SANCTIONING STEM CELL PATENTS ON THE BASIS OF MORALITY: LESSONS FROM EUROPE AND THE USA

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Introduction

The aim of this paper is twofold: firstly, to discuss and examine the morality element in the patenting of human stem cell based inventions, and secondly, to discuss its path with recommendations made in the light of the uncertainties surrounding the subject matter. What lessons can Malaysia take from Europe and the US in laying foundations for the journey towards attaining its objective of developing Malaysia into an industrialized country by the year 2020 in this era of rapidly evolving technology?

Biotechnological discoveries involving stem cells, with much commercial potential, have generated huge interest and controversies in the sphere of public health and morality. Programming genes to grow into a fully functioning heart, creating artificial life and other DNA forms that can survive in space and assist in cleaning up oil spills in the oceans, the production of synthetic food, the fight against Dengue fever, saving and reviving extinct species, are some of the possible outcomes resulting from such research. As the creation, operation and interpretation of the patent system are linked to moral standards, patent law has provided a forum for raising moral questions. Various moral approaches are used in assessing the expression of moral values by different writers.[1] These approaches provide some guidelines in assessing the expression of moral values, although they contradict and promote different values, rights and obligations.

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1 Shawn HE Harmon, 'From engagement to re-engagement: the expression of moral values in European patent proceedings, past and future' (2006) 31(5) EL Rev 642-665.

The ongoing controversy surrounding the research on the embryonic stem cells results in heated debates. The rapidly evolving technology, which holds both peril and promise, has divided public opinion as can be seen from the briefs of patent lawyers, biotech industry representatives, as well as ethical, religious and green groups. There is a need to find an acceptable pathway for the promotion of these discoveries that has the promise of improving human welfare.

Recent Developments

In May 2010, at the J. Craig Venter Institute[2] in Rockville, Maryland, the researchers created the first life form entirely with man-made DNA.[3] Venter and his team of scientists made a copy of a bacterium's entire genome and transplanted it into a related organism, where it functioned normally. The synthetic genome created is almost identical to that of a natural bacterium. This self-reproducing semi-synthetic micro-organism made in the laboratory, controlled by man-made genetic instructions with the aid of a computer, giving rise to a new life form is a gigantic step in the emerging field of synthetic genomics. According to experts, scientists have been altering DNA piecemeal for many years, producing genetically engineered plants and animals, but the ability to craft an entire organism and the creation of an artificial life offers a new power over life.[4] Venter wants to patent methods for making synthetic organisms. He and his research team are based at the non-profit J. Craig Venter Institute but they recently started a company to commercialize the work. The filing of such patent applications would give his

2 Venter is one of the scientists who developed fast DNA decoding techniques that helped bring the Human Genome Project to an early conclusion 10 years ago.

3 E Pennisi, 'Synthetic Genome Brings New Life to Bacterium', [2010] (5981) Science 328, 958 <http://www.sciencemag.org/cgi/content/full/328/5981/958> accessed 10 August 2010; Thomas H Maugh II and Shari Roan, 'Artificially created cell called a scientific feat' [2010], *Los Angeles Times* (Los Angeles, 20 May 2010) <http://www.latimes.com/news/science/la-sci-synthetic-genome-20100521,0,4710600.story> accessed 10 August 2010.

4 'Scientists play God; create first synthetic cell', *Indo-Asian News Service* (New Delhi, 21 May 2010) <http://www.hindustantimes.com/Scientists-create-first-synthetic-cell/Article1-546467.aspx> accessed 10 August 2010.

company, Synthetic Genomics Inc., exclusive rights to methods for making synthetic organisms. These are concerns arising from his future monopoly in this field of technology which would dominate the industry.

The work provides a blueprint for making organisms that would open the door to the manufacturing of vaccines, new drugs, better fuels, sources of food, manufacturing DNA [5] and other possibilities which had not been previously envisaged.

Also the stance taken by the UK government in 2008 [6] on the use of "human admixed embryos" involving human and animal genetic materials has added huge excitement and concern on embryonic stem cell research.[7] However, the above accomplishments will stir controversial questions of morality and public safety about artificial life form.

Embryonic Stem Cells - Recognition

The patentability of human embryonic stem cells is a highly controversial matter. The human embryos that are destroyed as a result of stem cell research have attracted much controversy with regard to the moral or ethical status of the embryo. For this reason, scientists are working to find new sources of materials to produce human embryonic stem cells deemed vital for research purposes. For instance, two research teams, one of which was headed by Professor Shinya Yamanaka and the

5 DNA is the code that tells cells when and how to make proteins, the building blocks of all life forms. Venter and his colleagues are researching ways to command cells to make substances such as efficient biofuels. The creation of a cell whose genome is completely under human control is a crucial step towards achieving those ends.

6 Catharine Paddock, 'Britain To Go Ahead With Human-Animal Embryos for Research' [2008] Medical News Today <http://www.medicalnewstoday.com/articles/71376.php> accessed 10 August 2010.

7 Kmietowicz Zosia, 'Regulator gives green light to using human-animal embryos' (2007) 7619 British Medical Journal 335, 531 <http://www.bmj.com/cgi/content/extract/335/7619/531-a> accessed 12 December 2009.

other by James Thomson reported in 2007 a method to generate human embryonic stem cell-like cells by reprogramming adult human skin cells with a cocktail of transcription factors, without the need of a human egg or embryo. [8] This breakthrough can lead to the production of patient specific embryonic stem cell lines that could potentially be used for cell replacement therapies. Initially there were some concerns relating to the risk of possible cancer, but the research team has made progress to deal with this problem.[9]

Also the use of human admixed embryos will aid in overcoming the shortage of embryonic stem cells. Human-animal hybrid creation is desirable because insufficient cell material from completely human sources is available. Public opinion is finely divided, with people generally opposed to such research unless it is likely to lead to medical advances.[10] Changes are outlined in the UK Human Fertilization and Embryology Act 2008[11] which amended the UK Human Fertilization and Embryology Act 1990 [12] in view of medical technology developments and changes in public ethical attitudes with respect to both human fertilization and stem cell research. This Act permits the creation of hybrid embryos for the purpose of stem cell production subject to certain restrictions, which can in turn be used to develop new medical treatments for various medical disorders. The Act created the Human Fertilization and Embryology Authority which allows women to donate their eggs for research purposes provided that there are safeguards

8 Laura Bonetta, 'European Stem Cell Patents: Taking the Moral High Road' (2008) 132 Cell 4, 514-516.

9 'Researchers get closer to safe stem cell treatments', *AFP* (14 February 2008) <http://afp.google.com/article/ALeqM5hA2tlpd1cGv2Y4H-21nArfgM98cA> accessed 10 August 2010.

10 David A Jones, 'What does the British public think about human-animal hybrid embryos?' (2009) 35 Journal of Medical Ethics 168-170.

11 Refer to Schedule 3 of the Human Fertilization and Embryology Act 2008 on 'Consent to Use or Storage of Gametes, Embryos or Human Admixed Embryos'.

12 The Human Fertilization and Embryology Act 1990 originally laid down the prohibition on buying or selling of gametes and embryos. Donation of eggs motivated by the desire to be financially rewarded through some form of remuneration may be a reality which may be seen as exploiting poorer women.

in place to ensure the women are properly informed of the risks of the procedure, and are properly protected from coercion.[13]

The stands taken by some countries will be looked at to appreciate the ethical concerns on the patentability of embryonic stem cells.

Few of the jurisdictions' laws prohibit discarding of human embryos that are surplus to use for purposes of in vitro fertilization. The UK Human Fertilization and Embryology Act 2008 compel discarding of preserved embryos in accordance with the Act when permission to retain them under the Act expires. The Act does not define the status of the embryo but allows the creation of embryos for research purposes by permitting research until day 14.[14]

The European Group on Ethics in Science and New Technologies,[15] which is an advisory group to the European Commission, on the issue of sources of stem cells made its position clear through two reports. In November 2000, it reported on ethical aspects of human stem cell research and concluded that research should first proceed with the use of spare embryos, foetal tissues, and adult stem cells, rather than by creating embryos for this purpose.[16] In May 2002, it reported that only stem cell lines which have been modified thereby acquiring characteristics for specific

[13] It is also referred to as HREA. It is UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. The HFEA licenses fertility clinics and centres carrying out in vitro fertilization (IVF), other assisted conception procedures and human embryo research. Detailed information available at <http://www.hfea.gov.uk/egg-and-sperm-donors.html> .

[14] Section 3 of the 1990 Act also prohibits placing in a woman anything other than human embryos or gametes, and placing embryos in animals. Licensing is regulated by Schedule 2 which allows HFEA discretion in determination of appropriate research activity.

[15] The Group is a neutral, independent, pluralist and multidisciplinary body. Its task is to examine ethical questions arising from science and new technologies and on this basis to issue Opinions to the European Commission in connection with the preparation and implementation of Community legislation or policies. Also refer to < http://ec.europa.eu/european_group_ethics/index_en.htm>.

[16] Anne McLaren and Göran Hermeren, 'Ethical Aspects of Human Stem Cell Research and Use' [2000] EGE Report No.15<http://europa.eu.int/comm/european_group_ethics > accessed 12 August 2010.

industrial application will satisfy the legal requirements for patentability and this report was criticized by some patent authorities.[17] The Group did not make any ethical objections to patentability involving human stem cells, irrespective of their source.

In Europe, various regulations and approaches are in place on the use of human stem cells for research.[18] The German Federal Constitutional Court has given some degree of recognition by stating that under the national Basic Law, the life of the unborn has value,[19] but not necessarily to impair rights to therapeutic or eugenic abortion. Germany has given the green light to restricted imports of embryonic stem cells from other countries.[20] Italy, Austria, Portugal, Luxembourg and Ireland provide some degree of recognition to embryo protection whereas the Czech Republic, Switzerland, Poland and Norway have inadequate domestic laws governing embryonic stem cell research. In Sweden, research with embryonic stem cells is allowed, but therapeutic cloning is not.[21] Spain is rapidly advancing into regenerative medical research and has provided new regulatory framework for such research to take place.[22] Interestingly, the most liberal approach is found in the UK,

[17] Linda Nielsen and Peter Whittaker, 'Ethical Aspects of Patenting Inventions Involving Human Stem Cells' [2002] EGE Report No. 16 <http://ec.europa.eu/european_group_ethics/publications/index_en.htm> accessed 12 August 2010.

[18] Marianne Minkowski and Others, 'Human stem cell research: scientific uncertainties and ethical dilemmas' [2001] European Science Foundation, 1-8 <http://www.esf.org/research-areas/medical-sciences/activities/science-policy/human-stem-cell-research-scientific-uncertainties-and-ethical-dilemmas.html > accessed 10 August 2010.

[19] HJ Reiger, 'Opinion of the Federal Constitutional Court on Abortion' [1993] Dtsch Med Wochensch, 118(31), 1127-30 <http://www.ncbi.nlm.nih.gov/pubmed/8344169> accessed 10 August 2010.

[20] 'Germany authorises stem cell imports' *BBC* (London, 30 January 2002) <http://news.bbc.co.uk/2/hi/europe/1791365.stm> accessed 9 August 2010.

[21] G Vogel, 'Germany dithers over stem cells, while Sweden gives green light' [2001] Science, 294 <http://web.ebscohost.com/ehost/detail?vid=4&hid=112&sid=a85fbafe-c13a-4325-9ff1-608fcc92d04e%40sessionmgr110&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#db=iih&AN=5856961#db=iih&AN=5856961> accessed 9 August 2010.

[22] Angel Raya, Juan Carlos Belmonte, 'Stem Cell Research in Spain: If Only They Were Windmills' [2009] 4 Cell Stem Cell 6, 483-486 <http://www.cell.com/cell-stem-cell/abstract/S1934-5909(09)00225-2> accessed 10 August 2010.

where the first human embryo research licences have been granted[23] and therapeutic cloning has been approved by Parliament. The bulk of the relevant law in the UK is contained in the Patents Act 1977.[24] Amendments were made to the 1997 Act by the Patents Act 2004.

In Malaysia, the Patent Act 1983 does not expressly exclude inventions that involve human biological materials. Non-patentable inventions are listed under Section 13 (1) (b) of the Act which excludes the patentability of plant or animal varieties or biological products for the production of plants or animals, other than man-made living microorganism, micro-biological processes and the products of such microorganism processes. Section 31 incorporates the element of "public order and morality" for the grant of patents. Research on human adult stem cell is allowed and research on stem cells derived from foetal tissue obtained from legally performed termination of pregnancy is also allowed. In relation to stem cell therapies, it is vital to obtain permission from the Ministry of Health which lays down the procedures to be followed for such therapies.[25] Syariah laws also play a part in a multiracial country like Malaysia with regard to intellectual property as well as moral rights. There are several similarities between intellectual property under man-made law and intellectual property in Islamic law on the prohibition of infringement of intellectual property rights and the protection of ideas and creativity from being copied by others.[26] With the rapid development of technology and the influx of contentious patent applications, Malaysia will have to be prepared to face

[23] S Mayor, 'United Kingdom grants first human embryo research licenses' [2002] BMJ, 324, 564 <http://www.bmj.com/cgi/content/extract/324/7337/562/a> accessed 10 August 2010.

[24] It is the main law that covers patents and is against the granting of patents for an invention the commercial exploitation of which would be contrary to public policy or morality - Section 1 (3).

[25] Malaysian Medical Council Guidelines 002/2009 on Stem Cell Research and Stem Cell Therapy<http://www.mmc.gov.my/v1/docs/MMC_Guideline_001-2009_Draft__Stem_Cell__-_040909_Print_Version2.pdf> accessed 1 September 2010.

[26] Haliza A Shukor, 'Cultivating Intellectual Property Protection Awareness Within A Research Environment' (2009) 5 MLJA 34, 3.

the challenge of narrowing the gap between the national and the Syariah laws, keeping in mind the religious sentiments of the various communities.

Nature of Patent Protection and the Morality Criterion

Patents are national rights and are recognized by the country which issued the patent. The local courts will decide on the validity and infringement of the patent. However in the case of the member states of the European Union, the patent may be granted for a group of countries within Europe. Some countries have similar legislation as a result of the Paris Convention for the Protection of Industrial Property of 1883, the Berne Convention 1886 and the Patent Cooperation Treaty (PCT) where countries entered into multilateral arrangements which allow member states to enforce their own laws. Malaysia acceded to the PCT in 2006 enabling it to make cross-border filing easier.

The scope of patents in both the UK and throughout Europe in the early days of biotech patenting had, by and large, been governed by the European Patent Convention 1973 (EPC).[27] Regarded as the effective pacemaker for patent law throughout Europe, it explicitly excludes from patentability certain types of inventions, the exploitation of which would be contrary to public policy even though they satisfy the usual conditions of patentability.[28] The patenting of uses of human embryos in Europe for industrial and commercial purposes is expressly

[27] The EPC provides the necessary legal framework for the granting of European patents through a procedure before the European Patent Office. In the UK, the revised version of the European Patent Convention (EPC 2000) is implemented by sections 1-5 of the Patents Act 2004 <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-law-guidance/p-law-changes.htm> accessed 18 August 2010.

[28] Article 53 (a) of the European Patent Convention does not allow the grant of patents in respect of inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, nor may it be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals <http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar53.html> accessed 18 August 2010.

prohibited by Article 53(a), although no specific reference is made to stem cells.[29] The European Patent Office (EPO) adopted a narrow approach in the interpretation of Article 53(a) concerning the application of morality criterion, as it will only be invoked in "rare and extreme cases".[30] The EPO revised the EPC resulting in the exclusion from patentability of certain inventions, *inter alia*, uses of human embryos for commercial exploitation and human cloning. Various other tests adopted by the courts have given the narrowest interpretation to the morality criterion.[31] For example, the patent will have to be "abhorrent to the overwhelming majority of the public",[32] or a "weighing up"[33] or a contravention of the "totality of the accepted norms".[34]

Amidst the uncertainty prevailing at that time, the Biotechnology Directive[35] on the legal protection of biotechnological inventions adopted by the European Union in 1998 achieved a degree of harmonization across Europe. It laid down a number of exclusions and takes the stance that the human body at the various stages of its formation, processes for cloning human beings and for modifying the germ-line genetic identity of human beings, will not qualify as patentable inventions.[36] The directive has been fully implemented by the EPO into the EPC and requires member states to protect biotechnological inventions.

The European patent system is not the only one to incorporate a morality exception, although it has taken upon itself a more responsible role. India,

[29] S Farnley, P Morey-Nase and D Sternfeld, 'Biotechnology – a challenge to the patent system', [2004] Science Direct 15 <www.sciencedirect.com > accessed 10 August 2010.

[30] The Edinburgh Patent - Opposition Decision in relation to European Patent 0 695 351 <http://www.elkfife.com/view_article.php?id=70> accessed 12 August 2010.

[31] Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) EIPR 21(9), 441-449.

[32] Hormone Relaxin O.J. EPO 6/1995, 399; See (n 31).

[33] Harvard/Onco-mouse [1990] EPOR, 513; See (n 31).

[34] Genetics Systems/Glutamine synthetase inhibitors [1995] EPOR, 366; See (n 31).

[35] Also known as the Biotech Directive 98/44/EC.

[36] Paragraphs 3(a)-(e) of the Patents Act 1977, Schedule A2 incorporates the key provisions of the Biotech Directive and declares that there are areas which are not patentable inventions by virtue of being contrary to morality.

Argentina, Bolivia, Peru, Brazil, New Zealand, the Philippines and China are some of the countries which incorporated the morality exceptions to patentability.[37] The law in Europe was influenced by the cases decided in the US. The landmark decision of the US Supreme Court in the 1980 case of *Chakrabarty*[38] played a part in moulding the law. According to this case, inventions could not be excluded from the patenting process merely because they involved living organisms. In the UK, the decision of the WARF patents case on the patentability of embryonic stems cells given by the highest appeal board of the EPO, the Enlarged Board of Appeal (EBA) is of significance.[39] The EBA ruled that the method for obtaining stem cells resulting in the destruction of the primate embryo is prohibited by the European Patent Convention. However, embryonic stem cell research in and of itself is not prohibited for patentability.[40]

[37] David Thomas and Georgina A Richard, 'The Importance of the Morality Exception under the European Patent Convention: The Oncomouse Case Continues' (2004) 26 EIPR, 98.

[38] *Diamond, Commissioner of Patents and Trademarks v Chakrabarty* [1980] 447 US, 206 USPQ 193< http://digital-law-online.info/cases/206PQ193.htm > accessed 20 August 2010.

[39] This case arose from an application which was filed previously by the Wisconsin Alumni Research Foundation (WARF) based on research carried out by James Thomson of the University of Wisconsin on the derivation of human stem cell lines. The U.S. Patent and Trademark Office previously ruled on the moral and ethical implications of the said research.

[40] Robert Fitt, 'New guidelines on the patentability of embryonic stem cell patents in Europe' (2009) 27 Nature Biotechnology 4, 338-339 <http://web.ebscohost.com/ehost/detail?vid=16&hid=107&sid=c56fe892-4cdd-42a0-b485-4429752a18f8%40sessionmgr114&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#db=a3h&AN=37347529> accessed 20 August 2010.

The law is far from settled on the extent to which the stem cells or human embryos are patentable. There is some degree of co-operation and harmonization amongst member states of WTO [41] and they are under an obligation to comply with TRIPS [42] in relation to the burden of proof in civil proceedings when process patents are infringed.

Benefits of Granting Patents for Stem Cell Innovations

The granting of patents to protect inventions in this era of rapid scientific and technological advancements is necessary to stimulate research and innovations. By unduly restricting patents, it will hinder innovation and block research.[43] If such protection is not provided by patents, industry and other inventors will be discouraged from undertaking the risk, investment and necessary research to make the advances in the modern experimentation of stem cell technology. The liberal attitude in some of the European Union member countries in approving patent applications encourages researchers to conduct their work in those countries.

Although the patenting of biotechnological inventions has proven to be controversial from the start, biotechnology tools and techniques opened new research avenues in relation to public health. This kind of research will be very helpful in the understanding of human development and the treatment of human diseases.[44] Its potential, *inter alia*, to cure many devastating diseases and helping in

[41] World Trade Organization.

[42] Article 34 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (also referred to as the TRIPS Agreement) is a major international arrangement regarding the treatment of all intellectual property. It established a minimum level of harmonised intellectual property law to be adopted by all members of the WTO.

[43] Laura Bonetta, 'European Stem Cell Patents: Taking the Moral High Road' (2008) 132 Cell 4, 516.

[44] R Nassiri, 'Stem cells - a new frontier in 21st century medicine' (2001) 7 Med Sci Monit, 1121-2.

the fight against epidemics such as the Dengue fever[45] has raised new hope in society. It is submitted that scientists should be given the legal framework to carry out the necessary research for the good of mankind.

Scientists have overcome moral objections to carrying out research which involves the destruction of human embryos. They have been able to obtain approval not only to use spare embryos but also to create embryos for research purposes. There exists a vast moral difference between producing human embryos with the purpose of destroying them to obtain stem cells, and destroying spare or abandoned human embryos. A large number of frozen embryos are produced through the use of in vitro fertilization process. The frozen embryos, if not used for implantation, will have to be destroyed according to law or in accordance with the wishes of their owners. Researchers are in favour of donating such embryos for research purposes when the legal time-limit on storage approaches. This prevents the destruction of the embryos. Some researchers feel that it would be immoral not to take advantage of such embryos because if those embryos are not used for research purposes, they will be destroyed as required by law.

Opposition to Embryonic Stem Cell Research

The controversy over the advantages and disadvantages of this research is pursued tirelessly by the two radically opposed groups - those who advocate total respect for human embryos and those who do not. Opponents to such research argue in favour of protecting and respecting human life which begins at conception and believe that human embryos must be treated with respect. The strong opposition stems from the source of which the human embryonic cells are obtained because it requires early human embryos to be destroyed in order to obtain embryonic stem cells. Producing stem cells for commercial purposes and extracting stem cells from aborted foetus

[45] Tami Dennis, 'Dengue fever now seems to be our disease too', *Los Angeles Times* (Los Angeles, 21 May 2010) <http://latimesblogs.latimes.com/booster_shots/2010/05/dengue-fever-now-seems-to-be-our-disease-too.html> accessed 20 August 2010.

further complicated the issue. Even the early embryo cannot be dismissed as a mere "loose collection of cells" but may can be claimed as the beginning of a new human life which contains all the genetic information and the capacity to differentiate and develop into a someone rather than a something, provided it is given a suitable nest and supplied with warmth and nutrition.[46]

In relation to the moral status of the human embryo, different views are expressed. Some consider the embryo as a life-saving tissue while others feel that it opens the doors to manipulate life on a previously unattainable scale even for commercial gain. It is submitted that human embryos must be treated with respect and such a conclusion is shared by many scientists, a wide sector of the general public and international groups such as the Coalition of Americans for Research Ethics.[47]

On many occasions, ethical requirements are side tracked for financial gain. Such a profit motive is also reflected in the premature publication of research to attract investors.[48] This can be seen in the case of the cloning of human embryos by Advanced Cell Technology which was criticized by scientists because it showed little experimental progress and advanced no new ideas.[49] Such publications are written more for commercial and political reasons rather than for scientific gains.

As a research subject, the human embryo is vulnerable, defenceless, unprotected and remains at the mercy of the law makers as research subjects. The value of human embryos depends on the reasons for which they have been created

[46] Stephen Crespi, 'The Human Embryo and Patent Law -A Major Challenge Ahead' (2006) 28(11) EIPR 575.

[47] Also referred to as CARE, this group clearly rejects the destruction of human embryos for research and promotes several alternatives to embryonic stem cell use.

[48] L Roberts, 'The Rush to Publish' (1991) 251 Science 4991, 260-263 <http://www.sciencemag.org/cgi/pdf_extract/251/4991/260> accessed 24 August 2010.

[49] Harold Varmus, 'The weakness of science for profit' [2002] (1) The Oncologist 4-5 <http://theoncologist.alphamedpress.org/cgi/content/full/7/1/4> accessed 24 August 2010.

and the changing circumstances. For example, human embryos become more valuable when they are created for reproductive and fertility purposes. Little value is accorded to such embryos when they are created for research purposes often by controversial procedures.

Conclusion

The main issues in the US revolve around the breadth of the patents and how they are being licensed whereas the main issue in the UK and Europe is centred on morality.[50] It is undeniable that there still exists uncertainty with regard to the laws on patenting surrounding embryonic stem cell research. The different laws on the subject matter in countries operating within relaxed regulatory framework fail to give clear guidance on the status of the human embryo. It is submitted that the embryo should not be treated as a commodity or a resource for research purposes as is the practice in some countries. It degrades mankind to see so many governments turning a blind eye to the misuse of embryos. If left unchecked, such unacceptable commercialization, monopolization and experimentation which breach all moral barriers thereby giving scientists more power over life, may stir fear and lead to dangerous situations. It is submitted that progress cannot be made at any cost no matter how important the innovation may be without addressing the inherent ethical problems.

Recommendations

In order to achieve meaningful progress across the European Union, the US and Malaysia, the patent regime should be reformed along with the restructuring of the patent proceedings. Recommendations are made with the aim to improve the patent regime. Some of these recommendations, if taken into account, will benefit Malaysia in bridging the gap between patents and morality. Malaysia, a country

[50] (n 43).

with different cultures will be able to overcome ethical hurdles by observing the strengths and weaknesses of other nations. The following are the recommendations:

a. Only methods for the extraction the human stem cells which do not destroy the actual embryo should be given recognition by law. Such approaches are justified and accepted by religious groups and other interested parties who may view this as a more humane and dignified form of research. In August 2010, Cambridge University scientists created liver cells from human skin using a technology that bypasses the need to use human embryos thus avoiding the kind of intense political and ethical rows over embryonic stem cells.[51]

b. Patents should only be granted to innovations with proven medical benefit claims that comply with national laws. This will prevent commercial exploitation by fraudsters operating in the field of stem cell research, who are making profits from unauthorized and unsafe stem cell therapies.[52] In Malaysia, the BioSafety Act 2007, gazetted on 30 August 2010, is a step in the right direction towards protecting human health from the possible adverse effects of unsafe biotechnological products. The establishment of the National Biosafety Board is provided by the Act to regulate the release, importation, exportation and contained use of living modified organism with the objectives of protecting human, plant, animal health, the environment and biological diversity. The Act also provides for the establishment of the Genetic Modification Advisory Committee to provide scientific and technical advice to the Minister or the Board and to make recommendations on application for approval.

[51] K Honey, 'Applying stem cell technology to liver diseases' [2010] Journal of Criminal Investigation, <http://www.eurekalert.org/pub_releases/2010-08/joci-asc082310.php> accessed 30 August 2010.

[52] 'Stem cells in China: Wild East or scientific feast?' *The Economist* (London, 14 January 2010) 74.

c. Enforcement is necessary to curb unlawful malpractices such as the practice to advertise and offer unproven stem cell therapies by companies because of the relaxed policies.[53] The judiciary can play a part by imposing the maximum penalty for breaches of the relevant statutes.

d. It is recommended that the relevant Acts and regulations be amended to stipulate a compulsory ethical evaluation in the patent application process with the possible inclusion of a two tier prohibition clause for highly contentious patent applications.[54] In Malaysia, the extent of the exclusion of contentious patent applications under section 31 of the Patents Act 1983 on the basis of "public policy and morality" is yet to be seen.

e. Legally established bodies should play a dominant role in dealing with controversial patent applications. In Malaysia, the Intellectual Property Corporation of Malaysia (MyIPO), the Ministry of Health, the National Fatwa Council on Stem Cells and other relevant bodies are encouraged to act boldly and not to appease parties for political gains. To discharge their roles, such bodies should be comprised of members representing the various stakeholders, ethnic and religious groups so as to make its recommendations credible and acceptable to society. The laws should also stipulate compulsory professional training for the persons involved in the patent process.

f. In order to resolve serious controversies surrounding patenting of embryonic stem cells and cloning, the matter should be resolved by a two-thirds majority in Parliament after necessary consultation with experts and interested parties.

[53] ibid.

[54] The European Biotechnology Directive and the EPC is a good model to follow.

g. Proven and effective international laws on the subject matter should be taken into account in the enactment of future regulations and guidelines so as to ensure uniform laws. In addition to the Patent Cooperation Treaty (PCT), Malaysia is encouraged to be a party to the remaining international treaties and keep itself up to date in this fast expanding field of Intellectual Property. A unified stand on human rights will provide a framework and the ethical legal space for continuing dialogue, which in turn will lead to progress and the much needed harmonization and reconciliation between nations.

There are bound to be challenges in the future and the patent system will continue to experience criticism. It will take commitment and co-operation on the part of the international community, in particular, the world's most powerful nations to bridge the gap between patents and morality.