOLOGY (Casey Walker ed., 2001).

³⁵ See Sahin Aksoy, *Personhood: A Matter of Moral Decisions*, 7 EUBOIS J. ASIAN & INT'L BIOETHICS, 3 (1997); Keller, *supra*, note 34.

³⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

³⁷ The 2001 Harvard Oncomouse European Patent Office decision limited the scope of the patent claims from transgenic mammals to mice. See *European Patent Office Limits Harvard Oncomouse Patent*, at www.european-patent-office.org/news/pressrel/2001_11_07e.htm. Ethical issues were apparently glossed over. See *id.*

associated with biomedical sciences. It has the duty of ensuring that the science is set on the path of excellence and "high ethical and legal standards."³⁸ The Committee is to be guided by the imperative for the protection of "the rights and welfare of individuals" without diminishing the prospect for the realization of biomedical science's full potential for growth in Singapore.³⁹ This is essentially a balancing act that underscores the government policy of making Singapore a beehive for life sciences research.⁴⁰

The policy is neither new, nor unique to Singapore. Both Taiwan and South Korea have also made biomedical research a national priority.⁴¹ Basic research is essential to reaching the goal of biotechnology transfer.⁴² Of equal importance to a pro-biotechnology strategy is a viable intellectual property regime and a judiciary versed in the technical intricacies of patent litigations. The patent law in Singapore is substantially compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"),⁴³ while the judiciary's thorough grasp and understanding of patent litigation was demonstrated in Singapore's first ever biotechnology patent litigation, *Genelabs Diagnostics v. Institute Pasteur*.⁴⁴

III. THE MORALITY AND "ORDRE PUBLIC" BAR EXCEPTIONS TO BIOTECHNOLOGY PATENTS

Patent law has the narrow purpose of protecting property rights to technological inventions. The ethical or moral propriety of patenting living things⁴⁵ is beyond the scope of the Committee's briefs. In fact, denying

³⁸ This construct is based on the information on the Committee's website, at <http://www.bioethics-singapore.org/bac/introduction.jsp>.

³⁹ *Id.*

⁴⁰ See *supra* notes 2, 5, and accompanying text.

⁴¹ See ROBERT T. YUAN, BIOTECHNOLOGY IN SINGAPORE, SOUTH KOREA AND TAIWAN 5 (1988).

⁴² *Id.*

⁴³ See Patents Act, No. 21, 1994 (as amended by Patents (Amendment) Act, No. 40, 1995) (Sing.). The Marrakech 1994 TRIPS agreement was a WTO trade based instrument that required a minimum level of intellectual property protection by WTO member countries. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, available at www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm [hereinafter TRIPS].

⁴⁴ *Genelabs Diagnostics v. Institute Pasteur*, [2000] 1 SLR 121, 2000 SLR Lexis 61. The Court of Appeal, while affirming the High Court Judgment, upheld the validity of Genelabs' patent in its HIV diagnostic kits (Genelabs Diagnostics HIV-2 Western-Blot Version 1.2 ("Blot 1.2") and Genelabs Diagnostics HIV Blot 2.2 ("Blot 2.2")). *Id.* The patent had been challenged mainly on grounds of lack novelty and obviousness. *Id.* at 14. For a discussion on the full ramifications of the decision for the budding biotechnology industry in Singapore, see Luck, *supra* note 4.

⁴⁵ The prevailing moral and ethical objections to the patentability of living things are anchored on their being products of nature. See BIOTECHNOLOGY, PATENTS, AND MORALITY, *supra* note 7. If a

patentability to genetically engineered life forms, mainly on ethical and moral grounds, could be antithetical to the realization of biomedical science's full potential in Singapore and elsewhere. Article 13 of Singapore's Patents Act provides thus:

- (3) An invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behavior is not a patentable invention.
- (4) For the purposes of subsection (3), behavior shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in Singapore.⁴⁶

The Japanese Patent Law has similar terms in article 32, which defines unpatentable inventions as "the inventions liable to contravene public order, morality, or public health . . .".⁴⁷ However, in both Singapore and Japan the key statutory terms are undefined. Consequently, courts and patent examiners are left to set the parameters of public order and morality.

For example, European courts have addressed the meaning of "public order" and "morality" when interpreting article 53(a) of the European Patent Convention ("EPC"), which is in *pari materia* with article 13(3) of Singapore's Patent Act and is similar to article 32 of Japan's Patent Law. The European Patent Office ("EPO") Board of Appeal, in *Plant Genetic Systems v. Greenpeace*, defined *ordre public* as follows:

It is generally accepted that the concept of "ordre public" covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Art 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being Contrary to public policy.⁴⁸

particular gene is isolated from nature and patented, its functionality still depends on the inherently regenerative nature of the whole organism, the scope of which is well beyond the patented gene. *Id.*

⁴⁶ Patents Act, art. 13(3) & (4).

⁴⁷ See Japan Patent Law, Law No. 121 of 1959 (as amended by Law No. 220 of 1999), art. 32 (entered into force in January 6, 2001.).

⁴⁸ *Plant Genetic Systems v. Greenpeace*, [1995] E.P.O.R. 357.

The EPO defined morality in the same case as follows:

The concept of morality is related to the belief that some behavior is right and acceptable whereas other behavior is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilization. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.⁴⁹

The relevance of pan-European cultural standards in gauging the morality of biotechnology inventions is doubtful in the context of today's global economy.⁵⁰ It appears irreconcilable with the notion of universal intellectual property standards embodied in the TRIPS agreement.⁵¹ How differently would people in Asia, America, Africa, and Europe view genetic engineering, stem cell research, and patents on living organisms? There is a growing body of empirical evidence supporting the concept of "universal bioethics."⁵²

Though it is not within the scope of this Article, the following examples underscore the nearly universal approach to the ethical and moral dilemmas posed by embryonic stem cell research:

- In Singapore, the Committee has recommended the establishment of a Statutory Board to regulate and monitor embryonic stem cell research, while human cloning has been prohibited.⁵³

⁴⁹ *Id.*

⁵⁰ See KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN GLOBAL ECONOMY* 3-6 (2000).

⁵¹ See TRIPS, *supra* note 43.

⁵² A survey conducted in the United States, Australia, Singapore, Japan, India, Thailand, New Zealand, Hong Kong, the Philippines, Israel, and Russia examining attitudes about biotechnology revealed that "people in different countries share very similar images of life and similar diversity of views on most of these issues on bioethics associated with genetics. . . . [T]he range of choices people desire is transcultural" See Darryl Macer, *Bioethics and Genetics in Asia and the Pacific: Is Universal Bioethics Possible?*, in *CHANGING NATURE'S COURSE: THE ETHICAL CHALLENGE OF BIOTECHNOLOGY* 183 (1996).

⁵³ See Chan Kay Min, *Statutory Board Right Move: Stem-Cell Researchers*, STRAITS TIMES INTERACTIVE, Jan. 14, 2002, at <http://straitstimes.asia1.com.sg/cybernews/story/0,1870,96409-1011045540,00.html?>.

- In the United Kingdom, the House of Lords Select Committee on stem cell research has recommended that research on human embryonic stem cells should be allowed under strictly controlled conditions.⁵⁴
- In Taiwan, human cloning in stem cell research was banned, but the health authorities were inclined to allow limited embryonic stem cell research.⁵⁵
- In Germany the importation of embryonic stem cell lines created before January 30, 2002 is now permitted, while research must be conducted under prescribed conditions.⁵⁶
- In the United States, human cloning has been prohibited by several states, while the Bush administration only allows limited federal funding for embryonic stem cell research under prescribed conditions.⁵⁷
- On February 25, 2002, the United Nations Ad Hoc Committee On The Convention To Ban Human Cloning met for the first time, and heard expert views on the science and ethics involved.⁵⁸

These examples depict a unanimous, universal, and spontaneous response favoring limited embryonic stem cell research for therapeutic purposes, while foreclosing human cloning. There is nothing to suggest that this

⁵⁴ See *Go-ahead for UK Stem Cell Research*, GUARDIAN UNLIMITED, Feb. 27, 2002, at <http://www.guardian.co.uk/genes/article/0,2763,658943,00.html>.

⁵⁵ The health authorities feared that an outright ban could stymie the development of Taiwan's nascent biotechnology sector. See *Taiwan Bans Human Cloning in Stem Cell Research*, REUTERS, Feb. 20, 2002, available at <http://ca.news.yahoo.com/020220/5/jmx8.html>.

⁵⁶ See Quirin Schiermeier, *German Parliament Backs Stem-Cell Research*, 415 NATURE 566 (2002), available at http://www.nature.com/cgi-taf/DynaPage.taf?file=/nature/journal/v415/n6872/full/41566a_.

⁵⁷ The House of Representatives voted to ban human reproductive and therapeutic cloning in July 2001 in a 265-162 vote. Declan McGulagh, *Senate's Turn in Clone Zone*, WIRED, Feb. 9, 2002, at <http://www.wired.com/news/print/0,1294,50297,00.html>. The measure stated that "it shall be unlawful for any person or entity . . . to perform or attempt to perform cloning or import a cloned human embryo" Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. § 302 (2001). The penalties would have been up to ten years in prison and a USD 1 million fine. *Id.*

⁵⁸ *Committee Charged with Elaborating Convention to Ban Human Cloning Concludes First Session at Headquarters*, UN NEWS SERVICES/PRESS RELEASES, at <http://www.un.org/News/Press/docs/2002/12996.doc.htm> (Mar. 1, 2002).

uniformity of views on embryonic stem cell research is either immutable or representative of the global overall perception of biotechnology industry.⁵⁹ It does, however contradict the culture-specific notion of morality espoused by the EPO in *Greenpeace*.

In the absence of guidance from Parliament, any number of morality objections might arise. For example, Singapore might recognize a cause of action challenging the validity of a patented cell line obtained from a stolen embryo. Similarly, a plaintiff might challenge the validity of a patented cell line derived, as in *Moore*, without the informed consent of the donor.⁶⁰ Although the plaintiff in *Moore* did not challenge the validity of the patented "Mo cell line," his claim to share in the proceeds of the invention derived from his cells, with a "potential market of approximately USD 3.1 billion by the year 1990," was declined. Based on California law, he had no ownership in his excised cells, and the patented cell line was "both factually and legally distinct from cells" originally taken from his body.⁶¹ The *Moore* decision vindicated the underlying policy of ensuring unhindered medical access to human cells and other genetic materials for basic research and clinical trials.

Though *Moore* was fought on grounds other than morality, a plaintiff in Singapore could arguably challenge the validity of a patent under section 13(3). It is the Intellectual Property Office of Singapore ("IPOS") or the Court's prerogative to decide whether the publication or exploitation of an invention would "encourage offensive, immoral, or anti-social behavior." It is most likely that, faced with a *Moore* scenario, Singapore's patent examiners or Courts would find the underlying policy in *Moore* to be more compelling.

Article 53(a) of the European Patent Convention,⁶² like section 13(3) of Singapore's Patent Act, has no guidelines for delimiting the concepts of "ordre public" and "morality," except as interpreted by the European Patent Office Board of Appeal in the *Greenpeace* decision.⁶³ Rainer Moufang has suggested that article 53(a) could be used to challenge the patentability of an invention on ethical grounds, if the sole purpose of the patent application is the invention's commercialization.⁶⁴ However, vitiating a patent on the

⁵⁹ Opinions still differ largely on other aspects of biotechnology such as patents on living organisms, genetically modified crops, etc. See SHIVA, *supra* note 31.

⁶⁰ *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

⁶¹ *Id.* at 141.

⁶² Convention on the Grant of European Patents, Oct. 5, 1973, art. 53(a), available at <http://www.european-patent-office.org/legal/epc/e/mal.html> [hereinafter European Patent Convention].

⁶³ *Plant Genetic Systems v. Greenpeace*, [1995] E.P.O.R. 357, 366.

⁶⁴ See Rainer Moufang, *Patenting of Human Genes, Cells and Parts of the Body?—The Ethical Dimensions of Patent Law*, 25 INT'L REV. INDUSTRIAL PROP. & COPYRIGHT L. 507 (1994).

basis of this reasoning could be problematic. It is axiomatic that patent monopoly is a means to an end. The end is an exclusive commercial exploitation either by operating and producing the invention, or through franchises and licenses.⁶⁵ In other words, the patent law system presumes a commercial motivation.⁶⁶

The circumstances under which article 53(a) may be invoked by patent examiners is contained in the Guidelines for Examination in the European Patent Office: "This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."⁶⁷

It is Sigrid Sterckx's view, however, that this guideline failed to stipulate the modality for discovering the attitude of "the public in general" towards the invention at issue.⁶⁸ This concept raises several questions. Would this be through a referendum or opinion polls? Would it be the prevailing "attitude of the public" in the corporate E.U. or in individual member states? Do we evaluate the general attitude of the entire public or just a segment (e.g., molecular biologists, professional ethicists, religious leaders, or ecologists)? How would the objectivity of these groups be assessed? What if public attitude differs from one country to the other or even within a country? Would referendums or opinion polls not derogate from the patent examiner's or court's authority in deciding what a patentable invention is? The problem could be further exacerbated if the invention in question has some political or religious coloration, or if public attitude is evenly divided.

These questions surfaced in *Howard Florey*, the "Relaxin case."⁶⁹ In *Howard Florey*, the EPO had, over strong opposition, allowed a patent for the genetic engineering of DNA from a pregnant woman's body for the production of H2-relaxin. It was contended that this was nothing short of patenting human life.⁷⁰ The objections were dismissed on the grounds, *inter*

⁶⁵ See WILLIAM R. CORNISH, *INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADEMARKS AND ALLIED RIGHTS* 117-18 (4th ed. 1999).

⁶⁶ Some scholars have hotly challenged this notion. See, e.g., David Vaver, *Some Agnostic Observations On Intellectual Property*, 6 INTEL. PROP. J. 125, 127 (1990-91) ("[I]ntellectual property regimes are said to encourage the initial creative act. Yet, in the centuries before copyright and patent laws were established or rigorously enforced, inventive and creative work flourished.").

⁶⁷ European Patent Office, *Guidelines for Examination in the European Patent Office*, pt. C, ch. IV, ¶ 3.1, available at http://www.european-patent-office.org/legal/guidelines/pdf/gui_e_full.pdf.

⁶⁸ See Sigrid Sterckx, *European Patent Law and Biotechnological Inventions*, in *BIOTECHNOLOGY, PATENTS AND MORALITY*, *supra* note 7, at 26-27.

⁶⁹ *Howard Florey v. Fraktion der Grünen Im Europäischen Parlament*; Lannoye, [1995] E.P.O.R. 541 [hereinafter *Howard Florey*].

⁷⁰ See CORNISH, *supra* note 65, at 230.

alia, that DNA was not "life," but rather a substance carrying genetic information for the production of medically useful protein. In dismissing the slavery contention, the EPO found:

[A]s for the opponent's assertions concerning slavery and dismemberment of women, these are considered to betray a fundamental misunderstanding of the effects of a patent. It can not be overemphasized that patents covering DNA encoding human H2-relaxin, or any other human gene do not confer on their proprietors any rights whatever to individual human beings any more than do patents directed to other products such as proteins, including human H2-relaxin. No woman is affected in any way by the present patent—she is free to live her life as she wishes and has exactly the same right to self-determination as she had before the Patent was granted [T]he exploitation of the invention does not involve dismemberment and piecemeal sale of women. The whole point about gene cloning is that the protein encoded by the cloned gene—in this case human H2-relaxin—is produced in a technical manner from unicellular hosts containing the corresponding DNA; there is therefore no need to use human beings as a source for the protein. The only stage at which a woman was involved was at the beginning of the making of the invention, as a (voluntary) source for Relaxin mRNA.⁷¹

Assuming, *arguendo*, that the EPO was correct, the analysis did not address the morality of Relaxin's commercial exploitation. This is symptomatic of the increasing tensions and conflicts between ethical or moral considerations and the commercialization of biotechnology. It is a contemporary conflict in which ethical and moral influences are, at best, tenuous.

During trial, the opponents had requested that a referendum be conducted on the issue. In rejecting the proposition the Opposition Division declared:

[T]he opponents requested that the EPO carry out a referendum This request is refused since in opposition proceedings the burden of proof lies with the opponent—if they felt that such a

⁷¹ Howard Florey, [1995] E.P.O.R. at 550.

survey might assist their case, it was up to them to carry it out. In any case, the Opposition Division wishes to point out that even if such a Referendum were feasible, there is no provision in the EPC that only those inventions actively approved by the public should be patented. If such a provision existed, it is arguable that the number of patents Grants would be decimated [O]nly in those very limited cases in which there appears to be an overwhelming consensus that the exploitation . . . of an invention would be immoral may an invention be excluded from patentability under Art. 53(a).⁷²

This argument begs the question. It offers no insight into what constitutes an "overwhelming consensus," and how it could be fairly ascertained. Even if it were possible to have "an overwhelming consensus," the EPO would most likely dismiss it as a non-EPC requirement for patentability of inventions or as indecisive of such patentable subject matter as it found in *Greenpeace*.⁷³ This stance underscores a pro-patent policy that the EPO was not ready to leave to the whims of an increasingly skeptical public.

This EPO pro-patent policy was clearly manifested in *Greenpeace* where the EPO dismissed a public survey showing opposition to genetically modified herbicide resistant plants.⁷⁴ A patent for such plants had been granted to Plant Genetic Systems. The opponent, Greenpeace, presented a survey of opinion polls among farmers in Sweden and Switzerland, in which a large majority of Swedish farmers were against herbicide resistant crops. In Switzerland, 69% of the respondents to opinion polls objected to patents on plants and animals. In rejecting the survey, the EPO Board of Appeal held that the survey "can scarcely be considered decisive per se when assessing patentability of a given subject matter with regard to the requirements of article 53(a) EPC"⁷⁵ The Board predicated its views, *inter alia*, on grounds that: surveys and polls could fluctuate within short periods, could be very easily influenced, and would not necessarily reflect *ordre public* and morality, and that the "morality assessment" had to be made on a case-by-case basis.⁷⁶

These findings obviously challenge the probative value of opinion polls. How then can public attitude be determined? The EPO had

⁷² *Id.* at 553.

⁷³ *Plant Genetic Systems v. Greenpeace*, [1995] E.P.O.R. 357, 373.

⁷⁴ *Id.* at 369.

⁷⁵ *Id.* at 368.

⁷⁶ *Id.* at 369.

apparently hinted in *Howard Florey* that the opposition could use a survey to demonstrate general opposition to a particular class of patents.⁷⁷

In delimiting the scope of *ordre public* of article 53(a) in *Greenpeace* the EPO Board of Appeal had noted that acts that are inimical to the environment would be considered violations.⁷⁸ But challenging a biotechnology invention on environmental grounds would require conclusive scientific evidence. The EPO, while noting the absence of such evidence in *Greenpeace*, found as follows:

The Opponent's inability to prove the extent of the risks . . . is hardly surprising since experts all over the world have for at least the past fifteen years been intensively addressing themselves to the question of possible risks associated with genetic engineering and in particular with the release of genetically engineered organisms into the wild. Despite all this effort, there is still no agreement concerning the extent of these risks and the Opponent has indeed conceded that the risks are impossible to determine with certainty [I]t is difficult to see how examiners could ever be in a position to take a stand on such questions If examiners were to attempt to do so, the result could only be arbitrary and superficial and thus unfair to applicants.⁷⁹

This finding quite predictably weighed unduly in favor of biotechnology patenting. The pertinent question is whether a particular technology poses a threat to the environment. Securing unanimity of scientific views on the effect of the release of genetically engineered organisms into the wild is virtually impossible, due to individual and industry vested interests. In a situation where an ecologist would readily disagree with a molecular biologist, and a basic researcher generally is more cautious than the clinical physician or industrial scientist, a convergence of opinion on topical biotechnology issues is extremely unlikely.⁸⁰

⁷⁷ Howard Florey, [1995] E.P.O.R. at 552. ("Obviously recognizing that the EPO is not the right institution to decide on fundamental ethical questions, the opponents requested that the EPO carry out a referendum to find out what the public in the Contracting States really wants to be patented. This request is refused since in opposition proceedings the burden of proof lies with the opponent—if they felt that such a survey might assist their case, it was up to them to carry it out.").

⁷⁸ Plant Genetic Systems v. Greenpeace, [1995] E.P.O.R. at 369.

⁷⁹ *Id.*

⁸⁰ It has been suggested that science is ethically neutral; while motivations for scientific research were listed in order of priority as: self-actualization, self-esteem, or individual ego; concern for society needs; the need for personal economic and emotional security; and the actual scientific urge that drives

The EPO's pro-patent stance is not without precedent. The Supreme Court of the United States had earlier charted the same path in *Diamond v. Chakrabarty*.⁸¹ In *Chakrabarty*, the respondent had filed a patent application for the invention of a bacteria, *pseudomonas*, stably transformed with plasmids that allowed the bacteria to degrade oil.⁸² The carbon containing genes for hydrocarbon degradative pathways are not found naturally in *pseudomonas* in the environment.⁸³ This invention was designed for bioremediation of oil spills. The Court held, *inter alia*, that a genetically engineered microorganism is not a product of nature, but rather a product of a person's work, and thus is patentable. In dismissing the argument that the invention would adversely affect the environment, the Court held:

We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life It is argued that this court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter

We disagree We are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.⁸⁴

But would the court have declined "competence to entertain these arguments" if they had been supported by scientific evidence? Did the issues really call for legislative intervention or was this a shirking of judicial

research scientists. See K.P. Kochhar, *What Has Ethics Got To Do With Research?*, 9 EUBIOS J. ASIAN & INT'L BIOETHICS 163. This order of priorities was said to have led "to acute pervasive and intractable dilemmas." *Id.*

⁸¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁸² *Id.* at 305.

⁸³ *Id.*

⁸⁴ *Id.* at 316-17.

responsibility? It should be noted that the United States Patent Act⁸⁵ has no language equivalent to section 13(3) of Singapore's Patent Act, Article 53(3) of the EPC, or section 32 of Japanese Patent Law. The United States Supreme Court relied on section 101 of the Patent Act, which defines patentable inventions as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title⁸⁶

The statute is silent on morality. The Court, while interpreting the section, held *inter alia* that Congress intended statutory subject matter to include "anything under the sun made by man" as long as it is a "new and useful process, machine, manufacture, composition of matter"⁸⁷ Undoubtedly, the bacterium was new and useful; but assuming that there was some cogent scientific evidence before the court highlighting the potential adverse effects of the bacterium on the environment and public health, would the court have deemed this sufficient to negate the invention's usefulness? The Court would obviously be serving public interest by rejecting patents for inventions whose usefulness to society would be overwhelmed by specific detrimental effects. Or would the Court still defer to Congress? This was definitely a policy decision, and the Court has passed on numerous policy judgments in the past.⁸⁸

⁸⁵ See Patent Act, 35 U.S.C. §§ 101-376 (2002).

⁸⁶ 35 U.S.C. § 101.

⁸⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 307 (1980). Note, however, that apart from satisfying section 101, the requirements of novelty and non-obviousness under sections 102 and 103 must be met. See 35 U.S.C. §§ 102-103.

⁸⁸ For instance, in *Feist Publ'ns, Inc. v. Rural Telephone Serv. Co.*, 499 U.S. 340, 353 (1991), the Supreme Court rejected the "sweat of the brow" doctrine earlier espoused by the Southern District of New York in *Jeweller's Circular Publ'g Co. v. Keystone Publishing*, 281 F. 83 (S.D.N.Y. 1922), and denied originality to Rural's copyright claims in their White pages telephone directory. The Southern District of New York held:

The right to copyright to a book upon which one has expended labor in its preparation does not depend upon whether the materials . . . are *public juris*, or whether such materials show literary skill or originality, either in thought or in language, or anything more than industrious collection. The man who goes through the streets of a town and puts down the names of each of the inhabitants, with their occupations and their street number, acquires materials of which he is the author.

Id. at 88. In *Feist Publications*, Justice O'Connor observed that the "sweat of the brow" doctrine effectively eroded the principle that no one could copyright facts or ideas. 499 U.S. at 353. The underlying

It would be interesting to know if the Court would still uphold *Chakrabarty* in light of the TRIPS agreement. Articles 27(1) & (2) of the TRIPS agreement are essentially analogous to both sections 13(3) & (4) of Singapore Patent Act and Article 53(a) of the EPC. The most likely outcome is that the morality provisions of TRIPS would take a back seat to the pro-invention policy embedded in U.S. patent law.

How would *Greenpeace*, *Howard Florey*, and *Chakrabarty* be resolved in Singapore? Singapore has an explicit policy promoting biotechnology. Further, there is no prohibition in Singapore against patents for animal or plant varieties, or biological process for the production of animals or plants.⁸⁹ In the United Kingdom, plant varieties are protected against patenting by the Plant Varieties and Seed Act,⁹⁰ while the EPO Examining Division in *Harvard Oncomouse* excluded animal varieties from patentable inventions ostensibly on moral and ethical grounds.⁹¹ But events in the United States since *Chakrabarty* seem to have influenced European Union policy on animal patenting as demonstrated by *Oncomouse*. The patent's principal claims were:

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into non-human mammalian animal at a stage no later than the eight-cell stage.
2. A transgenic non-human mammalian animal whose germ cells and Somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than eight-cell stage, said

policy in the Court's rejection of the district court's view in *Jeweller's Circular Publishing* was to prevent a monopoly over public domain materials. *Id.*

⁸⁹ Cf. European Patent Convention, *supra* note 62, art. 53(b) (disallowing patents for "plant and animal varieties or essentially biological processes for the production of plants or animals . . .").

⁹⁰ Under section 3 of the Act, plant breeders or discoverers of distinctive, uniform and stable plant varieties are granted proprietary rights for a period not exceeding thirty years. Plant Varieties Act, 1997, ch. 66, pt. 1, § 11. The minimum period of protection for trees and grapevines is twenty-five years, while it is twenty years for other plants. *Id.* See also *The Plant Varieties and Seed Act was Based on the Convention for the Protection of New Varieties of Plants*, Dec. 2, 1961, available at http://www.unep.org/gopher/un/unep/elipac/intl_leg/treaties/tre-0310.txt.

⁹¹ *Harvard/Onco-Mouse*, [1990] E.P.O.R. 4. The EPO Examining Division gave the rationale for the exclusion as follows: "[a]nimal varieties are not an appropriate subject-matter for patent protection". *Id.* at 7-8. See also Sigrid Sterckx, *European Patent Law and Biotechnological Inventions*, in *BIOTECHNOLOGY, PATENTS AND MORALITY*, *supra* note 7, at 33.

oncogene optionally being further defined according to any one of claims 3 to 10.⁹²

The Technical Board of Appeal overruled the Examining Division's refusal to grant the patent on various grounds, but required the Division to consider further whether exploitation of the invention would be contrary to "ordre public" or morality under article 53(a) of the EPC.⁹³ On remand, the Examining Division concluded that the invention could not be considered immoral or contrary to public order.⁹⁴ It noted further that the test animal was 'useful in cancer research, and therefore beneficial to mankind.'⁹⁵ Finally, on November 7, 2001, the EPO Opposition Division ruled that the patent claim must be limited to "transgenic rodents containing an additional cancer gene,"⁹⁶ instead of a transgenic non-mammalian animal. The ruling considerably narrowed the scope of the claim, not on ethical or moral grounds, but to encourage competition and facilitate the patentability of subsequent inventions in the field.

In Singapore, plant and animal variety inventions are patentable. The Select Committee recommended that Parliament not bar plants and animals from patentability.⁹⁷ This position is consistent with both the TRIPS agreement, which protects "any invention,"⁹⁸ and the U.S. Patents Act, under which plant varieties are patentable.⁹⁹ Furthermore, after *Oncomouse* the European ban on animal patents seems moot.

The Select Committee in Singapore had justified its recommendation for plant and animal patents to Parliament on the need to provide incentives to invest and innovate.¹⁰⁰ This conforms to Singapore's biotechnology

⁹² See *Harvard/Onco-Mouse*, [1990] E.P.O.R. at 6.

⁹³ *Harvard/Onco-Mouse*, [1990] E.P.O.R. 501, 504.

⁹⁴ *Harvard/Onco-Mouse*, [1991] E.P.O.R. 525.

⁹⁵ *Id.* at 527.

⁹⁶ See "*Oncomouse*" *Opposition Proceedings Resume at EPO*, EPO/PRESS RELEASE (Nov. 5, 2001), http://www.european-patent-office.org/news/pressrel/2001_11_07_e.htm.

⁹⁷ See Stanley Lai, *The Singapore Patents Act 1994: Whither Biotechnology Patent Law?*, 7 SINGAPORE ACADEMY OF LAW J. 397-98 (1995).

⁹⁸ Article 27(1) of the TRIPS protects "any invention" as long as it is new, inventive, and susceptible to industrial application. See TRIPS, *supra* note 43, art. 27(1).

⁹⁹ Section 161 of the United States Patent Act protects patents for plants:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

Patent Act, 35 U.S.C. § 161 (2002).

¹⁰⁰ See Lai, *supra* note 97.

policy. Besides, Singapore would be less competitive if it deviated from the pro-biotechnology patent policy of the United States and Europe.

Viewed from this perspective, it is highly improbable that *Greenpeace*,¹⁰¹ *Howard Florey*,¹⁰² *Chakrabarty*,¹⁰³ and *Harvard Oncomouse*¹⁰⁴ would run afoul of Section 13(3) of the Patent Act. This legal outcome is not assured, but reflects the expediciencies of economic policy. For instance, if an animal patent were challenged under Section 43(1) of the Prevention of Cruelty to Animals Act,¹⁰⁵ it is doubtful that the patent would be invalidated. The rationale of *Harvard Oncomouse*¹⁰⁶ and the policy of promoting biotechnology research in Singapore would most likely inform such a decision.

In arguing that Singapore's biotechnology patent policy should steer clear of moral judgments, Stanley Lai posited that ethics and moral issues are transitory, and that "moral norms in the field of biotechnology, or at least the courts' perception of them, are liable to change over time."¹⁰⁷ This uncertainty is understandably the down side of ethical and moral considerations and probably explains their negligible influence in shaping the course of biotechnology patenting. It is becoming increasingly clear that biotechnology's commercial promise is too bright and its public benefits too attractive for its fate to be decided by the vagaries of ethics and morality.

It can be gleaned from the foregoing that the morality of human gene patenting, or the propriety of plant and animal variety patenting, is clearly outside the ambit of the Committee. It is for the courts and patent examiners in Singapore to decide on a case-by-case basis, while interpreting the relevant statutory provisions. It is highly improbable that the Committee would advise the Parliament to deviate from *Greenpeace*. This would be true even if gene or plant and animal patenting were found to be morally reprehensible or unpopular in Singapore. The only way to remain competitive in this field is for Singapore to align itself with the major biotechnology players.

¹⁰¹ *Plant Genetic Systems v. Greenpeace*, [1995] E.P.O.R. 357.

¹⁰² *Howard Florey*, [1995] E.P.O.R. 541.

¹⁰³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁰⁴ *Harvard/Onco-Mouse*, [1991] E.P.O.R. 525.

¹⁰⁵ It is an offence punishable with fines not exceeding USD 500 or imprisonment not exceeding 6 months or both. Prevention of Cruelty to Animals Act § 43 (2).

¹⁰⁶ *Harvard/Onco-Mouse*, [1991] E.P.O.R. 525.

¹⁰⁷ See Lai, *supra* note 96, at 346-47 (explaining that patents for contraceptive inventions were refused on morality grounds).

IV. FOSTERING THE ETHICS OF BIOMEDICAL RESEARCH IN SINGAPORE

The Committee is to be guided by the imperatives of protecting “the rights and welfare of individuals” and promoting the realization of biomedical science’s “full potential in Singapore, and for the benefit of humankind.”¹⁰⁸ The terms of reference are:

1. Examine legal, ethical, and social issues, arising from research on human biology and behavior and its applications; and
2. Develop and recommend policies to the Life Sciences Ministerial Committee on legal, ethical and social issues¹⁰⁹

The Committee has the task of laying the groundwork for a prosperous Singaporean biotechnology industry that is fully responsive to people’s rights and welfare. Simultaneously, the Committee is charged with fostering certain legal, ethical, and social norms that are both supportive of the industry’s growth and protective of public interests.

This article explores how this task might be accomplished within Singapore’s ethical and legal framework and in the larger context of varied global perceptions of the biotechnology industry. The following are high priority items for policy makers.

A. Stem Cell Research and Human Cloning

Human stem cells are unspecialized cells with the potential to renew themselves, and differentiate into other cell types in the human body.¹¹⁰ There are three types of stem cells: adult, fetal, and embryonic.¹¹¹ Adult stem cells “are cells that can be isolated from adult tissues such as body, brain, intestine, skin, bone marrow, muscle and fat.”¹¹² Though recent research has shed light on the great potential of adult stem cells isolated

¹⁰⁸ See Bioethics Advisory Committee, <http://www.bioethics-singapore.org/bac/index.jsp>.

¹⁰⁹ *Id.*

¹¹⁰ See Bioethics Advisory Committee, FAQ, Stem Cells, <http://www.bioethics-singapore.org/bac/detailed.jsp?artid=15&typeid=2&cid=22&bSubmitBy=false>.

¹¹¹ *Id.*

¹¹² Bioethics Advisory Committee, FAQ, Stem Cells, Embryonic Stem Cells, <http://www.bioethics-singapore.org/bac/detailed.jsp?artid=17&typeid=2&cid=24&bSubmitBy=false>.

from bone marrow,¹¹³ embryonic stem cells have greater promise in research. This promise is due to their inherent ability to develop into almost all of the cell types of the body, such as "the muscle, nerve and blood."¹¹⁴ For instance, Israeli scientists have grown heart tissue from human embryo stem cells, while others in the United States have used stem cells to produce insulin.¹¹⁵

Singapore has made considerable progress in research on embryonic stem cell research. For instance, Singapore has six of the estimated sixty embryonic stem cell lines.¹¹⁶ Though this figure trails some countries, such as Sweden¹¹⁷ with nineteen, Singapore will undoubtedly improve in this area.¹¹⁸ Stem cell research is arguably one of the most controversial aspects of biotechnology. Since the creation of Dolly in 1997,¹¹⁹ speculation is rife that human cloning is afoot.

In Singapore, the immediate response of the National Medical Ethics Committee¹²⁰ at its meeting in June 1997 was that there should be a total ban on human cloning.¹²¹ From the United States,¹²² Germany,¹²³ Taiwan,¹²⁴

¹¹³ According to Gwen Lee, scientists can now cultivate both bone and cartilage cells and are close to the point of growing "specific tissues such as kidney, liver, and heart-muscle cells." Lee, *supra* note 2.

¹¹⁴ The scientific terminology for this unique quality is "pluripotentiality." See Bioethics Advisory Committee, FAQ, Stem Cells, Embryonic Stem Cells, <http://www.bioethics-singapore.org/bac/detailed.jsp?artid=17&typeid=2&cid=24&bSubmitBy=false>. Embryonic stem cells may be derived by applying the following four methodologies: human embryo created by in vitro fertilization (a method of infertility treatment), where excess embryos could be voluntarily donated by couples who have no need for them, and who would not want the embryos to be used otherwise; human fetal tissue, following an elective abortion or miscarriage; human embryos created by in vitro fertilization with sperm and eggs donated mainly for research purpose; and human or hybrid embryos generated asexually by somatic cell nuclear transfer of adult human cell nucleus into an enucleated human or animal egg (therapeutic cloning). *Id.*

¹¹⁵ Tim Radford, *Stem Cells Turned Into Heart Tissue*, GUARDIAN UNLIMITED, Aug. 2, 2001, <http://www.guardian.co.uk/genes/article/0,2763,530902,00.html>.

¹¹⁶ See Lee, *supra* note 2, at 14.

¹¹⁷ *Swedish Government Says Yes To Therapeutic Cloning*, Posting of Human Genetic Engineering, Human-GE@iatp.org (Feb. 8, 2002) (on file with author).

¹¹⁸ A solid academic and industry research base (actively funded and encouraged by the government) already exist in Singapore to facilitate greater scientific advancements in this field. See *supra* Part I; notes 5-7.

¹¹⁹ Dolly is the name given to the sheep cloned by scientists at the Roslin Institute, Edinburgh, Scotland in 1997. See Campbell et al.; I. Wilmut et al., *supra* note 27. Dolly was created through a technique that involves the transfer of the nucleus of a cell to an unfertilized egg whose genetic materials are removed. *Id.* The egg cell and the "reconstructed embryo" are activated to grow by a short electric impulse. *Id.* The embryos are then cultured in the lab for 5-6 days before being implanted into a surrogate ewe. *Id.*

¹²⁰ The National Ethics Committee (NMEC) was established in January 1994 as the national authority to assist the medical profession in addressing ethical issues in medical practice and to ensure a high standard of ethical practice in Singapore. It is instrumental to several ethical guidelines, to facilitate the making of sound ethical decisions by medical professionals in clinical practice. See NATIONAL MEDICAL ETHICS COMMITTEE, NATIONAL MEDICAL ETHICS COMMITTEE: A REVIEW OF ACTIVITIES 1, 1994-1997, available at http://www.moh.gov.sg/nmec/NMEC94_97.pdf.

¹²¹ However, the cloning of DNA and human cells in culture was to continue. *Id.* at 11.

India,¹²⁵ Australia,¹²⁶ Sweden,¹²⁷ and the United Kingdom,¹²⁸ the political and ethical objection to human reproductive cloning is unanimous, though acceptance of therapeutic cloning remains an open issue.¹²⁹ The Committee has recommended that cloning or copying of human beings be banned, but that research on human stem cells be allowed.¹³⁰ The Committee also recommended that, consistent with other countries,¹³¹ a Statutory Board be put in place to oversee stem cell research.¹³²

The ethical and moral objections to embryonic stem cell research and human cloning range from scientists wanting "to play God"¹³³ to the destruction of embryos, which some regard as humans.¹³⁴ The perception of embryos as humans has brought the concept of personhood to the forefront

¹²² The Bush administration is opposed to human cloning. See *supra* note 57 and accompanying text. Stem cell research for therapeutic purposes is allowed under prescribed conditions. *Id.* The House of Representative has voted to ban all forms of cloning; whether therapeutic or reproductive. *Id.* Some states, like California, already have laws in place against human cloning. See *America's Next Ethical War*, ECONOMIST.COM, Apr. 12, 2001, at http://www.economist.com/PrinterFriendly.cfm?Story_ID=568825.

¹²³ Authorities in Germany still prohibit human cloning, but allow for limited embryo stem research. See Schiermeier, *supra* note 56.

¹²⁴ Authorities in Taiwan have banned human cloning, but allowed limited stem cell research. See *Taiwan Bans Human Cloning in Stem Cell Research*, *supra* note 55.

¹²⁵ In India, the government has crafted rules that prohibit human cloning. Kalpana Jain, *Government Drafts Rules Banning Human Cloning*, TIMES OF INDIA, Feb. 2, 2002.

¹²⁶ Human cloning is prohibited in Australia. See NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, AUSTRALIAN HEALTH ETHICS COMMITTEE, SCIENTIFIC, ETHICAL AND REGULATORY CONSIDERATIONS RELEVANT TO CLONING OF HUMAN BEINGS 2 (1999).

¹²⁷ On January 29, the Government of Sweden, one of the leading countries in stem-cell research, declared that it favored cloning early-stage embryos for therapeutic purposes and was set to effect legislative amendments to reflect this policy. See *Swedish Government Says Yes To Therapeutic Cloning, posting of Human Genetic Engineering*, *supra* note 117. Though human cloning remained banned, the Social Affairs Minister was quoted as follows: "We have a positive view of somatic cell transfers on condition that they are done in ethically acceptable forms." *Id.*

¹²⁸ See *supra* note 54 and accompanying text.

¹²⁹ There are two types of cloning: therapeutic and reproductive. See Bioethics Advisory Committee, FAQ, Human Cloning, at <http://www.bioethics-singapore.org/bac/detailed.jsp?artid=14&typeid=2&cid=17&SubmitBy=false>. "Therapeutic cloning is the production of cloned cells to produce tissues and or organs mainly to improve health care treatments." *Id.* The technique can be applied to produce human proteins, replacement tissues, and organs, and cell-based therapies for chronic diseases where there is cell damage. *Id.* "Reproductive cloning results from the placement of a cloned embryo into the womb of a surrogate mother, to allow for pregnancy and a live birth." *Id.* It could be very useful in animal farming and for the preservation of endangered animal species. *Id.* Several animal species such as sheep, pigs, cows and bulls have been cloned in recent times. *Id.* The first of such species was a sheep known as "Dolly." *Id.* Human reproductive cloning is at present considered morally reprehensible and scientifically unacceptable by many governments and scientists respectively. *Id.*

¹³⁰ NATIONAL MEDICAL ETHICS COMMITTEE, *supra* note 118.

¹³¹ Such countries include the United States, United Kingdom, Canada, and others.

¹³² See Chan Kay Min, *Statutory Board Right Move: Stem Cell Researchers*, STRAITS TIMES INTERACTIVE, Jan. 14, 2002, at <http://straitstimes.asia.com.sg/cybernews/story/0,1870,96409-1011045540,00.html?l>.

¹³³ See ANDREW & NELKIN, *supra* note 34.

¹³⁴ For example, many religious leaders and religious groups regard embryos as humans.

of recent bioethics discourse,¹³⁵ and challenged the conventional legal concept of embryos.¹³⁶ For example, a French Judge ruled on July 5, 1995, that a fetus was a "future human being, already alive,"¹³⁷ while the Supreme Court of Canada ruled in 1999 that allowing children to sue their mothers for prenatal injuries caused by those mothers' negligence would violate the rights of pregnant women and "result in very extensive and unacceptable intrusions to the bodily integrity, privacy, and autonomy of rights of women."¹³⁸ Since the ruling did not expressly foreclose the fetus' *locus standi* to sue, there was implicit in the ruling a recognition of the personhood of the fetus or embryo. The branding of embryos and fetus as persons is the basis of pro-life advocates' objections to embryonic stem cell research.¹³⁹

Of equal importance is the danger that the market for embryos will be commercialized.¹⁴⁰ For instance, the National Institute of Health in the United States expressly prohibits the use of inducements, monetary or otherwise, for the donation of embryos, and emphasizes the distinction between fertility treatment and the decision to donate embryos for

¹³⁵ See Sahin Aksoy, *Personhood, A Matter of Moral Debates*, EUBIOS J. ASIAN & INT'L BIOETHICS 3-4 (1997). The author highlighted philosophical and monotheistic religions' contention of the separate existence of the 'soul' without which there could be no 'body', to canvass for determining the exact time of "ensoulment". *Id.* This, he believed, was the key to ascertaining when life came into being, and a proper understanding of this could put an end to termination of "human persons", such as performing abortions. *Id.* See also Jason T. Eberl, *The Beginning Of Personhood: A Thomistic Biological Analysis*, 14 BIOETHICS 134-53 (2000). Using a Thomistic hypothesis that human person is a composite of a biological organism and intellectual soul, the author posited that "the beginning of an individual human biological organism occurs at the moment when implantation of the zygote in the uterus occurs and the 'primitive streak' begins to form." *Id.* According to Eberl, this has serious "moral implications on the status of pre-implantation biological cell clusters." *Id.*

¹³⁶ Singapore's Penal Code (1985) does not define "human being". Section 45 defines life as the life of a human being. Section 10 defines "man" as a male human being, while a "woman" is defined as a female human being. Since it is impossible to determine the sex of an embryo, it cannot be properly regarded as a human being under the Penal Code.

¹³⁷ See Marc Gozlan, *Amnesty Denied to French Anti-Abortion Protestors*, 346 LANCET 111 (1995).

¹³⁸ Dobson (Litigation Guardian of) v. Dobson, [1999] D.L.R. (4th) 1. Implicit in this ruling is the notion that the conception was already a person. See *id.* The ruling overruled a New Brunswick Court of Appeal decision that allowed six-year-old Ryan Dobson the retroactive right to sue his mother for injuries incurred in a car accident. *Id.*

¹³⁹ For instance, at the heart of cell stem research debate in the United States is the conflict over when life begins. President Bush's contention, (which is shared by many pro-life groups in and outside the United States) is that "the embryo from which a stem cell is harvested is a human being." See *Bush Calls on Senate to Ban Human Cloning* (Fox News Channel broadcast, Apr. 10, 2002), available at <http://www.foxnews.com/story/0,2933,50004,00.html>. President Bush wanted the U.S. Senate to enact a Bill (like the House of Representative did in 2001) that would completely prohibit all forms of stem cell research-both therapeutic and reproductive. *Id.* According to Bush, "Life is creation, not commodity . . . Advances in new biotechnology must never come at the expense of human conscience . . . it would be a mistake for the U.S. Senate to allow any kind of human cloning to come out of that chamber." *Id.*

¹⁴⁰ In South Africa, this debate intensified when it was learned that placentas were sold to a French company. See BMJ 311 (1995), cited in Embryo Status News, available at <http://www.biol.tsukuba.ac.jp/~macer/NBB/NBBEM.html>.

research.¹⁴¹ Whatever the general attitude might be towards stem cell research, it is clear that Singapore will press ahead with embryonic stem cell research. This is good news for the biomedical community, but the Committee must develop a means of preventing abuse and protecting "the rights of the individuals."¹⁴²

Along these lines, the Ministry of Health in Singapore has guidelines regulating the practice of human embryology and in-vitro fertilization.¹⁴³ The guidelines prohibit the sale of embryos and require the informed, uncompensated consent of donors.¹⁴⁴ It is preferable, however, to have these ethical guidelines enacted into law by Parliament to clarify the scope of individual rights and create criminal sanctions for wrongdoing. The United Kingdom, for instance, has adopted the Human Fertilization and Embryology Act.¹⁴⁵ The Act clearly defines the rights and limits of all parties and creates penalties for violations of the statute.¹⁴⁶ The United Kingdom has also enacted the 2001 Human Reproductive Cloning Act, which criminalizes the placement of a human embryo, which has been created by means other than fertilization, in a woman. The statute provides a maximum penalty of ten years imprisonment, a fine, or both.¹⁴⁷ This is a clear signal that human cloning is unlawful in the United Kingdom. Singapore would do well to follow this example.

It does not necessarily follow, however, that government prohibitions on cloning have eliminated demand for the technology.¹⁴⁸ This has given rise to the theory of a reproductive right in cloning and the argument that the

¹⁴¹ Compliance with these guidelines is enforced by the requirement that a request for National Institute of Health ("NIH") funding for research using these cells must include a signed assurance that the cells were derived from human embryos or fetal tissue in accordance with these guidelines. See *NIH Fact Sheet on Human Pluripotent Stem Cell Research Guidelines*, NATIONAL INSTITUTE OF HEALTH, available at <http://www.nih.gov/news/stemcell/stemfactsheet.htm>.

¹⁴² Bioethics Advisory Committee, Introduction, Terms of Reference, <http://www.bioethics-singapore.org/bac/introduction.jsp>.

¹⁴³ See Ministry of Health, Guidelines On Human Embryology and the Practice of Reproductive Technologies in Singapore.

¹⁴⁴ *Id.*

¹⁴⁵ Human Fertilization and Embryology Act, 1990, available at http://www.hmsa.gov.uk/acts1990/Ukpga_19900037_en_2.htm.

¹⁴⁶ For instance, a person who creates an embryo or keeps or uses an embryo without a license would be guilty of an offence, and upon conviction, liable for a maximum of two years imprisonment or a fine or both. *Id.* at § 41(4)A.

¹⁴⁷ *Id.* at § 1(1)(2).

¹⁴⁸ For instance, an Italian scientist, Dr. Severino Antinori, recently announced at a conference in Dubai that a woman was pregnant with a cloned baby, the "son of a rich Arab." See Ananova, *First cloned baby is son of rich Arab*, Apr. 7, 2002, available at http://www.ananova.com/yournews/story/sm_561586.html.

right to clone is constitutionally guaranteed.¹⁴⁹ It would be interesting to see anti-cloning laws around the world challenged on constitutional grounds of free speech, related to scientific enquiries and reproductive rights.

In Singapore, challenging embryonic stem cell research and cloning on constitutional grounds would be a futile academic exercise. Assuming for the sake of argument that a human embryo is a person,¹⁵⁰ then research in embryos would violate section 9(1) of the Constitution of the Republic of Singapore,¹⁵¹ which provides that no "person shall be deprived of his life or personal liberty save in accordance with law," or section 10(1) which prohibits slavery. Conversely, aggrieved scientists might challenge a ban on human cloning as an infraction of their rights to make scientific enquiries as guaranteed by section 14(1)(a) of the Constitution. Of course, these analogies are far fetched. But should they ever arise, it is clear which view the courts would take.

B. Ownership and Sourcing of Genetic Materials

Another hotbed of ethical and moral controversies in biotechnology is the ownership of and prospecting for human genetic materials. In *Moore*,¹⁵² the defendant had developed a patented cell line worth millions of dollars, based on the plaintiff's genetic material without his knowledge or consent. The Supreme Court of California, relying on the Health and Safety Code, which prohibited patients' ownership interest in excised body parts,¹⁵³ held that the plaintiff had no property right in his excised cells. Consequently, he had no claim to the patented cell lines. The court also reasoned that allowing such ownership could stifle biomedical research. However, after *Moore*, the California Legislature enacted a tissue-specific bill, which prohibits the stealing of human eggs, sperm, or embryos.¹⁵⁴

Similarly, the question of ownership arose in *Del Zio v. Manhattan's Columbia Presbyterian Medical Center*.¹⁵⁵ In *Del Zio*, the ovum and sperm of a couple were destroyed in the course of in-vitro fertilization. The court held that the woman had no property interest in the destroyed material, but

¹⁴⁹ See Lori B Andrew, *Is There A Right To Clone? Constitutional Challenges To Ban On Human Cloning*, 11 HARV. J.L. & TECH. 647, 676 (1998).

¹⁵⁰ For a discussion of the French and Canadian rulings, respectively, see *supra* notes 135, 136 and accompanying text.

¹⁵¹ SINGAPORE CONST. (1963, revised 1985, 1999).

¹⁵² *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

¹⁵³ CAL. HEALTH AND SAFETY CODE §§ 7001, 4054.4.

¹⁵⁴ See ANDREWS & NELKIN, *supra* note 34, at 164.

¹⁵⁵ No. 74-35558, U.S. Dist. Lexis 14450 (SDNY, 1978).

she was awarded USD 50,000 damages for emotional distress.¹⁵⁶ However, in *Whaley v. Tuscola*,¹⁵⁷ it was held that relatives had a constitutionally protected property interest in the dead body of a relative. In the same vein, in *Brotherton v. Cleveland*,¹⁵⁸ a widow successfully sued an Ohio hospital for removing her dead husband's cornea without her consent. Although *Moore* and similar cases follow the traditional common law approach,¹⁵⁹ it now seems that courts in the United States are recognizing proprietary claims to body parts.

In the context of modern commercially-driven biotechnology, however, there is an increasing demand for a formula for appropriate sharing of benefits between individual donors and researchers. In India, for example, the Committee under the Department of Biotechnology recommended in February 2002 that "though human material in its natural state cannot be the subject of a direct financial gain . . . if any commercial use were to be made of the biological samples, appropriate benefit-sharing agreements would need to be made."¹⁶⁰

This reflects the mantra that dominates the discourse on trade and politics. The South demands acknowledgement of genetic sources in patent specifications or claims, as well as adequate remuneration for use of genetic material. It also demands that the provisions of the TRIPS agreement be aligned with that of the Rio Biodiversity Convention.¹⁶¹ The bio-prospecting activities of biotechnology companies are often deprecated as "bio-feudalism" that is designed to make "bioserfs" out of developing countries.¹⁶² For example, the Neem tree in India, which has been used pharmaceutically and agriculturally for centuries, became the subject "of sixty-five patents filed by U.S. and European companies."¹⁶³ This is no more than robbing the public domain. It is feasible because the conventional patent regime largely ignores such traditional uses as part of the prior art that could render the Neem tree and similar patents either unpatentable or invalid due to lack of novelty.¹⁶⁴

¹⁵⁶ *Id.*

¹⁵⁷ 58 F.3d 111, 112, 116, (6th Cir. 1995).

¹⁵⁸ 923 F.2d 477 (6th Cir. 1991).

¹⁵⁹ For a very detailed discussion of these cases, see Terry, Kaan Sheung-Hung, *Rights, Ethics And The Commercialization Of The Human Body*, SING. J. LEGAL STUDIES 483-508 (2000). See also N. Remigius Nwabueze, *Biotechnology and the New Property Regime in Human Bodies and Body Parts*, 23 LOYOLA L.A. INT'L & COMP. L. REV. 19 (2001).

¹⁶⁰ See Jain, *supra* note 125.

¹⁶¹ For a detailed discussion of these issues, see Vandana, *supra* note 31.

¹⁶² *Id.*

¹⁶³ *Id.* See also ANDREWS & NELKIN, *supra* note 34, at 71.

¹⁶⁴ For instance, under the United States Patent Act, 35 U.S.C.A. § 102, the prior art comprises the actual use of an invention, a previous patent or a written description of the invention in the United States or

Blood and other body samples are randomly taken from poor people around the world for genetic screening and the subsequent patenting of new drugs, diagnostic tests, bioengineered substances, or valuable genetic traits derived from them.¹⁶⁵ Such screenings are characteristically without informed consent of their subjects. Between 1990 and 1991, the U.S. government filed for patents on genes from Melanesians in the Solomon Islands, cell lines from a Guyami woman in Panama, and genes of a Hagahai man from Papua, New Guinea.¹⁶⁶ The ethical and moral issues raised here are patently clear: from *Moore* down to the Hagahai man, the moral and ethical propriety of genetic prospecting is clearly reprehensible.

In Singapore, trade in human blood is prohibited. Section 4(1)(a) of the Private Hospitals and Medical Clinics Act provides:

No person shall: (a) buy or offer to buy or (b) sell, or offer to sell human blood or right to take blood from the body of another person.¹⁶⁷

Violation of this Section is punishable by a maximum fine of SGD 20,000, or imprisonment for a term not exceeding two years, or both.¹⁶⁸ Similarly, section 14(1) of the Human Organ Transplant Act¹⁶⁹ prohibits trading in organs and blood. A contract in violation of this statute is void, and violators are subject to a fine not exceeding SGD 10,000, or to imprisonment for a term not exceeding a year, or to both.¹⁷⁰

The provision of section 14(4) is instructive. It exempts from prohibition the sale of "a specified class or classes of product derived from any organ or blood that has been subjected to processing or treatment." This protects biotechnology products derived from organs and blood samples including patented biotechnology products.¹⁷¹

A similarly favorable provision is section 16(1) of the Human Organ Transplant Act. Intended to promote organ transplants, it is no more than a

a foreign country. In India for example, traditional pharmaceutical products and medicine ("ayurveda") is based largely on unwritten traditional knowledge that has survived successive generations. See Edna Fernandes, *Alternative Medicine, Ancient Cures in a Global Market*, Fin. Times, Apr. 30, 2002, at 11. Such uses do not form part of the prior art in the United States. *Id.*

¹⁶⁵ See ANDREW & NELKIN, *supra* note 34, at 71.

¹⁶⁶ See *id.* The United States, however, withdrew the Guyami and Solomon Islands patents under pressure in 1995. *Id.*

¹⁶⁷ Private Hospitals and Medical Clinics Act, 1980, ch. 248 (Sing.).

¹⁶⁸ *Id.*, ch. 248, § 4(2).

¹⁶⁹ *Id.*, ch. 131, A (1987).

¹⁷⁰ *Id.*, ch. 131, § 14(2).

¹⁷¹ *Id.*

codification of *Moore*. Though express or implied consent is required for the removal of any organ from the body of a living person in the course of an operation or treatment, there is no a statutory penalty for failure to obtain consent, nor does lack of consent vitiate the subsequent use of the removed organ. This pro-biomedical research law is undoubtedly intended by Parliament to encourage research.

As noted earlier, the Committee has the duty to create a policy that both promotes biotechnology research and protects the rights and welfare of individuals. This is a delicate balancing act. Consequently, it is suggested that Singapore should adopt an enforceable regime that punishes lack of informed consent in biomedical research, though this would not necessarily invalidate the use of any organ derived under such circumstances.

Another pertinent issue that the Committee should address is compensation for the subjects of medical research. Is it fair for the human subjects to get nothing from products freely derived from their bodies? Is *Moore* good policy in today's multi-billion dollar biotechnology industries?¹⁷² What is wrong with getting paid for organs that could potentially save thousands of lives in pharmaceutical and medical products? Or is it in the interest of the "rights and welfare of the individuals"?

C. Genetic Testing and Discrimination

Genetic or DNA testing allows the detection of predisposition to many genetic diseases. The diagnostic kits for genetic testing are usually patented, and testing is usually done with the consent of the patentee, subject to the payment of licensing fees. Patenting of genetic tests therefore contributes to higher health care costs.

According to Ricarda Steinbrecher, "for the best health care, discovery about genes must be freely available, not just exclusively to profit the drug companies."¹⁷³ Sue Mayer underscored the real problem: "[C]ompanies are getting greedy, and the NHS could be bankrupted by having to pay royalties for gene tests and drugs."¹⁷⁴ In response, public

¹⁷² *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

¹⁷³ See *Patenting Genes—Stifling Research and Jeopardizing Healthcare*, GENEWATCH, available at http://www.genewatch.org/HumanGen/Press_Releases/pr18.htm. Another adverse effect of gene patenting is that it could stifle research. See James Meek, *Doctors Hindered By Company's Gene Patent*, GUARDIAN UNLIMITED, Feb. 7, 2002, available at: <http://www.guardian.co.uk/genes/article/0,2763,646089,00.html>. The high-level secrecy of data protection is fueled by the race for patents. *Id.* Data hoarding could cripple research since it is bound to constrain the flow of scientific information. *Id.* See also Merz, Jon F, et al, *Diagnostic Testing Fails The Test*, NATURE 415, 577-579 (2002) (finding that U.S. laboratories have refrained from offering clinical-testing services for haemochromatosis because of patents).

¹⁷⁴ See ANDREWS & NELKIN, *supra* note 34.

interest groups in the United States have opposed the first patent for diagnostic test kit for breast cancer genes, marketed by Myriad at a cost of USD 2,000. An absolute monopoly was alleged to be unfavorable to public interest.¹⁷⁵

As noted, the Committee has no authority over gene patenting. It is the prerogative of patent examiners and courts to determine the patentability of genes against the background of patent law requirements. But the Committee could certainly make recommendations to limit predatory marketing by companies that could inflate healthcare costs in Singapore. This would amount to a balancing act between the interests of rich biotechnology companies and ordinary citizens. The situation would be a good instance for protecting the "rights and welfare" of the people.

Another dimension to genetic testing is its potential for discriminatory use in employment and insurance, as well as the attendant privacy implications.¹⁷⁶ Apart from the adverse psychological effects on the individual, the revelation that one is predisposed to cancer, for instance, might lead to an adverse employment decision even though the disease might not appear for many years. According to Barbara Katz Rothman, "with genetic testing for the breast cancer gene, a three-year-old girl can have a diagnosis of breast cancer before she even has breasts."¹⁷⁷

Though the triggering of a genetic disease could depend on certain environmental factors or habits, the general perception of genetic diseases is they are largely governed by genetic determinism. This perception discounts the possible contribution of the environment and other factors that the individual cannot control.¹⁷⁸ Also, the advent of gene therapy has led to the prospect of "designer babies," and fueled speculations that the problem of eugenics will reemerge.¹⁷⁹ For instance, Chicago doctors recently helped a thirty year-old woman give birth to a baby free from her family's early Alzheimer's disease. The doctors had used sophisticated genetic tests on batches of human eggs. Without this screening, the newborn had a 50% chance of becoming senile by the age of forty. The feat was branded as "the latest step toward designer babies and . . . evidence of a trend toward

¹⁷⁵ See Caroline Ryan, *Demand For Gene Patent Rethink*, HUMAN GENETIC ENGINEERING NEWS CLIPPINGS, Feb. 18, 2002.

¹⁷⁶ See ANDREWS & NELKIN, *supra* note 34, at 83

¹⁷⁷ *Id.* at 87.

¹⁷⁸ See Justine Burley, *Bad Genetic Luck and Health Insurance*, THE GENETIC REVOLUTION AND HUMAN RIGHTS 56 (Justine Burley ed., 1999).

¹⁷⁹ See Symposium, *Human Genome Human Being*, ACADEMY OF SCIENCES (Feb. 25, 2002), available at <http://www.calacademy.org/symposia/hghb>. See also ALLEN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS AND JUSTICE (2000).

intolerance of human imperfection.”¹⁸⁰ It is feared that eugenics, which is concerned with improving the quality of human stock, could negatively impact the handicapped and foster a feeling of societal rejection.¹⁸¹

These issues raise fundamental human rights questions. In response, some governments have enacted specific legislations prohibiting discrimination based on genetic information, especially in insurance and the work place. In the United States, for example, Congress has considered the Genetic Nondiscrimination in Health Insurance and Employment Act (S. 318 & H.R.602). The bill would prohibit the use of genetic information in determining eligibility for insurance or adjusting of premium rates. It would also forbid a health insurer from requesting, requiring, collecting, or purchasing protected genetic information concerning an individual.¹⁸² Also, some states have enacted laws prohibiting genetic discrimination.¹⁸³ Furthermore, both the United Nations Economic and Social Council's (UNESCO) Universal Declaration on Human Genomes, and the Europe Convention on Human Rights and Biomedicine, prohibit discrimination based on genetic characteristics intended to infringe or that does infringe upon human rights, fundamental freedoms, and human dignity.¹⁸⁴

Though section 12(2) of Singapore's Constitution prohibits discriminatory practices against citizens on grounds of religion, race, descent, or place of birth, there is no express prohibition against genetic discrimination. The Committee should recommend to Parliament specific legislation that is similar to the proposed United States genetic nondiscrimination law or that embodies the ideals of the UNESCO Universal Declaration on Human Genome and the European Convention on Biomedicine. Such legislation is sure to uphold the “rights and welfare” of the people.

¹⁸⁰ See Rick Weiss, *Alzheimer's Gene Screened From Newborn*, WASH. POST, Feb. 27, 2002, at A1. See also James Meek, *Baby With Selected Gene Born In Britain*, GUARDIAN, Feb. 16, 2002. The baby had a desired genetic characteristic known in advance of her birth. *Id.* She was designed with “extra gift cells capable of saving her older brother if he suffers a relapse into leukemia.” *Id.*

¹⁸¹ See Simon Mawer, *Eugenics*, BBC GENE STORIES—GENES AND HISTORY-EUGENICS, available at: <http://www.bbc.co.uk/print/history/genes/eugenics/intro.html>.

¹⁸² The full text of the bill is available at the University of Houston Law Center's website, <http://www.law.uh.edu/healthlawperspectives/Genetics/010831HealthIns.html>.

¹⁸³ These include: Alabama (ALA. CODE SS 27-21 A-7, 27-52-20, 27-53-1 et seq.), California (CAL. HEALTH & SAFETY CODE §1374.7), Florida (FLA. STAT. ANN. §627.4301.34075), and Michigan (MICH. COMP. LAWS ANN. § 500.34075).

¹⁸⁴ See the Universal Declaration on the Human Genome and Human Rights, arts. 1-7, available at: <http://www.unesco.org>. See also the Europe Convention On Human Rights and Biomedicine (1997), available at <http://www.press.coe.int/cp/97/173a%2897%29.htm>.

V. CONCLUSION

The biotechnology industry unquestionably holds great promise for humanity. From boosting food production to improving the quality of healthcare, it is arguably the science to watch in the twenty-first century. But then, the risks of biotechnology may be as incalculable as its promise.

Though several ethical and moral issues remain unanswered, it is too early to announce their failure in reining in the biotechnology revolution. At least for now there are limited successes; human cloning has been put on hold and genetic discrimination has been outlawed. But, there are limited failures as well. Ethics and morality are too weak to contain gene and organism patenting, while the exploitation of human and other genetic resources remains largely unacknowledged and uncompensated.

Whether ethical and moral considerations are weak or not, they will linger as long as there is biotechnology. "Bioethics," after all, is about bringing responsibility and accountability to science. That is precisely what the Bioethics Advisory Committee in Singapore is set to do.

