THE ETHICS IN GENETICS – THE LEGITIMACY AND APPLICATION OF STEM CELL RESEARCH

by

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Summary

This dissertation provides an in-depth analysis of the practical application and judicial framework pertaining to stem cell research in South Africa. In the realisation of the above-mentioned analysis, and ultimate critique on the current and proposed legal position, focus is placed on aspects of Medical Law, Legal Philosophy and Human Rights. These include concerns on the procurement of informed consent from stem cell donors, ethical and religious influences on the regulation of biomedicine in general as well as the impact of socio-economic indicators in the realisation of the effective implementation of stem cell research. Focus is firstly placed on the medical aspects surrounding the research, whereafter an examination of the current legal position and its practical application is made. Following the discussion of the current legal position, with reference to the array of influences and concerns pertaining thereto, the newly proposed regulative measures are examined within the current international framework. These regulative measures are placed within context of the private and public sector with their different benefits and disadvantages. In a further discussion of the realisation of the private sector's interests, focus is placed on the role that Intellectual Property Rights play in the protection of monetary incentives to conduct stem cell research. All of the above ultimately leads the author to provide an informed set of recommendations in which the proposed regulative measures can be adapted to ensure the legitimate and practically sound implementation of stem cell research in South Africa.

Keywords

Stem cells
Medical Law
Legal Philosophy
Human Rights
Intellectual Property Law
Biomedicine
Socio-economic rights
Human Tissue Act 65 of 1983
National Health Act 61 of 2003
Ethics
Genetics
Foetus

Opsomming

Hierdie verhandeling bied ‘n in-diepte analise van die praktiese toepassing en juridiese raamwerk wat betrekking het op stamselnavorsing in Suid-Afrika. Ter realisering van die bovermelde analise en uiteindelike kritiek op die huidige en voorgestelde regsposisies is die fokus geplaas op aspekte van Geneeskundige Reg, Regsfilosofie en Menseregte. Hieronder ressorteer onder andere bekommernisse oor die verkryging van ingeligte toestemming van stamselskenkers, etiese- en geloofsoortuigings se invloed op die regulering van die biomediese veld in die algemeen sowel as die impak wat sosio-ekonomiese indikatore op die realisering van die effektiewe implementering van stamselnavorsing het. Die klem word eerstens geplaas op die mediese aspekte wat betrekking het op die navorsing, waarna ‘n ondersoek na die huidige regsposisie en die praktiese toepassing daarvan ingestel word. Opvolgend op die bespreking van die huidige regsposisie, met verwysing na die verskeidenheid faktore wat daarop betrekking het, word die nuut-voorgestelde regulerende maatstawwe binne die huidige internasionale raamwerk ondersoek. Hierdie regulerende maatstawwe word binne die konteks van die privaat- en publieke sektor geplaas, met hul onderskeie voor- en nadele. In ‘n verdere bespreking van die realisering van die privaat sektor se belange word die fokus geplaas op die rol wat Intellektuele Goedereregte speel ten einde beskerming te verleen tot geldelike oorwegings in stamselnavoring. Voorgemelde lei die outeur uiteindelik om ingeligte aanpassings tot die voorgestelde regulerende maatstawwe aan te beveel wat kan lei na die legitieme en prakties uitvoerbare implementering van stamselnavorsing in Suid-Afrika.

Sleutelterme

Stamselle	Sosio-ekonomiese regte
Geneeskundige Reg	Wet op Menslike Weefsel 65 van 1983
Regsfilosofie	National Health Act 61 of 2003
Menseregte	Etiek
Intellektuele Goedereregte	Genetika
Biomedisyne	Fetus

"…the more we imagine ourselves to be the masters of nature, the more we will forget our fundamental indebtedness to nature."[1]

[1] Parens E "On the Ethics and Politics of Embryonic Stem Cell Research" as published in Holland *et al* (eds) *The human embryonic stem cell debate: science, ethics and public policy* (2001) 37 at 47.

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Chapter 1

Scope, methodology and purpose

1.1 Introductory remarks

Throughout the world an upsurge is taking place in the genetics environment. Communities are exposed to various reports from the media proclaiming the dangers of genetic manipulation. The bigger picture is very seldom exposed to the man in the street, creating a situation where an unfounded fear of exploitation can hamper technological advancement.

Stem cell research and its application have become a very prominent issue in the last number of years. It is, however, important to distinguish between stem cell research, cloning and other forms of genetic enhancement. Most people see any research in this field as being a case of playing God. Even when the focus is only placed upon stem cell research, one faces a minefield of ethical issues that is strongly debated amongst ethicists, legal persona and religious groups. Amidst these debates, South Africa is taking the first vital steps towards the implementation of the latest technology. The National Health Act[2] has been drafted, newspaper reports on the opening of a stem cell bank, as well as numerous stories of success in the application of stem cell research procedures in medicine have attracted media attention.[3]

[2] 61 of 2003.

[3] "Bly by met kloning" (2004) *Volksblad* 8; Connor & Arthur "Scientists split over human embryo cloning" (2004) *Sunday Independent* 5; Kalb "The life in a cell" (2004) *Newsweek* 40; Lamprecht "Reeve se dood laat kollig weer val op stamselnavorsing" (2004) *Beeld* 2; Lourens "Human stem-cell bank planned for SA" (2004) *Business Day* 2; Lourens "John Daniels eyes stem cell research" (2004) *Business Day* 9; McDonough "Scientists seeking licence to clone" (2004) *Star* 8; "Mice cells hold out hope for baldies" (2004) *Star* 8; O'Connor "Stamselnavorsing of menslike cloning nie in SA verbode" (2004) *Volksblad* 8; Pomeroy "EU cash for stem cell research" (2003) *Business Day* 9; Schoeman "Rare op may save teen" (2004) *The Herald* 1; "The year of cloning dangerously" (2004) *This Day* 10; Utton "We're set for longer lives" (2004) *Star* 7; Van Dyk "Diereryk staan voor in stamselbank-tou" (2004) *Sake Beeld* 3; Van Dyk "SA kry bank vir stamselle van mense en diere" (2004) *Sake Beeld* 1; Van Heerden "Operasie kan verlamde Danie weer laat loop"

On International ground the debates are being fought with tremendous commitment. South Africa can gain immensely through the making of educated decisions based on what can be learned from the rest of the world. Part of the controversy is founded in the fact that governmental funding is seldom adequate to properly facilitate this type of endeavour. Private companies will only invest in stem cell research if they have some sort of way in which to protect their rights in the material that they are researching. On the international playing field this has been achieved through the granting of intellectual property rights to the individually identified stem cells being researched, but this might not be the best option available for South Africa. Taking stem cell research out of the public sector and exclusively into the private sector could place the benefits of the research beyond the monetary reach of the majority of the population.

South Africa is in the unique position of having to balance the interests of a country consisting of diverse people. Yet again it is of primary importance that the issues pertaining to ethics and Human Rights are adhered to in the strictest sense. Cognisance must be taken of the way in which the courts have addressed previous medico-legal principles as the field of biomedicine[4] is bringing a new set of challenges to the door of the legislator and the judicial authority.

(2004) *Rapport* 5; Van Heerden "Twee SA verlamdes kry weer hoop na stamseloorplantings" (2004) *Rapport* 7.

[4] Biomedicine is defined as: "medicine based on the application of the principles of the natural sciences and esp. biology and biochemistry." It amounts to the application of a wide array of fields to medicine in general, including biotechnology, which is defined as: "applied biological science (such as bioengineering or recombinant DNA technology)." See Mish *et al* (eds) *Merriam Webster's Collegiate Dictionary (10th ed)* (1993) 115. The use of the terms "biomedical" or "biotechnological" throughout the dissertation refers to this type of application of genetic sciences to health care.

1.2 Purpose

The purpose of this dissertation is to research the legitimacy and application of stem cell research, and in particular, that of human embryonic stem cell research within the South African legal setting. More particularly, the aim is to establish the specific requirements needed to be met in order to facilitate the development of a legal framework that can sufficiently support this particular field of biomedicine.

By examining the legal framework of other countries, it is endeavoured to comprehensively address the principles that have been documented as the main concerns in the successful application of stem cell research in practice. The ethical debates that have been put forward and the balancing of public versus private interests in the South African setting are of primary importance in this regard.

In the final instance, it is the aim of this dissertation to deliver edifying criticism of the current regulatory framework, and to propose measures that can be taken in order to facilitate the most beneficial management of all stem cell related endeavours.

1.3 Choice of legal system

A number of considerations led to the selection of the legal systems of the United States of America and United Kingdom for the comparative survey. In the United States of America the stem cell debate has led what seems to be a sometimes overly careful approach to its regulation in the public sector. The balance between the public and private sectors as well as the regulatory structures that are in place can provide much insight into the issues surrounding stem cell research. Statements made by their Trademark and Patent Office can help to establish a refined definition of the way in which similar applications are to be regulated in South Africa. Furthermore, because of the fact that the United States of America has a vast number of states whose interests are to be dealt with within the bigger nationwide framework, it

can provide much insight into the handling of diverse interests, as is the case in South Africa.

The speedy and uncomplicated way (in contrast to the United States of America) in which the United Kingdom set about in establishing the proper regulatory framework is a good example of how proactive management can facilitate the effective implementation of stem cell research. The oversight mechanisms that are in place can set a good example of how to address the interests of the public. The reliance upon only a limited number of advisory commissions before reaching a conclusion as to the legislative measures to be taken in the implementation of stem cell research is an exemplary method of dealing with the issues without any unnecessary time delays at governmental level.

Some reference is to be made to a number of international documents that attempt to establish bans on reproductive cloning and to formulate internationally recognised Human Rights principles that pertain to the genetics environment. These also provide insight into the global views on more controversial aspects such as the creation of embryos for the sole purpose of it being used in research and reproductive cloning.

1.4 Methods

The method employed to deal with the stem cell research in South Africa is to identify and discuss the principles that are context specific in establishing the legitimacy of this particular research. The focus will mainly fall on the South African judicial framework, but a strong emphasis will be placed on the ethical considerations that are internationally recognised. In establishing legitimacy the different requirements will be supplemented with reference to case law and legal opinion in the United States of America, and to a lesser extent, that of the United Kingdom. This use of international sources is due to the fact that the amount of legal material available on the subject in South Africa is very limited. Whilst the majority of legal opinion will be gained from American

sources, English sources assist in completing the scope of the stem cell related regulative framework.

Once the issue of legitimacy has been addressed it is necessary to analyse the current legislation regulating stem cell research in South Africa. It is of vital importance that the regulation of this field does not hamper the application thereof in the public and private sectors. A comparison is drawn between the South African framework and that of the United States of America and the United Kingdom. Because the author was in the position of spending some time in Germany in the completion of the dissertation, limited reference to the German regulations pertaining to stem cells has also been used.

Investors in the private sector attempt to secure their investments through the application for patent rights on their biological inventions. In order to complete the framework within which stem cell research finds application and to ensure the proper implementation thereof in the private sector, a discussion of the regulation of intellectual property rights in South Africa is also included.

In conclusion, an attempt is made to highlight further considerations in order to facilitate the effective incorporation of stem cell research into the South African judicial system.

1.5 Historical overview

Before delving into the legal issues surrounding stem cell research it is necessary to notice the accumulation thereto. Due to the complexity of this issue it would be impossible to discuss the history of stem cell research without a discussion of the clinical principles. A comprehensive set of definitions pertaining to the more complex principles to be discussed is provided in a glossary at the end of the dissertation whilst the chapter hereafter fully explains the medical aspects surrounding stem cell research.

1.5.1 The beginnings

Human embryonic stem cells were first isolated and cultured in November 1998, by Dr James Thomson, at the University of Wisconsin in the United States of America. Since the United States has a law forbidding the use of federal funds for research on human embryos, Dr Thomson conducted the work using private funds from Geron Corporation and the Wisconsin Alumni Research Foundation.[5] This set the stage for a vast number of debates surrounding the use of public funds for human embryonic stem cell research. Whilst the debates were feverously fought, the consistent use of private funding to conduct the research effectively placed the majority of the benefits to be gained from stem cell research beyond the reach of the public sector.

It is because of this string of events that the historical discussion starts by an analysis of the position in the United States of America. It establishes the playing field from which much of the decision-making in the rest of the world took place. During the discussion of the history of stem cell research it is necessary to draw the following preliminary distinction between human embryonic stem cell research and foetal tissue research: In the case of foetal tissue research the abortion has already taken place and the foetus is dead whereas in human embryonic stem sell research the actions of the researchers cause the embryos to die. This would for instance be where excess embryos from *in vitro* fertilization (IVF) treatment are taken and used to harness the stem cells.[6]

1.5.2 United States of America

During November 1998 President Clinton of the United States of America requested the *National Bioethics Advisory Commission* (NBAC) to undertake a full review of the issues associated with stem cell research. This followed on the announcement that human embryonic stem cell lines and human

[5] Tomossy & Weisstub (eds) *Human experimentation and research* (2003) 591.

[6] Fletcher "NBAC's Arguments on Embryo Research: Strengths and Weaknesses" as published in Holland *et al* (eds) *The human embryonic stem cell debate: science, ethics and public policy* (2001) 61 at 62.

embryonic germ cell lines had been successfully isolated.[7] Religious leaders reasserted their objections against the creation and destruction of embryos for research purposes and ethicists started to delve into the deeper morals involved. The NBAC's preliminary report was published during September 1999 and those recommendations form a large part of the public policy that is being addressed by the relevant forums.

1.5.2.1 Early developments in United States Medical Law

The quick response to the NBAC's report was due to the fact that the previous years' experience in the field of biomedicine had been riddled with numerous complications. Similar bumps had to be steered clear from in order to avoid costly reparations in the future. In 1973 the US Supreme Court Ruled that a foetus was not a person when it comes to constitutionally protected rights,[8] and thus opened the door for freedom of choice in abortion. Many parties were afraid of the possible use of aborted foetuses in experimentation, so the *National Institute of Heath* (NIH) placed an instant moratorium upon foetal tissue research. The US Congress went on to established the *National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research* (National Commission) in 1974, whose primary objective was to formulate public and policy guidelines with regards to foetal tissue research. Their report was issued in 1975, and started with a compromise between the liberal and conservative views on the use of abortive foetuses in research.[9] The commission encouraged foetal research in order to fully harness its potential to create medical advancement (and thus kept the liberals happy). On the other hand the commission laid strict ground rules in foetal research cases, stipulating for instance that foetuses to be aborted had to be treated equally to those to be delivered (and thus also keeping the conservatives happy).[10] Following the report of the National Commission, and the subsequent promulgation of regulations pertaining to

[7] Holland *et al* (eds) xv.

[8] *Roe v Wade* 410 U.S. 113 (1973).

[9] Fletcher "The Stem Cell Debate in Historical Context" as published in Holland *et al* (eds) 27 at 27.

[10] *Ibid* at 28.

foetal tissue research, the moratorium placed thereon by the NIH was lifted on 29 July 1975.

1.5.2.2 Small steps towards public sector endorsement

A moratorium on the federal funding of IVF treatment as well as a moratorium on the federal funding of foetal tissue transplant research in the USA was only lifted in 1993.[11] In response to a report by the *Human Embryo Research Panel* (HERP) in 1994, President Clinton expressed the view that he could endorse research on embryos originally created by means of IVF for the purpose of reproduction, but that he could not endorse using IVF for the sole purpose of creating embryos for research.[12] In 1996 a ban was placed on the federal funding of embryo research (distinguish this from the previous ban on foetal tissue transplant research), effectively halting any progress that the NIH had been able to make concerning the realisation of public projects pertaining thereto.[13] To a large extent this ban on federal funding for embryo research was only lifted by the Bush administration in August 2001,[14] as will be seen later in this chapter. President Clinton mentioned in 1998 that he was willing to endorse the use of somatic cell nuclear transfer (SCNT) to create embryos for research.[15] The entire process towards the federal use and funding of stem cell research (or any embryonic or foetal research for that matter) was an extremely slow one, with none of the policy makers wanting to cross the proverbial line too quickly in getting the ball rolling. This has resulted in major frustrations for many researchers who have been hampered by the slow system of change.[16] Furthermore, there has been a constant weighing of opinions by different ethical committees, the main players involved being the

[11] Blackbeard "Therapeutic cloning – ok?" (2002) 35 *De Jure* 318 at 322.

[12] Parens "On the Ethics and Politics of Embryonic Stem Cell Research" as published in Holland *et al* (eds) 37 at 37.

[13] Fletcher "The Stem Cell Debate in Historical Context" as published in Holland *et al* (eds) 27 at 29 and Jordaan "Human reproductive cloning: A policy framework for South Africa" (2002) 119 *The South African Law Journal* 294 at 295.

[14] Braswell "Federal funding of human embryo stem cell research: advocating a broader approach" (2003) *Chicago-Kent Law Review* 423 at 423.

[15] *Supra* note 10 at 37.

[16] "Prominent cell biologist to leave Iowa" (2003) *Biotechnology Law Report* 482.

NIH the NBAC and the *American Academy for the Advancement of Science* (AAAS). With all these parties trying to make themselves heard, it is no wonder that a cautious approach is being followed.

1.5.2.3 Private sector reaps benefits because of hesitant public sector

Companies in the private sector have realised what potential stem cell research has in both the general medical field as well as its' financial benefits, thus they provided the necessary funding to facilitate these projects.[17] At the start of the private sector's involvement it was interesting to note that despite the rigorous enforcement that was taking place in the public sector, the work done by individuals working in the private sector was relatively unregulated. In 1999 for instance, twenty-four of the US states had no laws specifically addressing the use of embryos and foetuses in research, which meant that it was only regulated by legal precedents such as informed consent, commercialisation and privacy.[18]

1.5.2.4 Limited federal funding allowed amidst controversial recommendations

The change from the Clinton to the Bush administration brought with it a new approach to the matter. President Bush authorised the use of federal funding for human embryonic stem cell research on the 9th of August 2001.[19] During this same speech, President Bush instituted yet another advisory commission: The President's Council on Bioethics, to "monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the

[17] Siegel (2000) *Emory Law Journal* 937-938 as referred to in Blackbeard (2002) 35 *De Jure* 318 at 323.

[18] Andrews (1999) "State regulation of embryo stem cell research" In National Bioethics Advisory Commission: *Ethical Issues in Human Stem Cell Research Vol II, Commissioned Papers.* Rockville, MD: National Bioethics Advisory Commission as referred to in Holland *et al* (eds) 30.

[19] Makdisi "The slide from human embryonic stem cell research to reproductive cloning: ethical decision-making and the ban on federal funding" (2003) *Rutgers Law Journal* 463 at 463.

medical and ethical ramifications of biomedical innovation."[20] This came almost two years after the NBAC released its report pertaining thereto in September 1999, entitled "Ethical issues in Human Stem Cell Research".[21] This was the same report that had been requested by President Clinton in November 1998. In this report the NBAC recommended the federal funding of embryonic germ cell research with foetal tissue and the derivation and use of human embryonic stem cells from embryos remaining after infertility treatments (in other words IVF treatments).[22] They furthermore made a large number of recommendations pertaining to the safeguards that have to be in place in order to regulate this process properly. These safeguards were, to a large extent, borne from the oppositions raised to the NIH's recommendation that federal support should be granted specifically for the use of embryos created with the sole purpose of being used in stem cell research, and not solely for embryos created for the purpose of IVF.

Following the September 1999 report by the NBAC, the NIH drafted its own guidelines with regards to human embryonic stem cell research. This set of draft guidelines was released during December 1999, and attempts to ensure that any research conducted with the use of federal funds is done in an ethical and legal manner.[23] The final drafting of these guidelines and the report by the NBAC did not come without its fair share of controversy. The NBAC originally recommended the use of federal funding in stem cell research based upon the overwhelming evidence that pointed out the potential medical and scientific advances that could be gained. At the same time the NIH had its own team of legal persona working on an analysis of the legislation that regulated the field

[20] Monachello "The cloning for biomedical research debate: do the promises of medical advances outweigh the ethical concerns?" (2003) *Tulsa Journal of Comparative and International Law* 591 at 599.

[21] Baylis "Human Embryonic Stem Cell Research: Comments on the NBAC Report" as published in Holland *et al* (eds) 51 at 51.

[22] Fletcher "NBAC's Arguments on Embryo Research: Strengths and Weaknesses" as published in Holland *et al* (eds) 61 at 66.

[23] Miller "Promoting life? Embryonic stem cell research legislation" (2003) *Catholic University Law Review* 437 at 450.

at that point in time. They came to the conclusion that the legislation prohibiting the use of federal funding, in cases where the embryo or organism used would be able to develop into a full human being if it were to be implanted into a woman's womb, is not applicable in this instance. Pluripotent stem cells were shown not to be able to fully develop into a human being, even if they had been implanted, with the result that a loophole was created through which the federal funding could be granted.[24] They pushed through with the recommendations despite a large number of ethical groups (and members of the US Congress) not agreeing with the legal opinion.

1.5.2.5 Federal funding not comprehensive enough

The federal funding that had been approved was, however, only applicable with regards to a limited group of stem cells that had already been identified at that point in time. Problems arose because of the fact that most of the sixty lines that had been identified up until then had already been patented and thoroughly researched, with the result that there were virtually no gains to be made through further research. Any work to be done on lines not patented almost always fell outside the scope of coverage that the federal funding provided, thus hampering the governmental projects substantially. On the other hand, the fact that only a small number of the lines were made available to research via federal funding effectively boosted the governments efforts to prevent a utilitarian upsurge, as opposed to a deontological viewpoint of scientists working for the "greater good", in crossing the line between human embryonic stem cell research and reproductive cloning, without the proper measures being in place.[25]

Following the President's speech in August 1999, the President's Council met regularly throughout a six-month period, holding discussions specifically pertaining to cloning for biomedical research. It issued its first report, entitled Human Cloning and Human Dignity: An Ethical Inquiry, during July 2000 in which the Council discussed both cloning to produce children and cloning for

[24] *Ibid* at 448.

[25] Makdisi (2003) *Rutgers Law Journal* 463 at 465.

biomedical research.[26] Even in this report there is a difference of opinion, with the minority supporting cloning for biomedical research with regulation, while the majority recommended a four year moratorium thereof, with a "federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field."[27]

One gets the feeling that the extreme caution when dealing with the stem cell issue is not so much because of the ethical issues pertaining thereto, but rather the result of decisions being taken according to documents that fail to draw a proper distinction between stem cell research and reproductive or therapeutic cloning.

1.5.2.6 Financial considerations not the only source of concern

The use of foetal tissue is still an issue that has many religious groups up in arms. Because of the fact that it is possible to use aborted foetuses in extracting stem cells, they reason that this type of research will increase the abortion rates. The NBAC responded to this allegation by stating that no data has thus far been able to indicate that foetal tissue research increases the abortion rate. In the same breath a further recommendation made by the NBAC was that any woman's request for abortion must precede the request for foetal tissue research and there may not be any payments given for foetal tissue either.[28] This is to avoid the risk that women could be convinced to undertake an abortion for any monetary or otherwise unethical reason. Each of these, as well as numerous other principles are vital stepping-stones in crossing the surging South African river of the stem cell debate successfully.

[26] Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 599.

[27] *Ibid*.

[28] Fletcher "The Stem Cell Debate in Historical Context" as published in Holland *et al* (eds) 27 at 31.

1.5.2.7 Other developments within biomedicine

On an even more global scale, but still within the field of bioethics and genetics, the *International Human Genome Project* was launched, which resulted in the complete mapping of every gene found in a human's DNA composition.[29] The human genome consists of three billion base pairs, which make up the entire genetic blueprint of a human being.[30] Knowledge of the human genome can lead to increased effectiveness of healthcare services based on the fact that, theoretically, the particular gene that can predispose an individual to a certain illness can now be identified and subsequently dealt with.[31] This raises an entirely different set of ethical issues all of its own. Fears of genetic information being used to discriminate between individuals, the harnessing thereof in the invasion of privacy[32] and the commercial exploitation of individuals base on their genetic make-up[33] has led to a further analysis of the application of any type of information in biomedicine. There are, however, numerous points of correlation between the different fields of biomedicine, with the result that many of the concerns raised by the cloning and stem cell debates have been reasonably well addressed by the various groups working on the Human Genome Project. From the documentation currently available on the subject it is clear that a primary part of the focus in the entire Genome Project was to clarify the principles surrounding intellectual property rights[34] and many of the general weaknesses in human experimentation.[35]

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[29] Lupton "Genetic engineering – the legal implications" (1996) *TSAR* 56 at 56.

[30] Annas "Mapping the Human Genome and the meaning of 'Monster Mythology'" as published in Burley & Harris (eds) *A Companion to Genethics* (2002) 127 at 127.

[31] Strydom (2003) 1 *TSAR* 37 at 37; Lupton "Genetic Engineering – Does it merely facilitate the process of evolution?" (1992) 55 *THRHR* 79 at 82.

[32] Lupton (1996) *TSAR* 56 at 63.

[33] Chadwick & Hedgecoe "Commercial exploitation of the Human Genome" as published in Burley & Harris (eds) 334 at 334.

[34] The University of Duesto and the Diputacion Foral de Biskaia *The Human Genome Project: Legal Aspects, Vol II* (1994 145-159.

[35] The University of Duesto and the Diputacion Foral de Biskaia *The Human Genome Project: Legal Aspects, Vol III* (1994) 273-288.

1.5.3 United Kingdom

Before taking a look at the South African history it is necessary to analyse the happenings in stem cell research in the United Kingdom. This is to place the intricate position in the United States into perspective with regards to the global happenings in biomedicine.

In the United Kingdom, as in the rest of the world, the debate surrounding the morality of embryo research has also been fought. Many of the ethicists support the view that a middle ground be found in which research on surplus embryos is acceptable, whilst the creation of embryos for research purposes is not. The legal regulation of embryo research in the United Kingdom started way before the current interest in stem cell research entered the arena.[36]

1.5.3.1 Effective licensing procedures facilitating efficient stem cell research implementation

The Human Fertilisation and Embryology Act of 1990[37] specifies that it is illegal to conduct any research on embryos in the United Kingdom without a license from the relevant authority, with the authority under the Act being the relevant forum created for that purpose - The Human Fertilisation and Embryology Authority. The original Act of 1990 only specified the giving of licences in cases where the project seemed to be aimed at seeking cures for infertility, the knowledge of congenital diseases, the causes of miscarriages, developing contraceptive methods, or the development of methods of detecting genetic or chromosomal abnormalities in embryos before implantation. Any further reasons could be added later by way of regulation.[38] The licences may not authorise the use of embryos older than 14 days after the gametes have been mixed and no human embryo may be placed in any other animal species.[39] The Parliament did not place any restrictions upon the source of the embryos used, and the authority has no power in placing any restrictions on the creation of embryos for the sole purpose of being used in

[36] Mason *et al Law and medical ethics (6th ed)* (2002) 610.

[37] As referred to in Mason *et al* 610.

[38] Schedule 2 paragraph 3(2).

[39] Section 3.

research. It is clear that the original Act did not specifically intend for the use of embryos in stem cell research.

Directly after the news of the successful production of stable stem cell lines in 1998, the British Parliament had to re-evaluate the 1990 legislation. An expert group was appointed by the Government with the purpose of looking into the ethical and scientific aspects of stem cell research. They recommended that embryonic stem cell research as well as therapeutic cloning involving cell nuclear replacement should be permitted. Following the report, parliamentary approval of an amendment to schedule 2 of the Human Fertilisation and Embryology Act was passed.[40] This means that embryonic stem cell research for therapeutic purposes is legal in the United Kingdom, provided a licence is obtained from the relevant authority.

1.5.3.2 United Kingdom reaps benefits of effective regulating mechanisms

The quick handling of this issue in the United Kingdom was a welcome change for many researchers who were frustrated about the cautious (and to a large extent politically driven), way in which many other countries were handling the issue. It even led to some cell biologists leaving their own countries in order to conduct research in the United Kingdom.[41] The collected manner in which the issue was handled, without time consuming squabbles surrounding federal funding for instance, can serve as a good example to South Africa in the future handling of many biomedical affairs.

1.5.4 South Africa

1.5.4.1 Constitutional principles, foetal tissue and public opinion

South Africa enacted the Interim Constitution of the RSA[42] in 1993 and the Final Constitution of the RSA[43] in 1996. It led to a vast number of minority groups having a very strong leg to stand on in the Constitutional Court with

[40] Mason *et al* 612.

[41] "Prominent cell biologist to leave Iowa" (2003) *Biotechnology Law Report* 482.

[42] Act 200 of 1993.

[43] Act 108 of 1996.

regards to the legalisation of many deeds previously deemed unlawful.[44] One such deed is the act of termination of a pregnancy. Despite the fact that the Choice on Termination of Pregnancy Act[45] had already been assented to in 1996 and commenced on 1 February 1997, there are still many ethical groups that are outraged by the fact that abortions have been legalised in South Africa. To even mention the possible use of those aborted foetuses in the harvesting of stem cells for the purpose of research is to throw fuel on a fire that has never truly been brought under control. When reading the above-mentioned Act and its regulations,[46] it is clear that no provision has been made with regards to the use of aborted foetal tissue in research. It is thus necessary to look towards other legislation in order to analyse not only the use of foetal tissue, but also the issue surrounding the use of spare as well as newly created embryos for the sole purpose of research.

1.5.4.2 The Human Tissue Act

One such piece of legislation is the Human Tissue Act.[47] Up until recently it was the primary legislative document regulating any affairs with regard to human tissue. It has, however, been repealed by the National Health Act.[48] The Human Tissue Act[49] is still important in order to compare the previous legal position in South Africa with the position we are currently busy developing. In terms of the Human Tissue Act the use of placenta, foetal tissue and umbilical cord was prohibited, except in cases where ministerial consent was given.[50] Any tissue removed from the body was only to be used for medical and dental purposes and, from the wording of the section, it seemed as if the use of gametes was mostly to be restricted to *in vitro*

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[44] In terms of sec 12(2)(a) of the 1996 Constitution everyone has the right to bodily and psychological integrity, including the right to making decisions regarding reproduction.

[45] 92 of 1996.

[46] As published in Government Notice R168 in *Government Gazette* 17746 of 31 January 1997.

[47] 65 of 1983.

[48] 61 of 2003.

[49] 65 of 1983.

[50] Section 19, provision iv.

fertilisation procedures.[51] The Minister of Health was able to pass regulations concerning the bringing together of male and female gametes outside of the human body, and the research upon such products of the union between the respective gametes, irrespective of the purpose for which such a product was being produced.[52] This means that researchers would have theoretically been able to create embryos for the sole purpose of research, had the Minister allowed the passing of regulations pertaining thereto.

Section 39A was specifically added to the Human Tissue Act through section 26 of Act 51 of 1989. This provided for the following: "Notwithstanding anything to the contrary contained in this Act or any other law, no provision of this Act shall be so construed as to permit genetic manipulation outside the human body of gametes or zygotes". It is clear that the legislature was preventing the possibility of anybody interpreting the rest of the Act in such a way as to allow for the conducting of experiments with reproductive cloning. This could, however, also be interpreted as to exclude the use of embryos in stem cell research, or at least to prevent the use of somatic cell nuclear transfer to create embryos.[53] Legal scholars criticised the Human Tissue Act[54] considerably with regards to the failure thereof to distinguish between therapeutic and reproductive cloning (with therapeutic cloning to a large extent including stem cell research), stating that provision should be made for the use of tissue in therapeutic cloning, bearing in mind that sufficient control mechanisms are in place.[55]

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[51] Section 19(c).

[52] Section 37(1)(e)(iv).

[53] See a further discussion of this section of the Act in Slabbert "Are the human embryo and the foetus *extra uterum* sufficiently protected in terms of South African law?" (2001) *Tydskrif vir die Suid-Afrikaanse reg* 495 at 505-508.

[54] 65 of 1983.

[55] *Supra* note 9 at 327.

1.5.4.3 Shaping a new era – the National Health Act

As was mentioned earlier, the Human Tissue Act[56] has been repealed by the National Health Act,[57] which brings with it a completely new set of principles that specifically focuses on stem cell research. These principles will be discussed thoroughly in later chapters. It is noteworthy to mention that the National Health Act[58] leaves a number of key issues surrounding stem cell research within the regulatory powers of the minister. This raises further questions pertaining to the constitutionality of such ministerial decisions, where these actions may amount to the Minister effectively playing a legislative role without having to comply with the strict provisions that befall the legislature.

1.6 Conclusion

In its short existence since the announcement of the successful derivation of stem cells, stem cell research has become an area of biomedical advancement to be reckoned with. The approaches by government, and private investors alike, reaffirm the fact that stem cell technology has sparked a gold rush.

This rush, however, is one that is riddled with other issues, such as the ethical considerations pertaining both thereto and to the other areas of healthcare that are indirectly affected by stem cell research. The medically related aspects surrounding stem cells will be discussed in more detail in the next chapter and provides an evaluation of just how wide the scope of this technology has become.

With each passing day the scope of stem cell research is increasing, resulting in the need for a constant re-evaluation of the regulatory principles thereto. At present it would suffice to state that this dissertation attempts to address the basic as well as most controversial ~~of~~ aspects of stem cell research and its

[56] 65 of 1983.

[57] 61 of 2003.

[58] *Ibid*.

application in the South African law. The new legislative framework launches a new era of healthcare applications whose effectiveness will only be proved through time. However, by making educated decisions based on the current knowledge of this field, both nationally and internationally, one is able to steer the future in a direction that will benefit all.

Chapter 2
Clinical Aspects of Stem Cell Research

2.1 Introduction

For many years scientists have been searching for the base cells that divide into all the different tissues that make up a human being. The cells are, in essence, immortal, with the ability to divide indefinitely without losing their genetic structure.[59] In November 1998 a scientist working for the University of Wisconsin in the United States of America, Dr James Thomson, announced to the world that he had managed to successfully isolate and derive these particular cells from a human embryo. The cells are known as human embryonic stem cells.[60]

Stem cells have a broad spectrum of possible applications in practice and can thus aid in the advances of medical technology. In order to fully appreciate the fundamental ethical debates surrounding human embryonic stem cell research, as well as the legal considerations, it is necessary to evaluate the ways in which stem cells are derived in practice. Many of the applications of this technology hold the potential for great discussion, even if the derivation of stem cells itself is deemed to be acceptable. For example, the use of *Prenatal Genetic Diagnosis* (PGD) in order to create a newborn child from whom

[59] Blackbeard "Therapeutic cloning – ok?" (2002) 35 *De Jure* 318 at 321; Braswell "Federal funding of human embryo stem cell research: advocating a broader approach" (2003) *Chicago-Kent Law Review* 423 at 425; Jordaan "Human reproductive cloning: A policy framework for South Africa" (2002) 119 *The South African Law Journal* 294; Kincaid "Oh, the places you'll go: The implications of current patent law on embryonic stem cell research" (2003) *Pepperdine Law Review* 553 at 564-565.

[60] Holland *et al* (eds) *The human embryonic stem cell debate: science, ethics and public policy* (2001) xv; Svendsen "Stem Cells" as published in Burley & Harris (eds) *A Companion to Genethics* (2001) 7 at 11; Makdisi "The slide from human embryonic stem cell research to reproductive cloning: ethical decision-making and the ban on federal funding" (2003) *Rutgers Law Journal* 463 at 467; Momeyer "Symposium on bioethics – thinking about biomedical advances: The role of ethics and the law: Embryos, stem cells, morality and public policy: Difficult connections" (2003) *Capital University Law Review* 93 at 95.

umbilical cord (or other tissue) stem cells are gathered and then used to treat a sick brother or sister. The creation of a child in order to possibly enhance the health of another can lead to arguments surrounding the commercialisation of human life.

In examining the topic of stem cell research, it is necessary to distinguish it from other forms of medical interventions, for example *in vitro* fertilisation. A distinction also has to be made between therapeutic and reproductive cloning. These distinctions as well as the acquisition, benefits and application of stem cell research to other areas of healthcare technology are discussed below.

2.2 Deriving and dividing – the clinical aspects surrounding stem cells

2.2.1 Acquisition, pluripotency, multipotency and immortality of stem cells

In order to understand human embryonic stem cells, it is necessary to understand the basic properties of early human embryos. After fertilisation, the single cell embryo undergoes a number of cleavage divisions, each time doubling in the number of cells. During the normal fertilisation process these divisions usually occur as the embryo migrates down the oviduct and into the uterus.[61] At this stage the cells inside the cleavage stage embryos are known as blastomeres. All of these embryo cells are undifferentiated. In other words they do not look or act like the specialised cell of an adult, and the blastomeres are not yet ordained to form any particular type of differentiated cell.[62]

One of the most fascinating hallmarks of these early embryos is their plasticity. If a pre-implantation embryo (an embryo that has not implanted into the uterus) is split in half, each half is able to develop normally to term, if

[61] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 15.

[62] *Ibid*; Kincaid (2003) *Pepperdine Law Review* 553 at 564.

implanted.[63] If two separate cleavage stage embryos are pushed together, the blastomeres can intermingle to form a single embryo that can develop to term. Such an individual would indeed have four different parents if done *in vivo*.[64]

Approximately five days after fertilisation, the first differentiation event occurs. An outer layer of cells (trophectoderm), which will ultimately become part of the placenta, separates from the inner cell mass. This inner cell mass consists primarily out of the cells known as blastomeres. Once this event has occurred, the embryo is known as a blastocyst.[65] The inner cell mass cells that are present within the blastocyst still hold the potential to form any cell type of the human body. It is from this inner cell mass that embryonic stem cells are derived. Once the stem cells are separated from the blastocyst, it is unable to develop into a child if implanted into a woman's uterus.[66] This is due to the fact that it lacks the trophectoderm layer which mediates implantation.[67] The abovementioned extraction of the inner cell mass cells (in order to harvest stem cells) effectively destroys the embryo.[68] It is thus impossible to implant and carry to term an embryo from which stem cells have been derived.

Under normal circumstances these inner cell mass cells would have differentiated into other cell types with more restricted developmental potential.[69] In the intact embryo, inner cell mass cells function merely as

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[63] Jordaan (2002) 119 *The South African Law Journal* 294 at 296. This type of embryo splitting is also one of the methods in which cells can be used for purposes of reproductive cloning. The definition of reproductive cloning is provided further on.

[64] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 16.

[65] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 8; Stevens "Embryonic stem cell research: Will President Bush's limitation on federal funding put the United States at a disadvantage? A comparison between U.S. and international law" (2003) *Houston Journal of International Law* 623 at 628.

[66] Kincaid (2003) *Pepperdine Law Review* 553 at 564.

[67] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 15; Blackbeard (2002) 35 *De Jure* 318 at 321.

[68] *Ibid*; Braswell (2003) *Chicago-Kent Law Review* 423 at 426.

[69] Momeyer (2003) *Capital University Law Review* 93 at 96 explains the rest of the differentiation process as follows:

precursor cells, but not as stem cells, and differentiate into tissue specific cells. There is a fine balance between the self-renewal, differentiation and cell death of tissue specific cells. If, for instance in skin cells, there is an excessive amount of self-renewal compared to cell death, it could lead to tumour formation.[70]

Had mammalian development been very rigid with developmental decisions inflexibly tied to a specified number of cell divisions, inner cell mass cells placed in culture would also just differentiate to more restricted lineages and not replace themselves, regardless of culture conditions. However, because of the developmental plasticity of mammalian embryos, if the inner cell mass is taken out of its normal embryonic environment and cultured under appropriate conditions, these cells can proliferate and replace themselves indefinitely, yet maintain the developmental potential to form any cell type. These pluripotent inner cell mass cells are embryonic stem cells.[71]

The pluripotency of cells that are referred to above simply indicates the specific characteristic of the derived cell. A pluripotent cell has the ability to give rise to virtually any tissue type, but not to a whole organism, and appears four days after fertilization.[72] This has to be distinguished from totipotent cells,

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> "A hallmark of the gastrulating embryo is evident at about 14 days. This is the 'primitive streak,' a dark line down the embryo that consists of three distinct levels of cells that will eventually differentiate into every distinct cell type in a human body.] About a week later, the top most layer of these cells differentiates into neuronal cells that will in time become the brain and spinal cord. By approximately eight weeks, cell differentiation and organogenesis that generates all the major tissue and organ systems of the human body has occurred, and the embryo is transformed into a fetus."

Many of the religious viewpoints on the ethics of stem cell research accept the formation of the primitive streak after 14 days as the cut off point between conducting morally acceptable and unacceptable research on human tissue.

[70] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 8; Newman "Averting the clone age: Prospects and perils of human developmental manipulation" (2003) *Journal of Contemporary Health Law and Policy* 431 at 448.

[71] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 17.

[72] Blackbeard (2002) 35 *De Jure* 318 at 321; Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 8.

which have the ability to give rise to virtually any tissue type, and in some instances to a functioning organism.[73] On the other hand, multipotent stem cells are cells that are more differentiated. They can give rise to only a limited number of tissues,[74] for instance a mesenchymal stem cell has been shown to specifically produce bone, muscle, fat and cartilage.[75] Svendsen[76] offers a good discussion of the balance between pluripotent and multipotent stem cells and progenitor cells:

> "There are also other types of stem cells that are more restricted in their potential. These are termed multipotent stem cells. These cells form founder colonies in specific regions of the developing embryo, which lay down the progenitor cell colonies required to build specific tissue types. Progenitor cells are rapidly dividing with a limited self-renewal potential – programmed to make one type of tissue fast and then stop. They are the workhorses of development, while the true stem cells remain quietly in the background, dividing just enough to maintain the progenitor cell pool. Once an organ is complete, a pool of stem cells will often reside in its deepest layers. These divide slowly under normal circumstances, but can be induced to divide faster by tissue damage, and have remarkable capacity for self-renewal. The stem cells of the blood system are perhaps the most studied, and were discovered over 50 years ago. The blood is one body tissue that needs continual replacement. Blood stem cells lied deep within the bone marrow, producing enough progeny to replace cells lost through wear and tear. Other tissues such as skin, gut, and liver have their own multipotent stem cell pools."

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[73] Chapman, Frankel & Garfinkel (1999) "Stem Cell Research and Applications – Monitoring the Frontiers of Biomedical Research" Produced by the *American Association for the Advancement of Science and Institute for Civil Society* 31-33; Braswell (2003) *Chicago-Kent Law Review* 423 at 425; Miller "Promoting life? Embryonic stem cell research legislation" (2003) *Catholic University Law Review* 437 at 451.

[74] Makdisi (2003) *Rutgers Law Journal* 463 at 469; Miller (2003) *Catholic University Law Review* 437 at 453 is of the opinion that more emphasis should be placed upon the use of multipotent stem cells. They are a viable and proven alternative to the much more controversial pluripotent embryonic stem cells. Miller further states that even though multipotent stem cells are more differentiated, it is still easier to utilise than pluripotent embryonic stem cells.

[75] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 1; At least one source (Makdisi (2003) *Rutgers Law Journal* 463 at 468) specifically mentions the fact that multipotent stem cells have been derived from fat drawn during liposuction.

[76] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 8.

The reason why human embryonic stem cells that are derived from very early embryos are able to proliferate unlimitedly[77] (thus in effect making them immortal) is the fact that they naturally express high levels of the enzyme called telomerase.[78] As a cell divides, the amount of telomerase that is present within it gradually decreases. At each division of a cell, different parts of various genes are switched on by molecules known as transcription factors. This leads to the cellular differences throughout the body, with some becoming either brain cells, heart, blood, kidney etc.[79] One of the main challenges for researchers is to establish the ways in which stem cells divide into specific tissues, in order to guide the cells into preordained areas within the clinical setting.

2.2.2 Utilising human embryonic germ cells

Human embryonic germ cells have also been used to develop pluripotent cell lines.[80] A germ cell is a specific cell that would normally develop into either sperm or egg. These cells are very important as a source of stem cells because of the fact that it can be derived from the gonadal ridge of a foetus.[81] This leads to the interesting argument surrounding the use of an aborted foetus for research purposes and the question of whether such use would encourage abortion. It is, however, accepted that the range of potential benefits from using germ cells is slightly narrower than with normal embryonic stem cells due to the fact that they are much further along in development.[82] Further research on the use of these types of cells is much needed, especially with regard to tumour formation and other abnormal development.

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[77] Braswell (2003) *Chicago-Kent Law Review* 423 at 427.

[78] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 19.

[79] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 8.

[80] Kincaid (2003) *Pepperdine Law Review* 553 at 565; Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 448.

[81] Deutsche Forschungsgemeinschaft *Forschung mit humanen embryonalen Stamzellen – Standpunkte/Research with human embryonic stem cells – positions* (2003) 84-85.

[82] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 3.

2.2.3 Utilising adult stem cells

Adult stem cells, derived from mature tissue, may also be used.[83] Even if an organism is completely matured, it is still necessary for cells to be replaced at certain times, for example blood cells. This is true for almost all of the body's tissues.[84] In the past it was believed that certain tissues, such as the heart, completely lack stem cells.[85] It has, however, recently been discovered that they do have stem cells, but they are hidden very deep within the tissue. At the moment researchers are still focussing on the use of embryonic stem cells because of the fact that there seems to be great difficulty in deriving and dividing adult stem cells.[86] Furthermore, it appears as if adult stem cells are merely multipotent, which means that the potential they hold for research currently compares poorly with the pluripotency of embryonic stem and germ cells.[87] Recently it has, however, been found that the multipotency of these types of cells does not pose as big a problem as was originally thought. Miller[88] describes the new results as follows:

> "Some scientists assume an adult stem cell will not be able to treat all of the diseases ESCs [Embryonic Stem Cells] potentially could treat simply because adult stem cells are further along in their differentiation process. However, recent scientific advances have proven the opposite. Researchers have recently isolated stem cells from fat cells, bone marrow, nerve tissue, umbilical cord blood, and other sources. Moreover, from this isolation process, scientists have taken the first steps in developing treatments for numerous diseases. For instance, adult bone marrow stem cells have been

[83] Deutsche Forschungsgemeinschaft 85.

[84] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 1.

[85] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 17.

[86] Makdisi (2003) *Rutgers Law Journal* 463 at 470; Once the use of adult stem cells is better established, it would definitely prove to be the better source of stem cells - especially in light of the fact that a lot of problems surrounding tumour formation and the directing of embryonic stem cells to divide into the correct tissue type is proving troublesome to researchers.

[87] Monachello "The cloning for biomedical research debate: do the promises of medical advances outweigh the ethical concerns?" (2003) *Tulsa Journal of Comparative and International Law* 591 at 593.

[88] (2003, Winter) *Catholic University Law Review* 437 at 469.

> coaxed into nerve cells in hopes of treating numerous neurological diseases, such as Parkinson's, Alzheimer's, and spinal cord injuries. Likewise, researchers working with stem cells from human fat cells have created cartilage, muscle, and bone cells, which advance the promise of growing various replacement tissues without the use of embryos. Unlike the use of therapeutic cloning to negate the histocompatibility problem, these alternative stem cells have been successfully used to treat human beings. These advances force the ethical question of whether using ESCs for research is even necessary."

If researchers were able to extract stem cells from mature tissue such as skin, it would greatly nullify any arguments against this form of healthcare technology. It would then be possible to create a stem cell line and even tissues without the risk of possible rejection by the patient's immune system, without having to go through the controversial process of therapeutic cloning, as is discussed below.

2.3 Benefits of stem cell applications

2.3.1 Drug screening

If it is possible to create large quantities of purified human embryonic stem cell-derived cells such as heart muscle cells or neurons, and these could even be used to screen new drugs.[89] This would greatly accelerate drug discovery, due to the fact that it would reduce the need for animal testing and other time consuming processes during the early screening phases, and lead to the rapid screening of thousands of chemicals.[90]

2.3.2 Heart tissue

In a heart attack part of the heart muscle dies because of a blockage of the blood supply to the muscle. The dead muscle tissue is permanently replaced by non-functional scar tissue. In the clinical setting, it has been shown that human embryonic stem cells spontaneously differentiate into heart muscle cells. Theoretically it is thus possible to place the heart cells back into the

[89] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 21; Braswell (2003) *Chicago-Kent Law Review* 423 at 428; Kincaid (2003) *Pepperdine Law Review* 553 at 566.

[90] Kincaid (2003) *Pepperdine Law Review* 553 at 579.

heart in order to replace the dead muscle or scar tissue, with a resultant restoration of full heart function.[91] This will, however, prove to be much harder in practice. The new heart cells must be integrated in a useful way with the surrounding muscle or they will die. This can only be done through the induction of new growth of existing blood vessels.[92] It is clear that the only way in which this particular research can be successfully applied is through the collaboration of many different fields of medicine, but the potential benefits that could be gained therewith are noteworthy.

2.3.3 Diabetes and transplantation in general

Type 1 diabetes is an autoimmune disease that destroys the insulin producing cells in the pancreas. At the moment there are limited amounts of success in efforts to treat these patients. Treatment consists of human islet transplantation in order to restore the insulin secretory function of the pancreas. The fact that there are very few donated pancreases each year, combined with the toxicity of the immunosuppressive drugs to prevent rejection, leads to a very low success rate.[93]

This problem could be overcome with the use of stem cells that differentiate into a particular pancreatic cell called a beta cell.[94] As will be seen below, the use of therapeutic cloning could also assist in the overcoming of any problems associated with the rejection of tissues.[95]

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[91] Braswell (2003) *Chicago-Kent Law Review* 423 at 427; Kincaid (2003) *Pepperdine Law Review* 553 at 566; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 593; Stevens (2003) *Houston Journal of International Law* 623 at 629; Gosden "Biomedicine, the family and human rights: Progress and achievements in biotechnology" as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) *Biomedicine, the Family and Human Rights* (2002) 13 at 15.

[92] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 22.

[93] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 5.

[94] Stevens (2003) *Houston Journal of International Law* 623 at 629.

[95] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 10; Momeyer (2003) *Capital University Law Review* 93 at 95; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 593.

Under the right circumstances pluripotent stem cells could be used to create an unlimited supply of cells, tissues and even organs.[96] Bone marrow transplantation for instance could become safe, cost effective and be used to treat a wider range of disorders with much more efficiency. A good example would be a case where persons have been exposed to high levels of radiation.[97] Although the "creation" of more complex organs such as kidneys has not been achieved as of yet, the general consensus is that it is only a matter of time before it would be done on a regular basis and the technology be made available to the general public.

2.3.4 Nervous system diseases

Nervous system diseases are particularly devastating to not only the victim, but their families as well. Many nervous system diseases result from loss of nerve cells. Mature nerve cells cannot divide to replace those that are lost, and without a different source of functioning nerve tissue, no therapeutic possibilities exist. In Parkinson's disease, nerve cells that make the neurotransmitter dopamine die, whilst in Alzheimer's disease, cells that are responsible for the production of certain other neurotransmitters die. In amyotrophic lateral sclerosis, the motor nerve cells that activate muscles die. In spinal cord injury, brain trauma, and even stroke, many different types of cells are lost or damaged. In multiple sclerosis, the cells that protect nerve fibres are lost. [98] Perhaps the only hope for treating such individuals comes from the potential to create new nerve tissue, restoring function from pluripotent stem cells.[99]

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[96] Kincaid (2003) *Pepperdine Law Review* 553 at 566.

[97] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 7.

[98] Chapman, Frankel & Garfinkel (1999 *American Association for the Advancement of Science and Institute for Civil Society* 5; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 593 and Stevens (2003) *Houston Journal of International Law* 623 at 629 mentions the use of stem cells for the treatment of Alzheimer's patients as well.

[99] Gosden "Biomedicine, the family and human rights: Progress and achievements in biotechnology" as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) 13 at 15.

Some amounts of success have already been achieved in the treatment of spinal cord injury victims. Recent indications in the general media shows that, depending on the extent of the damage, some of the nerve cells regenerate after the correct stem cell treatment has been administered, with the resultant regaining of control over the patients limbs.[100]

2.3.5 Immunodeficiency diseases

Researchers are expressing their confidence in the benefits that stem cells could hold for almost any immunodeficiency disease. Included here are diseases such as Wiskott-Aldrich syndrome, lupus and the immune deficiencies as a result of acquired immune deficiency syndrome (HIV/AIDS). With regards to South Africa, the possibility of treatment that could restore the immune systems of HIV/AIDS sufferers is very good news indeed. It wouldn't necessarily lead to a cure for the disease, but could significantly lengthen the life span of people suffering thereof.[101]

If the treatment of HIV/AIDS related immune system depletion is to be realised, it would open the window for another debate, namely the allocation of funds to make this technology available to the public in general. Chapter 4 addresses the application of financial resources to stem cell research and its related technologies.

2.3.6 Cancer

Bone marrow stem cells, which are multipotent in nature, are currently used to rescue patients following high dose chemotherapy. Unfortunately, these recovered cells are limited in their capacity to restore immune function completely and it is hoped that injections of properly differentiated stem cells may result in the return of the complete repertoire of the immune response of

[100] Schoeman "Rare op may save teen" (2004) *The Herald* 1; Van Heerden "Operasie kan verlamde Danie weer laat loop" (2004) *Rapport* 5; Van Heerden "Twee SA verlamdes kry weer hoop na stamseloorplantings" (2004) *Rapport* 7.

[101] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society* 6.

patients undergoing bone marrow transplantation. Complete and functional restoration could lead to the development of effective anticancer technology. Successful use of stem cell research in treating cancer patients would permit use of very toxic (and effective) chemotherapeutic regimens that could not currently be utilized due to an inability to restore marrow and immune function.[102]

Some companies currently specialize in removing blood stem cells prior to chemotherapy, and then replace it to repopulate the bone marrow afterwards. Some blood stem cells are also removed from fit, young people and stored in case they may need the cells later in life.[103]

2.3.7 Developmental biology

Currently human developmental biology is strained by various practical and ethical considerations. Human embryonic stem cells can assist researchers in examining how particular cells differentiate to form the different cells and tissue that make up the human body.[104] It could lead to greater understanding of the causes of cancer and birth defects, as well as their treatment. Human embryonic stem cells will offer insight into processes which currently cannot be studied in humans directly, or be fully understood through animal testing.[105]

2.3.8 Economic benefits

Although most of the authors of material surrounding the benefits to be gained through stem cell technology do not address the monetary side thereof directly, it is a very valuable (literally) consideration to mention. Kincaid[106]

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[102] Chapman, Frankel & Garfinkel (1999) *American Association for the Advancement of Science and Institute for Civil Society*; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 593 also mentions the use for stem cells is the treatment of cancer patients.

[103] Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 10.

[104] Braswell (2003) *Chicago-Kent Law Review* 423 at 428.

[105] Kincaid (2003) *Pepperdine Law Review* 553 at 579.

[106] (2003) *Pepperdine Law Review* 553 at 580-581.

states the opinion of many that this field could generate millions of dollars (or rands) in research and new business.

The economic benefits are, however, very dependant on factors such as the ability to attract necessary capital, continued research and the costly time lapses between the initiation of research and the approval of an applied product or process by the relevant Patent and Trademark offices. A large backlog of patent applications could prove to be devastating to the financial sector of a rapidly developing field such as stem cell research.

2.3.9 Gene therapy

Gene therapy (or genetic engineering as it is commonly known) can correct genetic deficiencies by replacing "defective" genes, whose nucleotides are not in the proper sequence, with genes containing the normal genetic sequence. The proper sequencing of the genes results in the alignment of amino acids in their correct order. This leads to the production of vital proteins in the body.[107]

Because of their differentiation potential, stem cells that are chemically treated through gene therapy can carry the gene correction that is necessary to produce the correct proteins once inserted into the person with the defective gene.[108]

2.3.10 Therapeutic benefits

The majority of the literature focuses on the prospective gains that could be made by the patient receiving stem cell therapy. Momeyer[109] approaches the

[107] Makdisi (2003) *Rutgers Law Journal* 463 at 468.

[108] Theoretically gene therapy seems to be a simple procedure, but in practice it has been plagued with many problems, especially tumour formation in the receptive individual. In explaining the risks involved in conducting germline therapy, Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 451 states that it has lead to many unforseen, and sometimes alarming, side effects in mice and needs careful analysis before an attempt is made to apply the technology to human subjects. Despite the distance that still has to be covered, the potential of future successful applications of this technology is encouraging.

[109] (2003) *Capital University Law Review* 93 at 98-99.

situation from a different angle, namely to evaluate the possible therapeutic benefits that it holds for the donors of stem cells, stating that implanted embryos are not the only embryos that are available for use in stem cell research. IVF embryos that are judged unsuitable for implantation for whatever reasons, albeit an earlier successful pregnancy, exhaustion, termination of attempts at pregnancy or unwillingness to donate the embryo to someone else leaves its "parents" with one of two choices: either the embryo will have alcohol dripped on it and flushed down the drain, or it will be material for basic medical research, specifically, the extraction of embryonic stem cells in a process that will also kill it. Fertility clinics typically set a five-year limit on the storage of frozen embryos, and typically charge as much as $1000 per year in storage costs in the United States of America. These embryos have no prospect of developing beyond the few cell divisions already achieved and have no potential for implantation, nor any prospect of becoming a person. They will not be accorded that one-in-three or four chance of successful implantation in a woman's body.

Momeyer believes that the most respectful way to end the life of an embryo conceived *ex utero* and with no prospect of proceeding to implantation is to extract from it embryonic stem cells that may prove highly beneficial to fully developed and very damaged human beings, with indisputably full moral status. The argument would be analogous to one given by those donating organs of a brain dead relative to others for transplantation sometimes give to themselves as solace when dealing with the reality of the death of a loved one and wanting to salvage something of value from an otherwise devastating experience. Therapeutic benefits are clearly a valuable contributor to stem cell research applications.

2.4 Genetic technology related to stem cell research

2.4.1 *In Vitro* Fertilisation[110]

The first time that this procedure was successfully performed in creating a so-called "test tube baby" was in 1978, when Doctors Steptoe and Edwards aided

[110] This is usually referred to as IVF.

a patient (Lesley Brown) in falling pregnant.[111] The patient was unable to fall pregnant because of an abnormal condition of her Fallopian Tubes. A ripe ovum (egg) was removed from her ovary using a needle (this procedure is called a laparoscopy),[112] placed in a laboratory dish (from there the term *in vitro*) and mixed with sperm from her husband. After a few days the fertilised egg (embryo) was placed back into the woman's uterus, and developed normally until the child was born. Usually, in order to enhance the process, women are administered hormones, which then result in the release of more than one egg. Under normal circumstances there are a number of fertilized eggs left over after the completion of the IVF treatment. These are frozen as per the instructions of the donor parents, usually for a period of five years.[113]

It is clear that there can be no ethical problem with IVF treatment. It is a procedure that merely serves as a method in which a woman who would ordinarily not be able to bear children is aided in doing so.[114] The primary

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[111] Strauss *Doctor, Patient and the Law: A selection of practical issues* (1991) 187.

[112] Batsedis "Embryo adoption: A science fiction or an alternative to traditional adoption?" (2003) *Family Court Review* 565 at 566.

[113] According to Batsedis (2003) *Family Court Review* 565 at 566 it was estimated that fertilisation clinics in the United States of America stored more than 150 000 frozen embryos in 1999, with another 19 000 added each year.

[114] The definition of artificial fertilization in terms of section 1 of the Human Tissue Act 65 of 1983 can be interpreted as to include IVF treatment. It reads as follows:

> "'artificial fertilization of a person' means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including -
>
> *(a)* the bringing together outside the human body of a male and a female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female person; or
>
> *(b)* the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body, in the womb of a female person,
>
> for such purpose."

The Children's Status Act 82 of 1987 defines artificial insemination as to include IVF treatment. Section 5(3) reads as follows:

> For purposes of the following section 'artificial insemination', in relation to a woman
>
> "*(a)* means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of that woman; or
>
> *(b)* means the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body in the womb of that woman,

concern surrounding IVF children used to be their status. This found some prominence in cases where donor sperm or eggs were used to create the IVF embryo,[115] although most of these concerns have been eliminated through section 5 of the Children's Status Act.[116]

IVF treatment is extremely important with regards to stem cell research, because any excess embryos that are left over after the completion of such treatment could be a valuable source of stem cells.[117] In most cases any excess embryos are eventually discarded, with the resultant argument from the researchers that an embryo donated to research is much better than one that is destroyed. Certain arguments surrounding ownership in human material,[118] a decrease of respect for the human embryo,[119] informed consent of the donor as well as the applicability of storage time limits[120] have been raised and are discussed in later chapters.

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for the purpose of human reproduction; 'gamete' means either of the two generative cells essential for human reproduction."

Taking the abovementioned legislation into consideration, it is clear that IVF treatment is well established in our legal system. It is, however, necessary to establish what the scope of the application entails with regards to the particular legislation that is applicable at any given point in time.

[115] This is commonly referred to as the distinction between AIH (where the husband's semen is used in the artificial insemination) and AID (where donor semen is used). See Strauss 181.

[116] 82 of 1987.

[117] Kincaid (2003) *Pepperdine Law Review* 553 at 565.

[118] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) *Legal rights on human genetic material* (1996) 51 at 68-70; Stauch, Wheat & Tingle *Sourcebook on medical law (2nd ed)* (2002) 387; Boyd "Considering a market in human organs" (2003) *North Carolina Journal of Law & Technology* 417 at 443.

[119] Parens "On the Ethics and Politics of Embryonic Stem Cell Research" as published in Holland *et al* (eds) 37 at 46-47.

[120] Stauch, Wheat & Tingle 386; Batsedis (2003) *Family Court Review* 565 at 567.

2.4.2 Somatic Cell Nuclear Transfer [121]

In transferring stem cell derived cells (for instance heart muscle cells) to a recipient patient's body, it is necessary to prevent the rejection thereof by the patient's immune system in much the same way that rejection has to be prevented in organ transplantation. Human cells have cell-surface proteins known as human-leukocyte associated (HLA) antigens.[122] The genes that code for these HLA antigens are highly polymorphic; that is, it is very rare for two individuals, save two identical twins, to have an identical set of HLA antigens. The human immune system uses these HLA antigens to identify cells as either belonging to the body or as foreign. Cells identified as foreign, the ones with HLA antigens different from those of the body's cells, are attacked by the immune system and poses a serious obstacle to transplant procedures. A key to success in creating transplantable products from human embryonic stem cell lines will be matching HLA antigens of the transplant recipient as closely as possible. [123]

One strategy that has been put forward in order to combat the problem surrounding rejection is to develop banks of histocompatibility complex-typed human embryonic stem cell lines.[124] These lines would be designed to be less immunogenetic, but this is not an easy task. Each individual's HLA proteins, located on the five separate HLA loci must match with those of the foreign cell.[125] Any treatment developed from cells that differ significantly from those of the patient will not succeed unless immunosuppressive drugs are taken.

Another strategy is to make use of cells that are compatible with one's own body, such as adult, umbilical or placental stem cells.[126] Unfortunately the technology has not been developed to properly utilise adult stem cells yet.

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[121] This is usually referred to as SCNT.

[122] Braswell (2003) *Chicago-Kent Law Review* 423 at 440.

[123] *Ibid*.

[124] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 23.

[125] Miller (2003) *Catholic University Law Review* 437 at 466.

[126] *Ibid* at 467; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 593; Stevens (2003) *Houston Journal of International Law* 623 at 627.

There are tissue banks opening throughout the world that specialise in the storage of umbilical cord and placental stem cells, but since it is highly unlikely that adults currently in need of such treatment would have had their cells stored since birth, these options would only truly become viable in the future.

The more effective, although more controversial, method is to use SCNT technology to create cells that are genetically identical to a specific patient.[127] This particular technology was used to facilitate the cloning of Dolly the sheep.[128] Thomson[129] discusses the cloning procedure as follows:

> "Dolly was cloned by transplanting the nucleus from a mammary epithelial cell to an enucleated oocyte, and by transferring the resulting nuclear transfer product to a recipient ewe. The same procedure could be performed with a human somatic cell nucleus transferred to an enucleated human oocyte, but instead of transferring the nuclear transfer product to produce a pregnancy, a blastocyst could be produced in vitro and an ES cell line derived. Through this method it might be possible to take a readily accessible cell type such as a skin fibroblast from a biopsy specimen, establish an ES cell line using nuclear transfer from the fibroblast, direct the cell line to heart muscle cells, and transplant those heart muscle cells back to the patient who donated the fibroblast. The heart muscle cells would be genetically identical to the patient's cells for all nuclear-encoded genes."

It is at this point that the important distinction between therapeutic and reproductive cloning finds prominence. If the genetic material of a human egg is replaced with the nucleus of an adult cell and cultivated in vitro until the production of stem cells in the blastocyst stage (in other words creating an

[127] Makdisi (2003) *Rutgers Law Journal* 463 at 492; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 592; Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 449; Deutsche Forschungsgemeinschaft 87.

[128] Haker & Beyleveld (eds) *The ethics in genetics in human procreation* (2000) 233; Kincaid (2003) *Pepperdine Law Review* 553 at 565; Rhodes "The difficulty of regulating reproductive and therapeutic cloning: Can the United States learn anything from the laws of other countries?" (2003) *Penn State International Law Review* 341 at 343; Taylor "The fear of drawing the line at cloning" (2003) *Boston University Journal of Science and Technology Law* 379 at 382. The process has not been perfected as of yet. In the case of Dolly the sheep, the procedure had been repeated more than 250 times before it was successful.

[129] Thomson "Human Embryonic Stem Cells" as published in Holland *et al* (eds) 15 at 22.

embryo using SCNT), it is called therapeutic cloning.[130] In this case the rest of the embryo is then discarded. If the embryo that is created using SCNT is not discarded, but rather implanted into a woman's uterus to develop into a baby, it is known as reproductive cloning.[131]

Throughout the world there are major efforts being made to establish a global ban on reproductive cloning, as will be seen in later chapters. The difficulty, however, lies in the very fine line that separates reproductive and therapeutic cloning. Many authors warn of the dangers of eugenics and how any type of research conducted with the assistance of SCNT is the first step on the slippery slope towards reproductive cloning.[132] Cognisance must be taken of the fact that it has been mentioned that SCNT could even lead to a situation where an intermediary ground between therapeutic and reproductive cloning is found. This would result in a case where embryos are to be implanted into the uterus and then aborted at a scientifically useful time, so that the foetal tissues could be utilized to treat the person whose somatic cells were used to create the embryo.[133] It is of vital importance that any such research be subject to very strict regulatory mechanisms, in order to adequately address any therapies that could result from the use of SCNT to harvest stem cells.

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[130] Makdisi (2003) *Rutgers Law Journal* 463 at 492; Rhodes (2003) *Penn State International Law Review* 341 at 346.

[131] Blackbeard (2002) 35 *De Jure* 318 at 321; Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 10; Jordaan (2002) 119 *The South African Law Journal* 294 at 296;

In terms of the National Heath Act 61 of 2003, the definition of therapeutic and reproductive cloning is very similar to the one provided for above. Sec 57(6) reads as follows:

> "For the purpose of this section-
> *(a)* 'reproductive cloning of a human being' means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose; and
> *(b)* 'therapeutic cloning' means the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues."

[132] Zaner "Surprise! You're just like me!: Reflections on human cloning, eugenics, and other utopias" as published in Humber & Almeder (eds) *Human Cloning* (1998) 103.

[133] Makdisi (2003) *Rutgers Law Journal* 463 at 496.

2.4.3 Human-animal chimerism

Some companies have begun conducting research (and applying for patent rights) in the creation of human-animal chimeras. What this basically means is that they create embryos through the procedure of SCNT using human cell nuclei and animal egg cells.[134] These embryos are then used in the harvesting of stem cells.[135]

Research has shown that the chance of such an embryo growing into a part human - part animal being, if implanted, is extremely slim. This fact has not kept ethicists from debating the issue. Without going into this method of stem cell acquisition too deeply, it has to be mentioned that valid arguments surrounding the possibility of new inter-species disease transfer have been raised. Other arguments include the proposition that the use of such embryos would be acceptable as long as it is not allowed to progress past the 14-day stage of development (at which point the primitive streak appears in the embryo).[136]

2.4.4. Parthenogenesis

A new development in the creation of embryos in order to obtain stem cells is a process called parthenogenesis. In this instance the egg cell is “tricked” into dividing and turning into an embryo, even though it has not been fertilized by a sperm cell. Scientists have yet to apply this technique to human cells, but have successfully used it to obtain stem cells from eggs obtained from monkeys.

Before the fertilization process, an egg sheds one of its two sets of chromosomes to make room for a new set from a visiting sperm. Scientists "tricked" an unfertilised egg to reclaim the shed chromosomes and develop with a double set as if it were fertilized. These eggs developed to the blastocyst stage, where scientists removed the stem cells. As with most biomedical technologies, this development, while exciting, raises several

[134] Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 456-457.

[135] Deutsche Forschungsgemeinschaft 96-97.

[136] Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 460.

issues including the fact that although scientists were able to retrieve stem cells that were coaxed to form specialized cells, it is uncertain whether the cells can produce viable tissue. Additionally, although the process was a success using monkeys, scientists do not know if the technique will work on humans. If the process does work on humans, its application will be limited to replicating women's cell lines. The embryo would be made solely of female chromosomes since the egg is not fertilised with sperm.[137]

Even though the destruction of the embryo remains an issue due to the fact that the pseudo-embryo created by parthenogenesis, called a parthenote, has no chance of being carried to term because men and women put different imprints on genes by using both the egg's and sperm's sets of chromosomes, the use thereof could prove to be less controversial than is the case if normal embryos are used. With only a female imprint, the embryo will not develop properly and cannot be carried to term. The result is that in obtaining stem cells from this embryo (parthenote), the researcher is destroying an embryo that would not have been able to develop further in any case. Some ethicists could argue that such a situation is more acceptable to one in which a viable embryo is destroyed in the derivation of stem cells.

2.4.5 Pre-implantation genetic diagnosis[138]

There are numerous ways for parents to overcome difficulty in conceiving children, for instance through the use of IVF treatment. Unfortunately, as with every child born, there is the risk of the child being affected by genetic diseases. In the past, procedures such as amniocentesis and chorionic villous sampling were performed on foetuses to detect any genetic defects.[139] A new technique in assisted reproductive technology called pre-implantation genetic diagnosis (PGD) can now assist parents in ensuring the genetic heath of their offspring. Due to the extremely complex medical procedure that is involved,

[137] Stevens (2003) *Houston Journal of International Law* 623 at 632.

[138] This is commonly referred to as PGD.

[139] Knox "Preimplantation genetic diagnosis: Disease control or child objectification" (2003) *Saint Louis University Public Law Review* 435 at 435.

the following explanation by Knox[140] is held as being an accurate description thereof:

> "PGD is a diagnostic procedure that is performed before the embryo is implanted into the woman's uterus. A simplified explanation of PGD may be outlined in three steps: first, several embryos are created using IVF; second, after reaching a certain stage in development, each embryo DNA is tested for genetic disease; third, embryos determined to be unaffected by genetic disease are implanted in the woman's uterus in hopes of a successful pregnancy. Although each step described above is important, the second step (testing for disease) is crucial to the PGD process. Detecting genetic disease in an embryo can be very complicated and should be explained more fully. First, oocytes are recovered by ultrasound-guided aspiration and grown in culture. Oocytes are then subjected to micromanipulation and the first polar body is removed. The polar body is then biopsied and undergoes genetic diagnosis. The oocyte is then injected with sperm for zygote formation. Next, the second polar body is removed for genetic diagnosis. The zygote is allowed to grow to a six-to-eight cell stage. [O]ne or two cells are then removed for genetic analysis. Analysis is performed by extracting DNA from the cells and subjecting it to polymerase chain reaction (PCR) or fluorescence in situ hybridization (FISH). Although PGD was first performed nearly 13 years ago and has successfully eliminated genetic disease in a number of children, clinical application of PGD has remained limited. Several reasons exist for its slow implementation. First, PGD is a multi-step procedure that requires combined expertise in reproductive medicine and molecular genetics. Second, genetic diagnosis of cells is challenging at all stages.[141]"

PGD can be divided into two groups namely: therapeutic and non-therapeutic. Therapeutic is when the procedure is used to treat genetic diseases in children, whilst the non-therapeutic procedure involves using it for non-medical reasons such as physical appearance and sex selection.[142] The use of PGD for non-therapeutic reasons is not of primary importance at this point in time, although it is notable that much debate has been led surrounding the ethics of "ordering" a child with certain traits such blue eyes or musical ability, and the risk of discrimination that can flow there from.

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[140] (2003) *Saint Louis University Public Law Review* 435 at 435-437.

[141] Most of the more complex medical terminology is defined in the glossary provided at the end of this dissertation.

[142] Knox (2003) *Saint Louis University Public Law Review* 435 at 437-438.

The normal use of PGD for therapeutic purposes would be to attempt the prevention of certain genetic diseases in a child, through genetic diagnosis at embryonic level.[143] A recent example is of a woman that carried the gene for the early onset of Alzheimer's disease. She used PGD to produce a daughter free from this particular gene.[144] Other diseases such as Down's syndrome and cystic fibrosis can be addressed as well. Because of the complexity of the procedure, there are some questions as to the accuracy thereof. At least one case has been reported of a couple that tried to sue the institution where they underwent the PGD. Even though they did have their embryos screened for cystic fibrosis, their daughter was born with the disease.[145]

The second use of therapeutic PGD is much more controversial. In this case the beneficial use of stem cells comes into play. This involves using the procedure to select a donor match for an existing ill child. It is possible to choose an embryo that may produce a child who will provide stem cells or bone marrow for a sibling or other relative. PGD has been used for such reasons in the United States of America and the United Kingdom. In 1999, a couple in the United States used PGD to screen their embryos for one that was a tissue match for their daughter who had Fanconi's anaemia. Five suitable embryos were implanted in the woman and one resulted in a successful pregnancy. When the new child was born, birth blood from the umbilical cord was harvested and used in a successful stem cell transplant for the daughter. In the United Kingdom, where the Human Fertilisation and Embryology Authority must authorize such uses of PGD, the parents of a 2-

[143] Wolf, Kahn & Wagner "Using pre-implantation genetic diagnosis to create a stem cell donor: Issues, guidelines and limits" (2003) *Journal of Law, Medicine and Ethics* 327 at 329 provides a fairly comprehensive list of possible diseases that could be treated using this form of treatment.

[144] Knox (2003) *Saint Louis University Public Law Review* 435 at 438.

[145] *Ibid* at 439.

year-old boy with beta thalassaemia were given permission to use PGD to produce a matching donor.[146]

The creation of a child for the sole purpose of being a donor for an ill child raises many well-founded fears of the commercialisation of human material.[147] If, for instance, the procedure of using stem cells collected from the newborn babies' umbilical cord is not a success, will they be willing to take the next step; a step which might be the harvesting of haemotopoetic stem cells from the bone marrow, or even organs from the healthy child?[148] If the parents of an ill child are willing to conceive another child, merely to facilitate the recovery of the ill child, it could lead to questions surrounding where to draw the line in the production of genetically enhanced materials. It is clear that one of the countless "slippery slope" arguments finds relevance in this case, namely that allowing this type of procedure is the first step towards human objectification, reproductive cloning and the ultimate demise of mankind.

On the other hand, if PGD is simply used to create an embryo that matches the genetic code of another ill sibling, and stem cells are harvested thereof without implantation into the mother's womb, the destruction of the embryo would remain an issue, but at least there is no creation of another child merely to serve the purpose of facilitator in another's recovery.

2.5 Conclusion

From the abovementioned medical information it is clear that stem cell research and its application has impressive potential to provide humanity with much needed answers to many pressing health related issues.

This potential has not passed unnoticed by Human Rights activists and other parties concerned. The beneficial possibilities of its use in healthcare

[146] Knox (2003) *Saint Louis University Public Law Review* 435 at 438. This particular case has also been described in Wolf, Kahn & Wagner (2003) *Journal of Law, Medicine and Ethics* 327 at 328-329.

[147] Newman (2003) *Journal of Contemporary Health Law and Policy* 431 at 453.

[148] Wolf, Kahn & Wagner (2003) *Journal of Law, Medicine and Ethics* 327 at 327.

applications also introduces the potential of wide spread discriminatory action and even forms of eugenics. Once SCNT procedures are used to clone an embryo, the only thing separating that embryo from being used for reproductive cloning procedures is whether or not it is used to impregnate a woman. Although the majority of debates focus on the ethical considerations surrounding embryonic stem cell research, most authors are in unison surrounding the fact that reproductive cloning should under no circumstances be commenced. Some have even attempted to draft provisional examples of international conventions that will outlaw reproductive cloning altogether as well as compel parties thereto to implement further legislation regulating the other aspects of biomedicine.[149] Amidst all of the input from different sources, it is still necessary for South Africa to control the field through its own regulatory and legislative actions.

Out of a purely medical perspective, stem cell research is a field that is rapidly becoming a presence to be reckoned with. The application thereof however cannot simply be regarded *in vacuo*. There are many legal and ethical issues at play which could seriously affect the question surrounding the legitimacy and application of stem cell research in the South African law. Included here are issues surrounding the informed consent process of potential donors, religious perspectives on stem cell research and the primary Human Rights instruments, both in South Africa and internationally.

These issues are discussed in the following chapter.

[149] See for instance the proposed Convention on the Preservation of the Human Species in Annas, Andrews & Isasi "Protecting the endangered human: Toward an international treaty prohibiting cloning and inheritable alterations" (2002) 28 *American Journal of Law and Medicine* 151at 154.

Chapter 3

Legitimacy

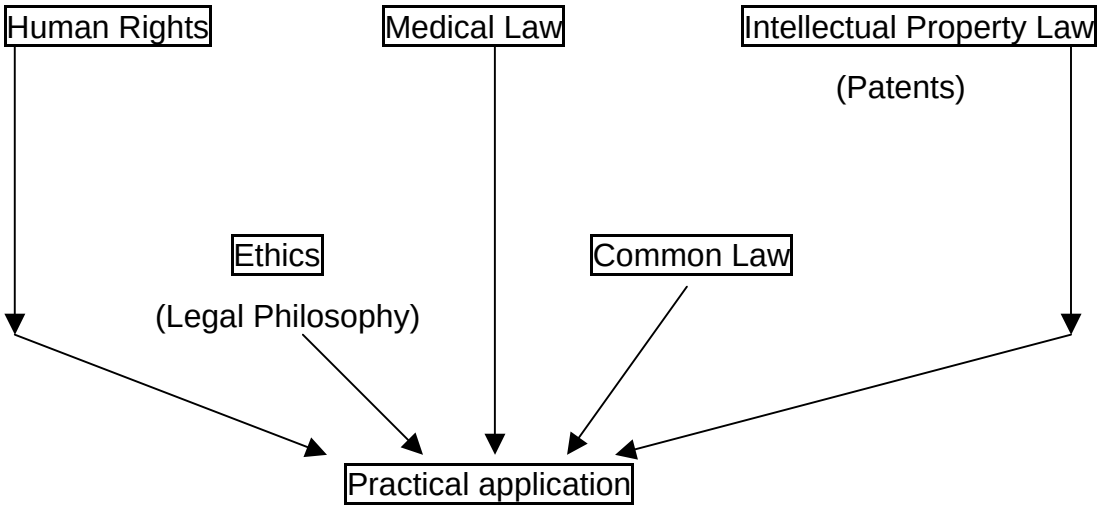
3.1 Introduction

In order to be able to fully address any legitimacy issues that befall the stem cell debate, one must be aware of the exact meaning of legitimacy itself. The generally accepted definition of legitimacy simply states that one has "the sanction of law or custom".[150] This is the strict interpretation thereof; one which does not necessarily encompass other possible factors which may play a role. Simply stated, it means the following: The fact that an act is legitimate in the strict sense of the word, does not mean it is legitimate in the sense that it is practically feasible. There are many other considerations that have to be met when dealing with a topic as hotly debated over such as stem cells. The religious viewpoints, principles surrounding ownership rights in human genetic material, consent and contractual limitations are amongst the facets that form part thereof. Legitimacy is not simply a concept that can be separated from the facts of a particular case. It's not merely a mathematical equation in which A + B = Legitimacy. The stem cell debate in particular has, for example, a number of different opinions surrounding the use of abortive foetuses in harvesting stem cells. These opinions have to be addressed before one can continue with the research, in order to avoid a public outcry that could veto an otherwise legitimate practise.

Research has identified a number of core fields within which the use of stem cells rotate. As with most legal questions, the field cannot simply be dealt into one particular area of legal expertise, but requires the balancing of numerous interests, particularly judicial and ethical considerations. The following diagram illustrates the primary focal points in addressing the legitimacy issues pertaining to the use of stem cells in South Africa:

[150] Funk & Wagnalls Standard Dictionary of the English Language – International Edition, Volume 1, 728.

Diagram 1.



These different fields should not be seen individually. Medical Law, for instance, focuses heavily on aspects of informed consent and patient autonomy. These principles can be observed in certain parts of Human Rights as well as the arguments provided by, for example, feminists in Legal Philosophical literature. Contractual agreements in Common Law could lead to the formation of Intellectual Property Rights. If the contract, however, is deemed to be *contra bonos mores* because of the fact that one is dealing with human material, it could have adverse effects on the Intellectual Property Rights obtained therewith.

It is clear that the different fields cannot be observed *in vacuo*. The end result of such an examination is surely to establish a sound legal basis from which the practical application of stem cell research and the opening of stem cell banks in South Africa could be launched. If the moral concerns are too grievous and lead to a large public outcry due to, for instance, the use of aborted foetuses in stem cell harvesting, it could force private investors towards a costly re-examination of the entire field. If all of these grievances were addressed before a practical campaign is launched, it would facilitate the speed with which such practices are implemented.

The abovementioned aspects are to be discussed with reference to the current legislation, with special emphasis being placed on the Human Tissue

Act[151]. The National Health Act[152] and its impending regulations will be thoroughly discussed in the following chapter and are not of such vital importance in establishing the current *boni mores* surrounding stem cells in South Africa. Before one can critically examine the future judicial position, one must first have a comprehensive grasp of the present situation. Once it is established that there are no unbridgeable judicial and ethical obstacles currently imposed on the matter, it is possible to evaluate the proposed legislative and regulatory measures to be taken.

There are a number of differences between umbilical cord stem cells, embryonic stem cells and stem cells derived from foetuses. These differences apply to both the method in which the relevant legislative measures will be used, as well as the viewpoints surrounding ethics pertaining thereto. As will be seen below, Human Rights and religious concerns play a much more prominent role in the use of foetal and embryonic stem cells, compared to umbilical cord stem cells which are derived from umbilical cord blood directly after birth.

3.2 Medical Law

3.2.1 Assessing the scope of Medical Law

In her doctoral thesis, Pearmain[153] refers to a description by Nys of the scope of Medical Law:

> "Medical law is an area of law, medical law does not respect traditional compartments with which lawyers have become familiar, such as torts, contracts, criminal law, family law and public law. Instead, medical law cuts across these subjects and today must be regarded as a subject in its own right. We maintain that it is a discrete area concerned with the law governing the interactions between doctors and patients and the organisation of health care."

But the scope of stem cell research applications stretches far beyond the mere interactions between doctors and their patients. The correct approach

[151] 65 of 1983.

[152] 61 of 2003.

[153] (2004) *A Critical Analysis of the Law of Health Service Delivery in South Africa* (Unpublished LLD thesis, University of Pretoria) xix.

would be to classify stem cell research within the wider scope of Health Law, of which Medical Law forms a part.[154] Health Law as such is a very wide field, encompassing a number of judicial bodies of law. Included are aspects of Human Rights, Law of Contract, Delict and Criminal Law. Furthermore, Medical Law addresses issues surrounding medical negligence, justification grounds for medical intervention, informed consent, patient privacy and euthanasia policies to name but a few. For purposes of this dissertation, reference is made to Medical Law in general as well as the other fields of law individually. It is, however, important to take cognisance of the fact that these different areas all form part of the bigger concept of Health Law.

It is sometimes a difficult task to establish the precise legal basis from which to approach a specific matter, because of the fact that a number of the abovementioned principles could be applied to any specific case. For this reason, the Human Tissue Act[155] and its regulations shall first be used to address a particular stem cell related problem. Thereafter the other legal questions that flow there from can be discussed, without losing sight of the fact that all of the principles are interconnected and need to be dealt with in order to make this a viable proposition in practice.

There are a number of companies worldwide that currently harvest stem cells from the umbilical cord of a newborn child.[156] The umbilical cord is discarded as medical waste in normal medical practice, which negates the controversial questions surrounding embryonic stem cells. These cells are then stored for a fixed time as per agreement, and can be used in the future if the child should become the victim of a disease that is curable through the use of stem cells. It is clear that there is room for legal action if, for instance, the storage facility loses the cells. The question, however, is which legislation and regulation has to be followed in order to set up such a facility in South Africa. The only piece

[154] *Ibid* xx.

[155] 65 of 1983.

[156] www.cryoclinic.com; www.lazaron.co.za.

of legislation currently available to such an applicant is the Human Tissue Act[157] and its regulations[158].

3.2.2 The application of the Human Tissue Act[159] to umbilical cord stem cells

Section 1 of the Human Tissue Act provides a number of definitions that are applicable to this case. Amongst these are definitions for blood, blood products and tissue.[160] It is clear that the stem cells derived from umbilical cord blood falls under the definition of "blood products" and that "use" of the cells includes the preservation (storing) thereof. One of the primary concerns of a company investing in this field would be to ensure that it is not viewed as a tissue bank by the local authorities. Tissue banks have different guidelines to follow compared to that of a facility that only uses blood products. The only possible sticking point would be the inclusion of "body fluid" in the definition of tissue. Umbilical cord blood (since it is not withdrawn in the traditional sense

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[157] 65 of 1983.

[158] "Artificial Insemination of Persons, and Related Matters" as published in GN (Government Notice) R1182 in *GG* (Government Gazette) 10283 of 20 June 1986 as amended by GN R1354 in *GG* 18362 of 17 October 1997; "Blood and Blood Products" as published in GN R1935 in *GG* 12695 of 17 August 1990 as amended by GN R298 in *GG* 14596 of 26 February 1993; "Importing and Exporting of Prescribed Tissue" as published in GN R2536 in *GG* 10537 of 5 December 1986; "Human Tissue Regulations" as published in GN R2876 in *GG* 12234 of 29 December 1989.

[159] 65 of 1983.

[160] The definitions that are the most applicable are the following:

> "'blood' means human blood;
> 'blood product' means any product derived or produced from blood;
> 'Director-General' means the Director-General: National Health and Population Development;
> [Definition of 'Director-General' substituted by s. 1 *(a)* of Act 51 of 1989.]
> 'export' means export from the Republic by any means;
> 'import' means import into the Republic in any manner;
> 'importer' includes a person who, whether as an owner, consignor, consignee, agent or broker, is in possession of, or is in any way entitled to the custody or control of, any imported tissue, blood, blood product or gamete;
> 'tissue' means-
> *(a)* any human tissue, including any flesh, bone, organ, gland or body fluid, but excluding any blood or gamete; and
> *(b)* any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person;
> 'use', in relation to a human body or tissue, includes preserve and dissect; and
> 'use', when used as a noun, has a corresponding meaning."

of the word) could be construed as to fall under this definition, and not under the definition of blood products, but the chance of this happening is very slim.

Once it is clear that one is dealing with the “blood products”, the next step is to evaluate whether it would be necessary to obtain any licences or permits in terms of the current legislation in order to set up such an umbilical cord stem cell derivation and storage facility.

3.2.2.1 Licensing requirements for umbilical cord stem cells

Section 19 of the Human Tissue Act[161] provides one with a wide definition of allowed actions to be taken whilst working with blood products.[162] The abovementioned section states that blood may only be used for medical purposes, including the administering thereof to another person or to produce a blood product. The handling of blood products by the applicant could be interpreted as to fall under section 19(b). However, subsection (iv) clearly

[161] 65 of 1983.

[162] Because of the fact that reference are to be made to particular subsections, section 19 is quoted as follows:

> **“**Any tissue, blood or gamete removed or withdrawn from the body of a living person shall, subject to the regulations, only be used for medical or dental purposes, including-
>
> *(a)* in the case of such tissue, the use or transplanting thereof in the body of another living person or for the production of a therapeutic, diagnostic or prophylactic substance;
>
> *(b)* in the case of such blood, the administering thereof to another living person or the production of a blood product; and
>
> *(c)* in the case of such gamete, the artificial fertilization of another person:
>
> [Para. *(c)* amended by s. 27 of Act 51 of 1989.]
>
> Provided that-
>
> (i) any tissue, blood or gamete of a person who is mentally ill within the meaning of the Mental Health Act, 1973 (Act 18 of 1973); or
>
> (ii) any tissue of a person who is a minor and which is not replaceable by natural processes or any gamete of any such person; or
>
> [Para. (ii) substituted by s. 13 *(a)* of Act 51 of 1989.]
>
> (iii) any gamete of a person who has been declared a habitual criminal in terms of section 286 of the Criminal Procedure Act, 1977 (Act 51 of 1977);
>
> (iv) placenta, foetal tissue and umbilical cord, except with the consent of the Minister and subject to any condition mentioned in the consent,
>
> [Para. (iv) inserted by s. 13 *(b)* of Act 51 of 1989.]
>
> shall not be used for any of the purposes referred to in paragraph *(a)*, *(b)* or *(c)* of this section.”

mentions that ministerial consent is required when working with umbilical cord. It is uncertain whether this refers only to the umbilical cord itself or whether it refers to the blood and blood products gathered from the umbilical cord as well.

Section 19 is subject to regulations.[163] These regulations introduce another new definition, namely a "blood component".[164] From the definition provided, it is uncertain how a "blood component" differs from a "blood product". There has to be some difference, because the definition of "batch" provided in section 1 of the regulations mentions both. Stem cells derived from blood products could be construed as to fall within the parameters of both of these definitions.

Section 2(1)(b)[165] appears to apply to the factual circumstances in this instance. The result is that it is necessary to apply for a licence in terms of section 3 of the regulations.

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[163] "Blood and Blood Products" as published in GN R1935 in *GG* 12695 of 17 August 1990 as amended by GN R298 in *GG* 14596 of 26 February 1993.

[164] The definition reads as follows: "'blood component' means any constituent of blood which is separated from blood by physical or chemical means".

[165] In order to grasp the relevance of subsection 2(1)(b) it is necessary to read the entire section 2, which is as follows:

> "(1) Subject to the provisions of section 23 *(b)* no organisation, institution or person, shall-
>
> *(a)* be involved in the withdrawal of blood from the body of any living person;
>
> *(b)* preserve, test, process, separate or supply or in any other manner dispose of blood so withdrawn or imported blood, for use, whether as whole blood, a blood component or in the form of any blood product;
> [Reg. 2(1)*(b)* amended by GN R298 of 26 February 1993]
>
> *(c)* produce, pack, seal and label any blood product or supply or in any other manner dispose of any blood product; or
> [Reg. 2(1)*(c)* substituted by GN R298 of 26 February 1993]
>
> *(d)* take or keep in storage blood withdrawn from any person for the later administering thereof to that person,
> [Reg. 2(1)*(d)* inserted by GN R298 of 26 February 1993]
>
> for any of the purposes referred to in section 19 unless-
>
> (i) it is the holder of a valid licence issued in the name of such organisation, institution or person in terms of regulation 3 (3);
>
> (ii) it conducts any activity referred to in paragraph *(a)*, *(b)*, *(c)* or *(d)*, as the case may be, in accordance with the provisions of these Regulations; and

The only methods in which the licence requirement could be bypassed are if:

1. In terms of section 2(2)(b) of the regulations the applicant is able to indicate that the blood products are not to be used for therapeutic purposes. (This option is probably not available to the applicants in this instance)
2. In terms of section 37(6) of the Human Tissue Act[166], the minister exempts the applicant from section 37(1)(b) of the Act. Section 37(1)(b) authorises the minister to make regulations that supplements section 19. This is further emphasized in section 13 of the regulations.

Because of the fact that the regulations were written a number of years ago, and seems primarily to be focussed on the acquisition of blood and blood products in the traditional sense of the word, there are certain duties that befall a licence holder which might not be applicable to the storage of blood products with the intention of harvesting stem cells. The best option available to an applicant is to request from the Director-General of Health (section 3 of the regulations), in co-operation with the minister, a licence that specifically exempts them from the unnecessary provisions, and inserts any other provisions that the Director-General may deem fit.

3.2.2.2 Importing and exporting umbilical cord stem cells

The Human Tissue Act[167] stipulates in section 25[168] that it is necessary to obtain a permit from the Director-General if the applicants want to import or

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[Reg. 2(1)(ii) substituted by GN R298 of 26 February 1993]

(iii) such activity complies with the minimum requirements as set out in the standards for practice.

(2) The provisions of subregulation (1) shall not prohibit-

(a) a medical practitioner or dentist from performing any professional act within the scope or his profession;

(b) in the case of subregulations 1 *(b)* and *(c)*, the production of a blood product which is not intended for therapeutic or prophylactic purposes in human beings."

[166] 65 of 1983.

[167] *Ibid*.

[168] It reads as follows:

export any blood or blood products. This permit is very important, because of the fact that it might be necessary in the future to urgently send some of the stored materials across borders to assist in a health related matter. Further regulations have been made in order to supplement section 25, namely:

"IMPORTING AND EXPORTING OF PRESCRIBED TISSUE
as published in
GN R2536 in *GG* 10537 of 5 December 1986
(Afrikaans text corrected by GN 295 in *GG* 10606 of 13 February 1987)

1 In these Regulations 'the Act' means the Human Tissue Act, 1983 (Act 65 of 1983), and any expression to which a meaning has been assigned in the Act bears such meaning and, unless the context otherwise indicates-
'prescribed tissue' means tissue, or any part of such tissue mentioned in the Schedule to these Regulations.

2 Application for a permit for the importing or exporting of prescribed tissue in terms of section 25 (2) of the Act is made on a form which can be obtained for that purpose from the Director-General.

SCHEDULE

(1) Human placenta.
(2) Human umbilical cord tissue."

If a strict interpretation is followed, the reference to "[h]uman umbilical cord tissue" in sec 2(2) does not refer to blood products as envisaged by applicants wanting to use umbilical cord blood and stem cells. Upon examining sec 25(1) of the Human Tissue Act[169], it is clear that a permit is required for the import or export of human tissue as well as for blood, blood products and gametes. The regulations however only refer to "prescribed tissue". The form (sec 2 of the regulations) that can be used for the purpose of applying for a permit does not seem to apply to an application to export blood or blood products. In cases where blood or blood products is imported without or contrary to a permit, the

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(1) "No person other than a person to whom the Director-General has issued a permit in terms of subsection (2) may import or export any tissue or any blood, blood product or gamete.
[Sub-s. (1) substituted by s. 18 *(a)* of Act 51 of 1989.]

(2) The Director-General may on application in writing issue a permit in a form determined by him to a person authorizing such a person to import or export, subject to such conditions as the Director-General may determine and record on the permit, any tissue or any blood, blood product or gamete.
[Sub-s. (2) substituted by s. 18 *(b)* of Act 51 of 1989.]"

[169] 65 of 1983.

Director-General can dispose of it (sec 26 of the Human Tissue Act[170]). Such a situation could have adverse effects for a patient that wants to utilise the imported blood or blood products.

In terms of sec 28 of the Human Tissue Act[171], only an authorised or prescribed institution may receive payment for the supply of blood or blood products. A prescribed institution is one that is prescribed in terms of regulation. Since there is no specific mention of when an institution becomes a prescribed institution, it is assumed that once they have complied with the licence or permit regulations, as the case may be, an institution becomes prescribed (and can legally receive remuneration).

Notice is taken of the fact that such applicants store and utilise cord blood, which is discarded in general medical practice. Regulations have been made regarding the disposal of human bodies and tissue,[172] but not for the disposal of blood or blood products. Unfortunately this leaves somewhat of an open answer when it comes to utilising blood that would have been discarded in any case.

3.2.3 The application of the Human Tissue Act to embryonic germ cells derived from foetal tissue

An equally useful, but much more debated topic is the derivation of stem cells (or as they are correctly known, germ cells) from foetal tissue. These cells have the same characteristics and are, in essence, stem cells,[173] but have to be distinguished from stem cells because of the method and area from which they are extracted.[174] The use of foetal tissue in the derivation of germ cells from aborted foetuses raises questions about whether such an act could encourage woman to undergo abortions. These questions have to be addressed and the moral dilemmas mitigated by, for instance, a thorough

[170] *Ibid*.

[171] *Ibid*.

[172] Government Notice R2876 in Government Gazette 12234 of 29 December 1989.

[173] For a comprehensive discussion, see chapter 2, paragraph 2.2.2 above.

[174] Embryonic germ cells are extracted from the gonadal ridge of a foetus.

informed consent process. For the purpose of this section, the focus falls upon the legislative framework currently in place and how it affects the use of aborted and other foetal material in the conducting of research and storing of embryonic germ cells. It is necessary to look at the requirements that have to be met practically if an institution wants to harvest these cells. The cells do not necessarily have to be used for the direct benefit of the donor patient. It could be used to set up a national germ or stem cell bank, as has been proposed in the United States of America. Such a cell bank could provide sufficient cells to match the profile of almost any person, even if they did not donate cells originally.

This section does not focus on the further provisions that have to be met on an individual basis when obtaining the consent from a patient, albeit a minor or major person. Those issues will be addressed further on in this chapter.

3.2.3.1 Licensing requirements for embryonic germ cells derived from foetal tissue

Unlike the case when umbilical cord stem cells were dealt with, embryonic germ cells could be construed as falling within the definition of tissue, and not blood or blood products as provided for by section 1 of the Human Tissue Act.[175] If the germ cells removed from the gonadal ridge of an aborted foetus were regarded as being blood products and not tissue, the same licensing requirements that were needed for umbilical cord stem cells would have to be met.[176] Section 19 of the Human Tissue Act[177] specifically refers to "foetal tissue" which means that the cells derived there from would most likely still fall under the wider definition of "tissue". A further question is whether a foetus

[175] 65 of 1983. The definition of tissue as provided by section one of the act reads as follows:

> "'tissue' means-
>
> *(a)* any human tissue, including any flesh, bone, organ, gland or body fluid, but excluding any blood or gamete; and
>
> *(b)* any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person."

[176] See the application of the following regulations above: "Blood and Blood Products" as published in GN R1935 in *GG* 12695 of 17 August 1990 as amended by GN R298 in *GG* 14596 of 26 February 1993.

[177] 65 of 1983.

should rather be regarded as being a dead body, with the applicable legislation relating to the donation of dead bodies being applied. Strauss[178] sets out the position quite clearly through a reference to the Registration of Births, Marriages and Deaths Act[179]:

> "The issue can only be resolved by referring to the general principles of common law. A point of departure would be the view that a dead body is *res extra commercium* and as such is not capable of being owned by anyone, and should be buried. […] However, the fact that dead bodies should be buried (or cremated) does not mean that the same rule applies to foetuses. As was pointed out, the statutory provisions relating to burial and cremation only apply to dead bodies, including *viable* foetuses. Judged in the light of general principles, it would seem as though non-viable foetal remains would definitely not qualify as human bodies and should therefore simply be dealt with on the basis of being a tissue removed from the mother's body. It is therefore submitted that a foetus may lawfully be destroyed in a hospital incinerator, unless the woman has before removal or shortly afterwards laid claim to it. […] Note that in terms of the Abortion and Sterilisation Act [2 of 1975] the fruit of coitus undoubtedly is a foetus for the purposes of that Act as long as it is *in utero*, ie before birth. In terms of the Human Tissue Act [65 of 1983], again, a foetus *in utero* clearly is "tissue" for the purposes of the latter Act. However, these two Acts do not in any way prevent a woman from consenting to the destruction of a still-born foetus. In particular such consent does not amount to an anatomical donation by virtue of the Human Tissue Act. On the other hand, there is nothing in the latter Act to prevent a woman from donating for medical or scientific purposes a foetus lawfully removed from her body in terms of the Abortion and Sterilisation Act."

The Abortion and Sterilisation Act[180] referred to above has been repealed insofar as it relates to abortion by the Choice on Termination of Pregnancy Act.[181] The latter Act makes no mention of a prohibition on the donation of an aborted foetus, with the result that the abovementioned principles would apply to it as well.

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[178] *Doctor, Patient and the Law: A selection of practical issues* (1991) 163-166.

[179] 81 of 1963.

[180] 2 of 1975.

[181] 92 of 1996.

Cognisance must be taken of the fact that foetal tissue (as with umbilical cord tissue and blood following a child birth) is disposed of as medical waste in general medical practise. This is gathered from the Regulations under the Choice on Termination of Pregnancy Act.[182] An interesting scenario is created in which the foetus, if not specifically donated or claimed by the aborting parent, befalls the designated facility at which the termination of pregnancy took place. The facility then incinerates the foetal remains.[183] A question arises of whether it would be unlawful for the facility to utilise the foetal remains for the purpose of the creation of a national stem cell bank before destroying it? Section 36 of the Human Tissue Act[184] states that:

> "Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of this Act, shall, subject to any restrictions in terms of this Act or any other law and provided he uses the body, tissue, blood or gamete for the purposes for which it has been donated, handed over or supplied to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof."

The section only allows the recipient use insofar as the provisions and restrictions imposed by such a donation provide. The handing over of foetal tissue by the patient to the designated facility most likely does not provide for the derivation of germ cells there from, the resultant effect being that the facility is only allowed to derive the cells if informed consent thereto has been given by the donor prior to the harvesting of such cells.

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[182] *Ibid*. There are a number of regulations entitled "Designation of Facilities for the Surgical Termination of Pregnancies". It has been published in GN (Government Notice) R78 in *GG* (Government Gazette) 24243 of 17 January 2003, GN R823 in *GG* 23517 of 21 June 2002 and GN R784 in *GG* 23486 of 10 June 2002. Sec 2 of each one of these regulations state the requirements that have to be met by a facility in order to be designated in term of sec 3 of the Choice on Termination of Pregnancy Act. Sec 2(i) states that a facility must have access to a safe waste disposal infrastructure. This leads to the conclusion that foetal tissue is regarded as medical waste.

[183] In terms of sec 2 of the "Human Tissue Regulations" as published in GN R2876 in *GG* 12234 of 29 December 1989. Read together with sec 1 of the Human Tissue Act, 65 of 1983, the "burial" referred to in the abovementioned regulations include the cremation thereof in the hospital incinerator.

[184] 65 of 1983.

Section 18 of the Human Tissue Act[185] stipulates that consent is required before any tissue is to be removed from the body of a living person. The removal must take place in accordance with "the prescribed conditions".[186] The section further provides that a person who is a competent witness can, either orally or in writing, give consent to the removal of tissue that is replaceable through natural processes. Had the Choice on Termination of Pregnancy Act[187] not provided for the fact that a minor is allowed to consent to a termination of pregnancy without parental approval, it would have created the opportunity to argue that foetal tissue is replaceable through natural processes. This could lead to arguments that a minor can terminate a pregnancy in terms of the Human Tissue Act.[188] Section 18 of the aforementioned Act is subject to section 19 thereof. Section 19 is subject to regulations, and furthermore states that ministerial consent is required before one is allowed to use foetal tissue for any of the purposes of paragraphs (a)-(c) of said section.[189]

The regulations that apply to blood and blood products[190] are not applicable in this case, because of the fact that use is made of tissue and not only blood. These regulations refer to a specific license that has to be obtained before one can utilise blood or blood products. However, the fact that ministerial consent is required in order to use foetal tissue does not mean that no license is needed. In practice the ministerial consent to be provided will most likely take the form of a licence.

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[185] *Ibid*.

[186] Sec 18(a). These conditions include the fact that, in terms of sec 23 of the Human Tissue Act, 65 of 1983, only a medical practitioner, dentist or person acting under his/her supervision may remove any tissue from the body of a living person.

[187] 92 of 1996.

[188] 65 of 1983.

[189] Sec 19(iv).

[190] "Blood and Blood Products" as published in GN R1935 in *GG* 12695 of 17 August 1990 as amended by GN R298 in *GG* 14596 of 26 February 1993.

Further ministerial consent that is required flows from the provisions of section 24(b)-(c) of the Human Tissue Act[191], namely:

> "The Minister may by notice in the *Gazette* authorize any institution which is not an institution referred to in section 3 (1) *(a)* or *(b)* and which complies with the prescribed conditions, subject to any further conditions (if any) which the Minister may determine in any particular case and which shall be stated in the said notice, to-
>
> *(a)* acquire, use or supply bodies of deceased persons for any of the purposes referred to in section 4 (1); and
>
> *(b)* acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 4 (1) or 19, as the case may be;
>
> *(c)* supply any tissue preserved by it to an institution or person referred to in section 3 (1) *(a)*, *(b)*, *(c)*, *(d)* or *(e)* for any of the purposes referred to in section 4 (1) or 19;
>
> *(d)* .....
>
> [Para. *(d)* deleted by s. 17 *(b)* of Act 51 of 1989.]
>
> [S. 24 amended by s. 17 *(a)* of Act 51 of 1989.]"

This required consent would most probably take on the form of a license as well. There are a number of penalties in place in the case of an institute that has not been authorised for acquiring, supplying and storing such tissues.[192]

3.2.3.2 Importing and exporting embryonic germ cells derived from foetal tissue

The import- and exportation of embryonic germ cells derived from foetal tissue, as was the case with umbilical cord stem cells, could pay a key role in stem cell related healthcare. It could be necessary to move some of the cells across borders, in order to treat a sick patient whose cells are stored in South Africa in another country. Section 25 of the Human Tissue Act[193] provides for such an occurrence, and stipulates that it is necessary to obtain a permit thereto from the Director-General of Health. The regulations supplementing section 25[194] is not applicable in this instance because foetal tissue does not fall within

[191] 65 of 1983.

[192] Sec 34 of the Human Tissue Act, 65 of 1983.

[193] 65 of 1983.

[194] "Importing and Exporting of Prescribed Tissue" as published in GN R2536 in *GG* 10537 of 5 December 1986 (Afrikaans text corrected by GN 295 in *GG* 10606 of 13 February 1987).

the parameters of "prescribed tissue" as provided in the schedule to the regulations.[195]

It is necessary to take cognisance of the fact that the Director-General may even order an importer to destroy the imported tissue[196] if it is shown that the importation thereof took place contrary to the provisions of section 25 of the Human Tissue Act.[197] If the importer is not an "authorised institution" as contemplated in section 24 of the abovementioned Act, the importer is not allowed to receive payment for the importation of the tissue.[198]

3.2.4 The application of the Human Tissue Act to human embryonic stem cells

The most widely discussed source of stem cells is without a doubt those derived from human embryos. The reason for this is mainly due to the fact that it touches on aspects surrounding when human life starts and whether destroying a foetus amounts to murder. Even though many of the questions surrounding foetal life have been addressed through the Choice on Termination of Pregnancy Act[199], it remains salt in the wounds of many pro-life activists.

The primary source of embryonic stem cells is those derived from embryos left over after IVF treatment. The embryos are normally kept for a contractually agreed upon time (five to ten years), where after they are destroyed. Individuals opposing the use of embryos in the derivation of stem cells have a limited chance of success when the potential benefits of stem cell research are weighed up with the fact that the embryos used would have been destroyed in any case. Activists do have a stronger leg to stand on when it comes to embryos created for the sole purpose of being used in research. Many

[195] "Prescribed tissue" as found in the schedule to the regulations is only human placenta and human umbilical cord tissue.

[196] Sec 26(1)(a) of the Human Tissue Act, 65 of 1983.

[197] 65 of 1983.

[198] Sec 28(1).

[199] 92 of 1996.

arguments from pro-life and religious scholars oppose the creation of a potential human life purely for research purposes. These arguments invariably amount to a balancing of moral concerns against the potential benefits to be gained through the research (particularly stem cell research in this case).

One other method of deriving stem cells that deserves discussion is through the use of SCNT[200] in the creation of an embryo.[201] This has been a cause of great concern to many activists, due to fears of eugenically driven individuals using SCNT not merely for the purpose of therapeutic cloning, but for reproductive cloning purposes as well.[202] The fact that a cloned human being is merely an implantation of a SCNT created embryo into a woman's womb away, is a very valid reason for concern. Very clear regulatory mechanisms need to be in place in order to ensure that SCNT is not used to clone a human being.

The first step is to assess what that current legislative position is, primarily in terms of the Human Tissue Act[203]. The focus is on embryos created outside the human body, through the bringing together of male and female gametes. The principles gathered from the Choice on Termination of Pregnancy Act[204] will be discussed in more detail when issues surrounding consent is addressed.

3.2.4.1 Licensing, import- and exportation requirements for human embryonic stem cells

The embryo is formed through the bringing together of male and female gametes. In this case it mostly happens in a test tube outside the human body

[200] Somatic Cell Nuclear Transfer.

[201] The use of SCNT have been thoroughly discussed in chapter 2.

[202] Freedman *Legal issues in biotechnology and human reproduction: Artificial conception and modern genetics* (1991) 16-17; Zaner "Surprise! You're just like me!: Reflections on human cloning, eugenics, and other utopias" as published in Humber & Almeder (eds) *Human Cloning* (1998) 103.

[203] 65 of 1983.

[204] 92 of 1996.

(from there the term *in vitro*). The Human Tissue Act[205] excludes gametes from the definition of tissue.[206] On the other hand, "tissue" includes "any flesh, bone, organ, gland or body fluid", with the result that an embryo would fall within this definition. The resultant effect is that researchers do not have to satisfy the requirements pertaining to tissue until they fertilise an egg cell to create an embryo.

Also of relevance in section 1 of the Human Tissue Act[207] is the definition of "artificial fertilization of a person".[208] Part A of the definition provides for the creation of an embryo outside the human body, similar to the procedure performed in the creation of embryos for the sole purpose of being used in research. Part B, however, stipulates that such an embryo has to be placed back into the womb of a female person. It is clear that this does not directly address the needs of researchers attempting to create embryos solely for the derivation of stem cells. Regulations[209] have been promulgated to supplement the Human Tissue Act[210] with regards to the artificial fertilisation of a person, but provide no further insight besides the fact that only a medical practitioner is allowed to remove gametes for such purposes from a person.[211]

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[205] 65 of 1983.

[206] Sec 1.

[207] 65 of 1983.

[208] The definition being the following:

> "'artificial fertilization of a person' means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including-
>
> *(a)* the bringing together outside the human body of a male and a female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female person; or
>
> *(b)* the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body, in the womb of a female person."

[209] "Artificial Insemination of Persons, and Related Matters" as published in GN R1182 in *GG* 10283 of 20 June 1986 as amended by GN R1354 in *GG* 18362 of 17 October 1997.

[210] 65 of 1983.

[211] Sec 3.

Section 18 of the Human Tissue Act[212] specifically provides that written consent is required in cases where tissue, blood or gametes are removed from the body of a living person. Subsection (aa) makes provision for the following:

> "[I]n the case of the removal of tissue which is replaceable by natural processes, or the withdrawal of blood, from the body of a person who is a competent witness, the consent of that person to the removal of that tissue or blood shall be sufficient, whether it be granted in writing or orally."

At first glance it would appear as if the oral consent of a donor would be sufficient when obtaining gametes because it is "replaceable by natural processes". However, the subsection only provides for naturally replaceable "tissue", and gametes are explicitly excluded from this definition in section 1 of the Human Tissue Act[213].

Section 19 of the abovementioned Act states that tissue, blood or gametes shall only be used for medical and dental purposes *including*, in the case of gametes, the artificial fertilisation of another person. The word "including" in section 19 leaves room for the interpretation that a person is not bound to only use gametes for the purpose of artificial fertilisation, but could also utilise it for stem cell related endeavours. Subsections 19(I-iii) prohibit the use of gametes obtained from mentally ill persons, minors or habitual criminals so declared in terms of the Criminal Procedure Act[214]. However, the prohibition is only relevant to the acts specified in sections 19(a-c), with the result that gametes obtained from the abovementioned excluded groups could very well be utilised for purposes of creating embryos for the derivation of stem cells. Section 19 is subject to regulations, but there are no regulations pertaining to the use of embryos for stem cell purposes, with the result that no further licensing requirements apply.

Section 23 of the Human Tissue Act[215] states that only a medical practitioner is allowed to remove tissue or blood from the body of a living person. This

[212] 65 of 1983.

[213] 65 of 1983.

[214] 51 of 1977.

[215] 65 of 1983.

section does not specify directly whether only a medical practitioner is allowed to remove gametes from the body of a living person but, in terms of the regulations pertaining to artificial fertilisation[216] of a person only a medical practitioner is allowed to remove gametes. It would be safe to assume that this allocation of removal rights vesting in a medical practitioner for purposes of artificial fertilisation stretches to any other medical intervention, including the removal of gametes for stem cell research purposes.

In order to legally receive any payment for services rendered, an institution has to be classified as an "authorized institution" in terms section 24 of the Human Tissue Act[217]. Although there is no mention of gametes, and only of tissue in section 24, once a private institution brings together male and female gametes to form an embryo they will be classified as dealing with "tissue" as such. The result is that it would be best if an institution that proposes to create embryos for the sole purpose of it being used in the derivation of stem cells apply for such authorisation from the minister.

As was the case with foetal tissue stem cells and embryonic germ cells above, it would be necessary for any applicant to obtain an import- and exportation permit from the office of the Director-General in terms of section 25 of the Human Tissue Act[218], before any gametes, embryos or stem cells could be taken across borders.

3.2.4.2 Other legislative requirements provided by the Human Tissue Act pertaining to human embryonic stem cells

There are numerous sections of the Human Tissue Act[219], particularly section 33, which protects the identity of a donor or recipient of human materials. These sections make great reference to the fact that informed consent is required before there can be any waiver of the privacy provided there through.

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[216] "Artificial Insemination of Persons, and Related Matters" as published in GN R1182 in *GG* 10283 of 20 June 1986 as amended by GN R1354 in *GG* 18362 of 17 October 1997.

[217] 65 of 1983.

[218] *Ibid*.

[219] *Ibid*.

One key aspect, however, is to establish the extent to which the recipient of human materials are to be protected from later infringement of their rights. The recipient in this case, not being a physical person, but is an institution wanting to use the materials to create embryos and derive stem cells there from. A good example of this was the American case of *Moore v Regents of the University of California,*[220] in which the plaintiff successfully held that the University used cells derived from his spleen to create a valuable new cell line.[221] The plaintiff argued that the University used his cells without his consent thereto, with the result that they did not have any rights in the product thereof. This case is discussed more thoroughly further on. Section 36 of the Human Tissue Act[222] states quite clearly that any person receiving human tissue, blood or gametes shall acquire exclusive rights to such materials. These rights can only be acquired if the original acquisition took place with the consent of the donor party, again showing that informed consent is vital in any medically related endeavour. Informed consent is also discussed more thoroughly further on in this chapter.

In terms of section 37 of the Human Tissue Act,[223] the minister may promulgate regulations with regard to the use of human tissue, blood or gametes. As have been discussed above, there are no regulations that regulate the use of gametes besides those addressing the issue of artificial fertilisation of a person.[224]

Arguably the most important section in the Human Tissue Act[225] for researchers wanting to derive stem cells from embryos is section 39A. It simply reads as follows:

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[220] 793 P.2d 479 (Cal. 1990).

[221] Boyd "Considering a market in human organs" (2003) *North Carolina Journal of Law & Technology* 417 at 444.

[222] 65 of 1983.

[223] *Ibid*.

[224] "Artificial Insemination of Persons, and Related Matters" as published in GN R1182 in *GG* 10283 of 20 June 1986 as amended by GN R1354 in *GG* 18362 of 17 October 1997.

[225] 65 of 1983.

> "Notwithstanding anything to the contrary contained in this Act or any other law, no provision of this Act shall be so construed as to permit genetic manipulation outside the human body of gametes or zygotes".

"Genetic manipulation" is not defined in the Act with the result that one is forced to employ a wide interpretation thereof.[226] The result being that the use of SCNT for the purpose of therapeutic cloning of embryos is prohibited through this section.[227] This could hold dire results for individuals who were planning on, for example, using SCNT to create matching embryos of a person in need of skin grafts following a serious burn. If SCNT cannot be used to created the embryos and derive the stem cells there from, it could prove to be extremely difficult to obtain matching stem cells. If the cells do not match, the recipient's body would reject the skin graft.

One final aspect that deserves mention is the fact that the Human Tissue Act[228] does not explicitly prohibit the creation of embryos for the sole purpose of it being used in research. Although it is clear that the Act provides mainly for the use thereof in artificial fertilization procedures, the fact remains that a researcher is not bound thereto to only utilise left over IVF embryos in the conduction of stem cell related research. Strauss[229] reasserts that the minister has the power to make regulations relating to research on embryos outside the human body. If the research were to amount to genetic manipulation it would contravene the Act.[230] He further states the following:

> "The South African Medical Research Council has laid down important ethical guidelines on research relating to *in vitro*

[226] Strauss 192 and 200 also makes mention of the lack of a definition of "genetic manipulation" in the Human Tissue Act 65 of 1983. Also see Slabbert "Are the human embryo and the foetus *extra uterum* sufficiently protected in terms of South African law?" (2001) *Tydskrif vir die Suid-Afrikaanse reg* 495 at 505-508.

[227] Jordaan "Human reproductive cloning: A policy framework for South Africa" (2002) 119 *The South African Law Journal* 294 at 303 is of the opinion that sec 39A does not prohibit cloning, even reproductive cloning, by means of SCNT due to the section becoming inapplicable for vagueness.

[228] 65 of 1983.

[229] 200.

[230] Sec 39A.

> fertilization (IVF) and embryo biology: Research on IVF may only be conducted in approved institutions and in accordance with the provisions of the Human Tissue Act and the regulations contained in Government Notice R1182 of 26 June 1986 in so far as these are applicable. A research unit must maintain thorough documentation of all its activities. The unit will be subjected to regular inspections. *The exclusive production of embryos for research is unacceptable.* Embryo research cannot be conducted without the written permission of the donors of the gamete or the embryo. It is advisable to inform the donors of the gametes or embryo about the nature of the planned research. [Own emphasis]"

This forms part of the guidelines on research that have been provided by the South African Medical Research Council. The council provides for further regulation above and beyond that of the Human Tissue Act[231] itself and is often much more comprehensive with regard to the position of the individual researcher when conducting research. The scope of this dissertation, however, does not allow for an in-depth analysis of the workings of the research council, but it is encouraging to know that there is a body that is providing guidance to researchers at ground level.[232]

3.2.5 Consent

Arguably the backbone of any medically related intervention is the consent thereto.[233] This is particularly important when it comes to stem cells. A good example being cases in which a cell line is created using materials gathered from a donor. Had the consent to use these materials not been given by the donor, the company developing the cell line faces the risk of being held

[231] 65 of 1983.

[232] See the website of the Medical Research Council at www.mrc.ac.za, as well as their book addressing the specific issues pertaining to genetic research at www.sahealthinfo.org/ethics/book2.htm.

[233] Also see a discussion on consent in medical interventions and research in the United States of America in Schneider & Wardle "Genetics and artificial procreation in the U.S.A." as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) *Biomedicine, the Family and Human Rights* (2002) 55 at 56-61. Also see Freid *Medical experimentation: Personal integrity and social policy* (1974) 18-28 in which some of the basic consent requirements are described.

accountable.[234] Consent has a further goal other than simply providing the doctor or researcher with a method in which to bypass accountability for certain types of foreseeable mishaps. It provides the patient with the opportunity to make informed decisions about his or her own well-being.

There are a number of aspects that pertain specifically to consent in stem cell therapies. One such aspect being the amount of disclosure needed to be given to a donor when a researcher wants to use discarded foetal material following a termination of pregnancy. It is clearly a very traumatic time for the aborting mother and such a proposal should be done at a very specific time and in a specific manner. If such a proposal is placed before a person prior to undergoing the termination of pregnancy, that person might feel forced into following through with the procedure, even though they might have not done so previously.

Van Oosten[235] provides a good framework within which one can discuss the concept of consent, dividing it into the following subsections: legally recognised consent, legal capacity to consent, informed consent,[236] free and voluntary, clear and unequivocal and comprehensive consent.[237] A similar framework is to be employed in the discussion of stem cell related consent.

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[234] See the American case of *Moore v Regents of the University of California* 793 P.2d 479 (Cal. 1990).

[235] *Medical Law: South Africa – International Encyclopaedia of Laws* (1996) § 111-129.

[236] Arguably one of the most comprehensive works on informed consent to date is the 1989 unpublished doctoral thesis by Van Oosten, titled *The doctrine of informed consent in Medical law*. Although the thesis is not referred to directly in this dissertation, the views of Van Oosten, as gathered from numerous other publications are presented as an accurate representation of the field.

[237] In a discussion on informed consent in Australia, Dharmananda identifies the component of consent as being information or disclosure, competency, understanding, voluntariness and decision. See Dharmananda *Informed consent to medical treatment – Processes, practices and beliefs* (1992) 9.

3.2.5.1 Legally recognised consent

This principle means that law must recognize the consent.[238] In other words, it must conform to the current *boni mores* surrounding it.[239] Strauss[240] gives the example of a young man giving consent to the amputation of his perfectly normal and healthy hand in order to evade military duty, as being *contra bonos mores*. Consent surrounding stem cells could encompass various different types of actions, some arguably being justified, while others could be *contra bonos mores*. For instance: If the frozen embryos left over after IVF treatment are used to derive stem cells, the consent given thereto would most likely be approved by the general public. These embryos would have been destroyed in general medical practice in any case. The situation becomes more complicated when one is dealing with cases in which foetal material following terminations of pregnancy are used. Another example of a highly contentious provision of consent is where a donor agrees that his or her gametes are used in the creation of embryos for the sole purpose of ~~it~~ being utilised and destroyed in the derivation of stem cells for research.

The only way in which to fully establish the *boni mores* with regard to stem cells in South Africa is by weighing up all the different viewpoints thereto. These legal and religious assessments of the situation are to be discussed later on in this chapter. It is a difficult task, when considering the fact that South Africa consists of a diverse people, all of whom having a particular opinion thereof. The *boni mores* is a legal concept that is inherently intertwined with the viewpoints of the public.

3.2.5.2 Legal capacity to consent

There must be distinguished between adults and minors when assessing a person's legal capacity to consent. Adults have the capacity to validly consent to medical interventions, provided they are sane, sober and not incapable of

[238] Van Oosten "The law and ethics of information and consent in medical research" (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 14.

[239] Van Oosten § 111.

[240] 286.

consenting because of another reason.[241] In the case of married couples, the parties must consent to their own medical intervention. A husband cannot force his wife to undergo a procedure against her will.[242]

A specific order of precedence has been drawn up in the Mental Health Care Act[243] in the case of mentally ill persons.[244] These persons listed in the order of precedence are granted the power to consent to medical and other interventions on a mentally ill person.[245] Van Oosten[246] has provided one mention of the acquisition of consent from a mental patient with regards to research in an article focussing on the topic. It states the following:

> "Although mentally ill or mentally defective patients may, in principle and in fact, be capable of consenting to medical research, it is submitted that their capacity to consent should be limited to therapeutic research on account of (i) it's potential personal benefit; and (ii) the undeniable potential of undue influence being exerted, wittingly or unwittingly, on such patients. A possible exception would be where the proposed form of non-therapeutic research *involves no risk or danger at all* as, for instance, in cases of an unlinked and anonymous (i) gathering of information about the patient by means of questionnaires or from medical records, or (ii) *examination of a specimen taken from the patient*. [Own emphasis]"

Under strict interpretation this could mean that stem cells obtained from mentally ill patients could be examined and utilised, following the consent thereto by the patient only and not any of the persons listed in the Mental Health Care Act.[247] Although this might be the case in theory, it is submitted that researchers should refrain from using mentally ill patients in research.

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[241] Van Oosten § 113; Wear *Informed consent – Patient autonomy and physician beneficense within clinical medicine* (1993) 10.

[242] *Palmer v Palmer* 1955 (3) SA 56 (O).

[243] 17 of 2002, sec 9, 27, 33.

[244]Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 15.

[245] Also see Strauss 37-39 and Van Oosten § 114 & 117.

[246] Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 16.

[247] 17 of 2002.

Of primary importance, however, is the position of minors in the consent process. In terms of section 39(4) of the Child Care Act[248] minors are allowed to consent to the following procedures without parental assistance:

> "(4) Notwithstanding any rule of law to the contrary-
> *(a)* any person over the age of 18 years shall be competent to consent, without the assistance of his parent or guardian, to the performance of any operation upon himself; and
> *(b)* any person over the age of 14 years shall be competent to consent, without the assistance of his parent or guardian, to the performance of any medical treatment of himself or his child."

A question that arises is how these provisions would affect the derivation of stem cells. It is best to distinguish between the three different types again, namely umbilical cord stem cells, foetal tissue germ cells and embryonic stem cells.

3.2.5.2.1 Consenting minors and umbilical cord stem cells

In the case of umbilical cord stem cells the solution is provided by section 39(4) of the Child Care Act[249] itself. A person over the age of 14 years is competent to consent to medical treatment on himself or his child. It could be argued that the collection of umbilical cord stem cells during the birth of a minors' child is the first step in the possible future medical treatment of the newborn baby. The fact that the use of umbilical cord stem cells merely requires the collection of human materials, which would have been discarded in any case, prevents any unnecessary complications.

Section 39(4) only applies to cases in which there are no legislative provisions to the contrary in place. One such a legislative provision is section 18(b)(ii) of the Human Tissue Act[250], which requires the written consent of the guardians or parents of the minor for the removal or withdrawal of tissue, blood or gametes from such minor. The valid argument could be made that the umbilical cord blood and tissue from which the stem cells are derived is not

[248] 74 of 1983.

[249] *Ibid*.

[250] 65 of 1983.

removed from the minors' body solely for stem cell purposes, but are done so during the minors' newborn child's birth. The result being that no further parental consent is required to harvest the cells, seeing as that no further tissue needs to be removed from the body of the minor.

One practical issue that is not covered by the abovementioned provisions, however, is the question whether a minor would be able to contractually close any agreements with the biomedical companies in charge of storing the umbilical cord stem cells. There are a number of principles that could play a role in this case (for instance whether the minor is emancipated or not), but the general rule is that parental assistance in required before a minor can close a contract that is binding and poses obligations upon him or her.[251]

3.2.5.2.2 Consenting minors and foetal tissue germ cells

The consent of a minor to use her aborted foetus' tissue in the harvesting of embryonic germ cells is a more complicated matter. Being able of validly give consent thereto could prove to be very important in the future, for example: If South Africa decides to set up a national stem cell bank, from which almost any person in the country could be provided with a sufficiently matching line of stem cells, one of the primary sources of these cells would be those derived from aborted foetuses. Many minors abort foetuses without their parents being informed of the fact and it is essential to establish which consent is required to legally obtain these germ cells.

The primary piece of legislation pertaining to this case is the Choice on Termination of Pregnancy Act.[252] Section 5(1-3) of the abovementioned Act reads as follows:

> "(1) Subject to the provisions of subsections (4) and (5), the termination of a pregnancy may only take place with the informed consent of the pregnant woman.
> (2) Notwithstanding any other law or the common law, but subject to the provisions of subsections (4) and (5), no consent other

[251] For a thorough discussion hereof, see Davel & Jordaan *Personereg Studentehandboek Derde Uitgawe* (2000) 56-84.

[252] 92 of 1996.

than that of the pregnant woman shall be required for the termination of a pregnancy.

(3) In the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be, shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is terminated: Provided that the termination of the pregnancy shall not be denied because such minor chooses not to consult them."

Subsections (4) and (5) that are referred to in subsections (1) and (2) above state which consent is required in cases where a person is mentally disabled or the pregnancy is past the twenty week gestation period, but is not of vital importance for the purposes currently under discussion. It is clear that even though a minor has to be advised to consult with her family or friends, only her consent is required for the termination to take place. An interesting situation arises: in practice it might prove necessary to operate on a woman if any complications arise because of the termination of pregnancy. Section 39(4)(a) of the Child Care Act[253] prohibits a person under the age of 18 years to validly consent to an operation upon him- or herself. The regulations[254] to the Choice on Termination of Pregnancy Act[255] attempts, but fails to, fully rectify this situation.

Section 1 of the abovementioned regulations provide the following definitions of specific consent forms used in obtaining consent to a termination of pregnancy:

"'form' means a form drawn up and made available by the Director-General with regard to the termination of a pregnancy;
'form 1' means the Departmental form set out in Annexure A which is used to notify the person in charge of a facility of the termination of a pregnancy in terms of section 2 (1) *(a)* or *(b)* of the Act;
'form 2' means the Departmental form set out in Annexure B which is divided into the following two (2) parts:

(a) Part I to be completed by a minor who requests the termination of her pregnancy;

(b) Part II to be used to request the termination of the pregnancy of a woman who is severely mentally disabled or

[253] 74 of 1983.

[254] "Regulations under Choice of Termination of Pregnancy Act 92 of 1996" as published in GN R168 in *GG* 17746 of 31 January 1997.

[255] 92 of 1996.

> in a state of continuous unconsciousness;
> 'standard consent form' means a form provided by a facility for recording the consent to the administration of a local general anaesthetic and an accompanying surgical procedure;"

Had the regulations required a minor to complete both part I of form 2 as well as the standard consent form, that minor would have been able to consent to the possible surgical procedure as well. However, section 4 of the abovementioned regulations states that the minor only has to complete part I of form 2 and not the standard consent form. Section 6(b) of the regulations states the following:

> "The consent of a woman to the procedure to terminate her pregnancy shall include consent to other surgical procedures which may be necessary as a result of complications associated with the termination of her pregnancy."

The legislature has not mentioned the standard consent form in section 4 of the regulations and distinguishes between minors and "woman" throughout the regulations. The resultant lack of reference to minors in section 6(b) creates a vacuum in the Act as to the consenting boundaries of a minor. This forces a fallback towards section 39(4) of the Child Care Act[256], which requires parental consent for operations on a minor below the age of 18 years.[257]

The reason for examining these boundaries of a minors' consent is to establish whether it would be possible for the minor to agree to the use of her foetal tissue in the derivation of germ cells without parental assistance. It has been argued that the consent to a surgical operation is a natural extension of

[256] 74 of 1983.

[257] Strauss 7 provides a good description of what happens in these cases in practice. It reads as follows:

> "Must the provisions of section 39(4) of the Child Care Act be interpreted in such a manner as to prohibit a minor below the age of 18 from consenting independently? This question is controversial. My submission is that the Legislature did not intend the subsection to embody such a prohibition and that an intellectually mature minor may consent independently to any medical procedure properly understood by him or her."

minors consenting abilities in cases of pregnancy termination.[258] Would it be possible to include the consent to germ cell derivation under this blanket of consenting extensions of minors? The final decision would have to either be made by the legislature through the promulgation of further regulations, or by the court. The derivation of germ cells from aborted foetuses would most likely be construed as falling within the ambit of tissue donation. Strauss[259] states the following:

> "It is therefore submitted that a foetus may lawfully be destroyed in a hospital incinerator, *unless the woman has before removal or shortly afterwards laid claim to it*." [Own emphasis]

The same method of "laying claim" to a foetus and then donating it to a stem cell facility could be employed in this instance.

3.2.5.2.3 Consenting minors and human embryonic stem cells

Human embryonic stem cells are harvested from the inner cell mass of human embryos.[260] These embryos are generally obtained from one of two sources: Embryos left over after the completion of IVF treatment and embryos created solely for the purpose of being used in research.

IVF embryos do not create too many problems, since IVF procedures are well regulated.[261] Parental consent is required before a minor is allowed to donate gametes for the purpose of possible IVF procedures as well, with the effect being that if one wishes to use IFV embryos created by a minor for the derivation of stem cells, the parental consent might have already been given.

If no parental consent has been obtained, such donation of the embryos by a minor would be invalid because of the following reasons:

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[258] Van Oosten "The Choice on Termination of Pregnancy Act: Some comments" (1999) 116 *The South African Law Journal* 60 at 67.

[259] 164.

[260] For a complete discussion, see chapter 2 above.

[261] "Artificial Insemination of Persons, and Related Matters" as published in GN R1182 in *GG* 10283 of 20 June 1986 as amended by GN R1354 in *GG* 18362 of 17 October 1997. Also see the definition of artificial insemination provided in section 5(3) of the Children's Status Act, 82 of 1987.

- The original donation of the minors' gametes in order to create an embryo would have taken place without any parental consent as required by section 18 of the Human Tissue Act;[262]
- The donation of the embryos by a minor could be interpreted as falling within the scope of acts requiring parental assistance, as stipulated by the Law of Persons.[263]

The use of embryos created solely for the purpose of being used in research is still a very hotly debated issue. Whereas IVF embryos have been created for reproductive purposes and only the left over embryos that would have been destroyed anyway used, embryos created for the sole purpose of being used in research have many ethicists up in arms. It is sprouting similar arguments to those present during the height of the abortion debate concerning the moment at which life begins, when a foetus obtains personhood, and the balancing of scientific and religious interests. These will be discussed later on in this chapter, but it would suffice to note that it would be in the best interest of researchers to refrain from using embryos obtained from minors, unless public interest dictates otherwise.

3.2.5.3 Informed consent

Informed consent is a doctrine in which patient autonomy has been able to triumph over the previous system of medical paternalism.[264] This means that the ultimate decision to undergo any type of medical decision rests with the

[262] 65 of 1983.

[263] Davel & Jordaan 56-84.

[264] Van Oosten § 120; See Holm "The Role of Informed Consent in Genetic Experimentation" as published in Burley & Harris (eds) *A Companion to Genethics* (2002) 82 at 83 and Maloney (1984) *Protection of human research subjects – A practical guide to federal laws and regulations* (1984) 118-124 for a discussion on the international development of the doctrine of informed consent in research. Giesen "From paternalism to self-determination to shared decision making in the field of medical law and ethics" as published in Westerhäll & Phillips (eds) *Patient's rights – Informed consent, access and equality* (1994) 19, Switankowsky *A new paradigm for informed consent* (1998) 1-15 and Wear 22-27 provides for a further explanation of the concepts of patient autonomy and paternalism within medical decision making.

patient and not with the doctor. This type of decision can only be made by a well informed patient; a patient that has been disclosed with the right amount of knowledge that that particular patient would deem necessary to make a calculated decision.[265] The patient may even make decisions contrary to what a medical practitioner advises to do with possible detrimental effects, as long as that patient has been informed properly beforehand.[266] It is clear that the information given to the patient surrounding his or her medical condition should be accurate and understandable to that patient. This led to the affirmation of the pillars of informed consent in the case of *Castell v De Greef,*[267] namely knowledge and appreciation.[268] Informed consent ensures the patient's right to self-determination[269] and freedom of choice, as well as encourages rational decision-making.[270]

The scope of informed consent, pertaining to disclosure by a medical practitioner to a patient,[271] provides a further example of how the right to self-

[265] Freid 20; Van Oosten § 119; Wear 10.

[266] Van Oosten "*Castell v De Greef* and the Doctrine of Informed Consent: Medical Paternalism Ousted in Favour of Patient Autonomy" (1995) 28 *De Jure* 164 at 176, Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 24.

[267] 1994 (4) SA 408 (K). Also see one of the more recent cases involving informed consent, namely *Oldwage v Louwrens* [2004] 1 All SA 532 (C). In this case the plaintiff successfully claimed damages following an operation that he had undergone that proved to have been unnecessary. He had not been informed fully as to the nature of the operation and the risks related to it. The doctor was also negligent because of the fact that he had not made proper notes about the patient's health in his files. The court further reaffirmed that a medical intervention undergone without the patient's consent amounts to assault on the part of the doctor.

[268] Strauss 8.

[269] Self-determination is the right decide for ones' self to refuse or undergo medical treatment. The decision to undergo medical treatment is that of the patient and not the doctor. See Van Oosten (1995) 28 *De Jure* 164 at 167 and Earle "'Informed consent': Is there room for the reasonable patient in South African law?" (1995) 112 *The South African Law Journal* 629 at 629.

[270] Van Oosten § 121.

[271] Wear 12.

determination and freedom of choice is protected thereby.[272] All serious and typical risks and dangers should be disclosed, but not unusual or remote risks and dangers, unless they are serious or typical, respectively, or if the patient enquires about them. The test of disclosure amounts to an examination of whether the risk or danger involved in a medical procedure is material.[273] A risk or danger will be material if a reasonable patient, if warned thereof, would be likely to attach significance to it, or if the doctor is or should reasonably be aware that the individual patient, if warned of the risk or danger, would be likely to attach significance to it.[274]

A further matter surrounding the scope of disclosure in medical interventions can be brought back to the doctor. Even though it is not a fallback towards the ousted "reasonable doctor" test of disclosure, there is still a limited amount of discretion resting in the doctors' hands.[275] Van Oosten[276] states the following:

> "What a careful and responsible doctor would disclose would depend upon circumstances, such as the nature of the matter to be disclosed, the nature of the medical intervention, the patient's desire to be informed, the patient's temperament and health and the patient's intelligence and understanding. However, the doctor should avoid causing the patient anxiety and distress by an unnecessary disclosure of an adverse diagnosis or the adverse consequences of the proposed intervention."

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[272] See Laurie *Genetic privacy – A challenge to medico-legal norms* (2002) 185-194 for a discussion on patient autonomy within medical law.

[273] Van den Heever "The patient's right to know – Informed consent in South African medical law" (1995) 325 *De Rebus* 53 at 56.

[274] (1996) § 122. Also see a definition of informed consent, specifically with regards to research being conducted, in Barber B *Informed consent in medical therapy and research* (1980) 43.

[275] The medical profession has raised certain objections towards the doctrine of informed consent. Amongst these are the fact that doctor's are the experts in medical matters and know best about what is in their patient's interest and that patients are unable to grasp and judge the real meaning and significance of certain medical interventions. See Van Oosten (1995) 28 *De Jure* 164 at 168.

[276] § 123. Also see the discussion hereof in Noah "Informed consent and the elusive dichotomy between standard and experimental therapy" (2002) 28 *American Journal of Law and Medicine* 361 at 368.

Under certain circumstances disclosure is not necessary, for instance when the defence of therapeutic privilege is used.[277] This is the case where a doctor withholds certain information from the patient because the harm caused through the disclosure would be greater than the harm caused by non-disclosure.[278]

The abovementioned principles surrounding informed consent finds different methods of application in stem cells, depending on the type of cell (umbilical, foetal or embryonic) to be derived and age of the stem cell donor.[279] Umbilical cord stem cells are generally handled through the Law of Contract seeing as it is mostly the pregnant mother that approaches the cell bank to collect and store the cells upon the birth of her child. The mother would have been informed of the procedure and benefits thereof well in advance of the birth and the cells are generally derived and stored with the sole purpose of benefiting the newborn child itself. In the case of the cells not being derived and stored for the benefit and at the monetary expense of the parents, for instance when it is simply used for research or to set up a national stem cell bank, obtaining informed consent thereto becomes a little more complicated. During labour is most likely not an ideal time to discuss the possible uses of a soon-to-be-newborns umbilical cord blood. A possible method of obtaining these cells

[277] Freid 21; Van den Heever (1995) 325 *De Rebus* 53; Van Oosten (1995) 28 *De Jure* 164 at 177; Wear 16-17.

[278] Strauss 10; Weltz "The boundaries of medical-therapeutic privilege" (1999) 116 *The South African Law Journal* 299 provides a comprehensive discussion on therapeutic privilege.

[279] See Katz "Human Experimentation and Human Rights" as published in Tomossy & Weisstub (eds) *Human experimentation and research* (2003) 225 for a comprehensive discussion of consent in research and how the respect for patient autonomy and right to self-determination cannot be realised without radically transforming the interaction between researchers and patients.

Internationally, a research subject sometimes even have a right to being given the opportunity of providing informed consent on the use of his genetic material, this gathering of informed consent then being checked when a patent application for an invention that used his material is filed. For instance the European Union Biotechnology Directive, as referred to in Van Owerwalle "Legal and ethical aspects of bio-patenting. Critical analysis of the EU Biotechnology Directive" as published in Baumgartner & Mieth (eds) *Patente am Leben? Ethische, rechtliche und politische aspekte der biopatentierung* (2003) 145 at 150.

would be to store the cord blood after every birth in certain prescribed institutions where the personnel is trained in the procedure and then ask the parents shortly thereafter whether they would prefer to have the cells destroyed or donated for research.

Foetal tissue germ cells could prove the most challenging to obtain. A woman undergoing a termination of pregnancy is not in the clinic for a long period of time. The time spent in the clinic is mainly used for basic administrative tasks and ensuring that the woman fully understands the scope of an abortion. It is a very emotional time for the woman, in which a full discussion of stem cell research could interfere with her decision-making. For example: if a woman goes to an abortion clinic to find out about the procedure, she might still decide not to undergo the abortion. If, on the other hand, she is told about the benefits of stem cells beforehand she might feel forced into undergoing the procedure because of the researchers anxiously awaiting the cells. The opposite is also applicable: the knowledge that her foetal germ cells could lead to the enhanced health of another person could provide much needed therapeutic comfort following an emotional abortion experience.[280]

One possible solution is to add another form into the list of forms that currently needs to be completed by a prospective abortion patient.[281] This form could be used as a standard dismissal form to be completed when the patient leaves the medical facility following an abortion. The scope of the form might prove to be problematic though. South Africa has a diverse people all with a differing degree of educational background, some of which who would simply not comprehend the stem cell issue. It could prove to be an unfortunate task to set

[280] Momeyer "Symposium on bioethics – thinking about biomedical advances: The role of ethics and the law: Embryos, stem cells, morality and public policy: Difficult connections" (2003) *Capital University Law Review* 93 at 99.

[281] See the consent forms in Annexure A and B provided in the following regulations to the Choice on Termination of Pregnancy Act "Regulations under Choice on Termination of Pregnancy Act 92 of 1996" as published in GN R168 in *GG* 17746 of 31 January 1997.

up a standard form that has to accommodate everybody.[282] A possible solution could be a system of presumed informed consent to conduct research on foetal tissue left over following a termination of pregnancy.[283] The most practical solution would be to select a number of institutions (for instance academic hospitals in the large cities) that are able to deal with stem cell related matters. Medical personnel at such an institution, who have been informed on the medical aspects of stem cell research, could assist in providing the aborting mothers with explanations of the uses of stem cells and how their foetal tissue germ cells can be utilised.[284] Such an endeavour however, would place an additional monetary burden upon the State. As will be seen in the next chapter, any public funding directed away from the most crucial of medical dilemmas is simply not a viable proposition at this point in time.

Obtaining informed consent from parents to use the stored embryos following IVF treatment would prove, in practice, to be the most workable of the prospects. An agreement could be made between a stem cell facility and an IVF treatment facility to send all the parents of stored embryos an information sheet about stem cells just before their contractual storage time of the embryos ends. In this way the parents can make an informed decision well in advance about their embryos, which would have been destroyed in any case.[285]

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[282] Federal rules in the United States of America require that informed consent forms be used for any research and that it should be in understandable language, but it has become evident that many subjects are still unable to comprehend the information provided to then. See Noah (2002) 28 *American Journal of Law and Medicine* 361 at 368

[283] See the discussion of presumed consent further on in this chapter.

[284] Having personnel allocated specifically to the task of obtaining informed consent could prove to be a time consuming process. In the case of *C v Minister of Correctional Services* 1996 (4) SA 292 (T) at 304 one of the factors determining whether informed consent to undergo medical testing had been obtained was whether the patient had been awarded reasonable time to make such a decision.

[285] Also see Chapman *et al* (1999) *American Association for the Advancement of Science and Institute for Civil Society* 14-15.

Notwithstanding any other legal principles, subjects wanting to donate their gametes for the creation of embryos that will be used solely for research purposes would have to provide the researchers with informed consent thereto before the gametes could be used. The question that has arisen previously features again: at which point is the information given to a person about stem cells sufficient to justify the conclusion that the resultant choice would be an informed one?[286] It is not necessary for a donor to know all the technical aspects surrounding stem cells, but of vital importance is the assurance that the necessary privacy safety measures are in place to protect his or her genetic information.[287] This again leads to the conclusion that it is essential that the relating of stem cell information be done in person and not simply through the filling in of a prescribed form. The same principles surrounding discretion that are used by a doctor when informing a patient of a proposed medical intervention, needs to be used in describing the scope of stem cell research to a prospective donor.

Arguments have been made that the protection of a research subjects' right to self-determination cannot be safeguarded until certain underlying problems affecting the informed consent process are resolved. These problems include:

- The inability of both doctors and patients to distinguish between therapy and research;
- The impact that the ideology of medical professionalism has on conduct during medical experimentation;
- The unclearness on the different tasks that medicine and research have; and
- The principles that govern the invitation to participate in research.[288]

[286] This is a question that becomes increasingly difficult to answer when placed within the larger setting of implementing new health care technologies in developing countries, South Africa included. See Macklin *Double standards in medical research in developing countries* (2004) 139-145.

[287] See Strauss 12 for a discussion of the dangers of "over-informing" the patient.

[288] Katz "Human Experimentation and Human Rights" as published in Tomossy & Weisstub (eds) (2003) 225 at 229-230.

Although warranted, these are concerns that have been expressed about informed consent throughout its implementation and are not only applicable to research situations. Informed consent provides an opportunity to ensure patient participation in all aspects of interventions, albeit medical or research orientated. The distinction between medicine and research, although important, do not affect the scope of informed consent.

3.2.5.4 Free and voluntary consent

Consent must be freely given. It must not be induced by force, fear or fraud.[289] This relates back to the fact that the time at which a person is informed about stem cells is crucial. If a pregnant woman that was simply considering an abortion feels forced into following through with the procedure because of pressure asserted by eager stem cell researchers, it could have an effect on the voluntary aspect of the consent given.[290]

One aspect of consent that needs to be addressed is whether it is possible to submit a person to a certain medical procedure against his or her will. Take for example the case in which a couple has a sick child. This child can be cured through the use of stem cells. The parents discover that they are able to use Prenatal Genetic Diagnosis (PGD) to select embryos that match the genetic profile of their sick child. If these embryos are implanted into the woman's womb and carried to term, the umbilical cord blood of the newborn child can be used to cure the sick child.[291] The question that arises is whether, for instance, the father can be forced to provide a gamete sample in order for the embryos to be created through the same methods used in IVF treatment. There are certain times at which a person could be asked to subject himself to

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[289] Van Oosten § 127, Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 29.

[290] A discussion of the timing of consent in terminations of pregnancy and the use of foetal tissue is provided in Kennedy & Grubb *Medical Law (3rd ed)* (2000) 1894-1895.

[291] See chapter 2 for a discussion of these techniques. This was done in the so-called "Nash case" as discussed in Wolf, Kahn & Wagner "Using pre-implantation genetic diagnosis to create a stem cell donor: Issues, guidelines and limits" (2003) *Journal of Law, Medicine and Ethics* 327 at 328.

a medical intervention against his will, for instance in emergency situations,[292] through statute[293] and sometimes through court orders in criminal proceedings,[294] but the future development of stem cell technologies could introduce another factor to this list.

At the moment stem cell technology is still a fairly new field in which perfect results cannot be guaranteed. But if the assurance can be given that a sick child can be cured through such a procedure, the situation might arise in which the parents' Constitutional Rights[295] to make choices concerning reproduction[296] and their freedom and security of their own body's[297] are limited in favour of the sick child.

The limitation of rights in order to enhance the health of a sick child does not merely involve the parents. If a healthy child is born with matching HLA-antigens to those of the sick child, following the successful use of PGD procedures, the newborn child could be subjected to serious exploitation. At first the umbilical cord blood of the healthy child will be used to obtain stem cells, which will then be transplanted into the sick child. If the umbilical cord stem cell transplant fails, the next step is a bone morrow harvest and transplant. This, too, might not engraft or the illness (for example leukaemia) may recur, requiring yet another bone marrow transplant. Further, once an HLA-matched donor is created, the need for tissues beyond bone marrow may arise. After a bone marrow transplant, toxicities related to chemotherapy and irradiation or immunosuppressive drugs could produce organ failure involving

[292] Freid 21; Van Oosten § 146.

[293] Van Oosten § 143.

[294] See for instance the case of *Minister of Safety and Security and Another v Qaqa* 2002 (1) SACR 654 (CPD) in which an order was granted for the removal of a bullet from the accused' leg for the purposes of a murder and robbery case. At almost the same time as the abovementioned case, as similar case was heard in Durban, namely: *Minister of Safety and Security and Another v Xaba* 2003 (2) SA 703 (D&CLD) in which the court refused to grant an order for the removal of a bullet from the leg of the accused.

[295] Constitution of the Republic of South Africa, Act 108 of 1996.

[296] Sec 12(2)(a).

[297] Sec 12(2)(b).

the kidneys, liver, or other organs. The question would then arise whether to harvest a solid organ from the healthy child.[298] Such a possibility might seem absurd, but desperation could force parents to take drastic measures. If such a situation occurs it is vital that any steps taken, considers not only the interests of the sick child, but those of the donor child as well.

Another factor that may affect the granting of consent is when financial rewards are given for a person's genetic material.[299] In the United States of America various cosmetic companies even purchase placental or foetal tissue from parents following a live birth or abortion.[300] There are many valid concerns about a market in human material.[301] The primary worry appears to be a fear that the altruistic market in human material would disappear if a compensation system were implemented.[302] If consideration is leant to the current HIV/AIDS statistics in South Africa, monetary incentives could lead to a

[298] Wolf, Kahn & Wagner (2003) *Journal of Law, Medicine and Ethics* 327 at 328.

[299] Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 29. The financial gains could be a monetary benefit, which befall both the patient and the doctor obtaining informed consent to the procedure. If the doctor does not disclose his interests in the matter, his attempts to obtain informed consent from a patient could amount to coercion.

[300] Boyd (2003) *North Carolina Journal of Law & Technology* 417 at 461.

[301] Amongst these concerns are the effects that financial incentives would have on both the informed consent process, as well as the effect on governmental attempts at regulating the industry. Svendsen "Stem Cells" as published in Burley & Harris (eds) 7 at 16-17 puts the position into perspective with the following words:

> "Should there be financial gain from using cells derived from human embryos? If there is commercial gain, the woman donating the eggs or terminating her pregnancy must be made aware of this as part of the informed consent process. This has the danger of encouraging egg and fetal donations simply for financial gain, and should clearly not be encouraged. One possible way to avoid this scenario is for government to take a more active role in embryo-based stem cell technologies, to regulate this field of research and invest in developing cell therapy methods, from the basic science to the establishment of "cell factories" for the production of tissues for transplantation. In this way, although it would be expensive at the start, governments would be able to utilize these technologies within nonprofit systems, thus overcoming commercial complications connected with selling human tissues."

See the section on the Common Law hereunder for a further discussion of the proprietary rights and profits on human genetic material.

[302] Laurie 324.

large number of diseased tissues being used.[303] All of the abovementioned incentives could play a leading role in a person's decision-making when considering whether an abortion should be done and the foetal germ cells donated (or sold) to willing institutions.

There have, however, been suggestions of using a hybrid model of financial reward in which people still donated tissue, foetuses and embryos through the normal altruistic market, but that donors of tissue from which significant utility benefits are gained, be compensated monetarily.[304]

3.2.5.5 Clear and unequivocal consent

The consent given must be clear and unequivocal.[305] Consent given must state the facts clearly and must preferably be in writing.[306] Certain guidelines surrounding the sufficiency of oral consent in research have been drafted,[307] but it is submitted that written consent be obtained for all research procedures. Cases in which oral consent have been argued to be sufficient were those in which a patient would only be subjected to a minimal amount of risk. Due to

[303] A number of positive results flowing from a market in human organs have been highlighted by Boyd (2003) *North Carolina Journal of Law & Technology* 417 at 471. A further aspect to take cognisance of is the fact that, in order to ensure that no diseased materials are introduced into the system, the donated tissue would have to be tested for diseases including HIV. This could lead to the discrimination of persons based on their genetic information, if their HIV status is to be made public. See for instance the case of *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A).

[304] Harrison "Neither *Moore* nor the market: Alternative models for compensating contributors of human tissue" (2002) 28 *American Journal of Law and Medicine* 77 at 78.

[305] Strauss 12.

[306] There are certain consent forms available that could provide insight as to the format that a written granting of consent should take on. See for example Knoppers, Caulfield & Kinsella (eds) *Legal rights on human genetic material* (1996) 179-180. The strict adherence to consent forms may, however, do damage to the prospect of effectively obtaining informed consent due to the varied degree of educational backgrounds of the prospective stem cell donors.

[307] Van Oosten (2000) 63 *Tydskrif van die Hedendaagse Romeins-Hollandse Reg* 5 at 13-14.

the subjective nature of the concept of "minimal" any attempt at conducting research by only acquiring oral consent should be avoided.[308]

3.2.5.6 Comprehensive consent

The consent must extend to the entire transaction and its consequences.[309] Consent that is not comprehensive could lead to costly legal action being taken at a later stage.[310] A good example is the American case of *Moore v Regents of the University of California*[311] in which the plaintiff successfully sued for damages following the patenting of a cell line derived from his spleen without his consent. Litman and Robertson[312] states that in order for a patient to make an informed decision, the patient must be informed of all the consequences of their decision, including financial gains that the physician attending to that patient may have in the granting of consent.

3.2.6 Presumed consent

One question that arises when examining the principle of consent is whether there is an easier way in which to obtain stem cells from human subjects. Is it even necessary to obtain consent from people whose foetuses, embryos or umbilical cord blood would have been destroyed in any case? Such an endeavour would not be a case with no consent being given, but rather one in which consent is presumed unless that donor states otherwise.

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[308] *Ibid*.

[309] Van Oosten § 129. This further ensures that later exploitation of the consenting party does not take place. See De Castro "Ethical Issues in Human Experimentation" as published in Kuhse & Singer (eds) *A companion to bioethics* (1998) 379 at 381.

[310] See, for instance, the case of *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T) in which the plaintiff was badly injured following x-ray treatment. The plaintiff was not informed as to the possible side effects that such severe irradiation could hold. The court reaffirmed that, unless it is an emergency situation, consent should first be obtained from the patient, or other party that possess consenting power, before commencing the treatment.

[311] 793 P.2d 479 (Cal. 1990).

[312] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 56.

Presumed consent is especially effective in situations of organ procurement. In an article on human organ procurement, Boyd[313] presents an interesting example of what happens when the supply and demand of any type of material (including human genetic material) is out of balance:

> "There are reports that the black market in human organs has resulted in the exploitation of the poor, including many terrible and dishonest acts, and disease transmission. It is important to note that many of these ills, like black market pricing, should not be extrapolated on to what would occur in a legal regulated market. To illustrate this point, consider the United States during prohibition or during the period in which abortion was generally illegal. There was certainly a time when dealing with alcohol or having an abortion was a dangerous prospect. Today, however, both exist under regulated systems. There are some arguably negative consequences that have resulted from each practice. Discussion continues on many levels debating the merits of each, but the general environment for drinking and medical abortions is much safer than it was during their periods of prohibition. It would have been difficult, if not impossible, to imagine the current relative safety we enjoy under our legal system by citing examples based on practices during a period of prohibition. Likewise, it is inappropriate to use the evils apparent in a black market for organs as indicative of the problems that may result from a legal market in organs…. One could argue that property rights in body parts are being established, that organs have value, and that a market for these organs does exist in the United States. The altruistic market is a procurement side market with the United States government as the only allowable bidder. The bidder has set the price in the legal market to zero. This is the lowest possible monetary incentive to compensate suppliers in the current market. The unregulated black market thrives in the background while the legal, price fixed, and under-priced market fails to provide for legitimate market needs, resulting in the deaths of thousands and the suffering of tens of thousands."

The quoted discussion states the position quite clearly: There is a high demand for human materials, and once the full potential and marketability of stem cells is realised, that high demand would spread to cells derived from umbilical cord blood, foetal material or embryos. The only viable options available is to start providing the donors of these materials with rewards

[313] (2003) *North Carolina Journal of Law & Technology* 417 at 468.

(mostly financial),[314] or to introduce a system of presumed consent in order to avoid the creation of a black market in stem cells and foetal tissue.[315] Presumed consent would result in a large amount of genetic material to satisfy the demand and hence negate any black market prospects.

The implementation of a system of presumed consent is not without its challenges. The derivation of stem cells is still a fairly contemporary issue for many people, mainly because of its narrow links to abortion and the right to life. If a procedure is incorporated in which all embryos would be handed over to the state for the setting up of a national stem cell bank following IVF treatment, widespread objection to even IVF procedures could follow. It is clear that presumed consent is an option of which cognisance should be taken, but is not yet ready for implementation with regards to stem cells in South Africa.

3.2.7 Closing remarks

The principles of, amongst others, privacy, bodily integrity and proprietary rights in human material are all applicable to Medical Law. In order to avoid repetition it will only be discussed below in the assessment of its original fields, for instance, Human Rights and the Common Law. All of the different aspects pertaining to stem cells are to be seen as forming an intricate structure from which the harmonising of the entire stem cell debate can be achieved. Individuals are allowed to dispose over their bodies as they wish, as long as that disposal is not in conflict with the overriding "social interest."[316]

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[314] See the section on proprietary interests in human material in the discussion of the Common Law hereunder, in which a hybrid model of financial reward versus proprietary interests is suggested. Such a system could prove to be an effective alternative to the implementation of presumed consent procedures. For a further discussion see Harrison (2002) 28 *American Journal of Law and Medicine* 77 at 78.

[315] Also see Laurie 324-325.

[316] Strauss 30. This reference by Strauss to the "social interest" is none other that a reference to the *boni mores*. The *boni mores* with regards to stem cells shall be assessed further on in this chapter.

Upon re-examination of the legal framework above, it is clear that there are no major legitimacy issues that could hamper stem cell development as of yet. The only aspect that has to be taken notice of is the fact that section 39A of the Human Tissue Act[317] prohibits the genetic manipulation of gametes and zygotes. This could play a cardinal role when SCNT practices become more prominent. Consent remains one of the most important factors in the conducting of research on human beings. In quoting Sir Isaiah Berlin, Katz[318] describes the implications of not obtaining consent in research:

> "[T]o manipulate [men], to propel them towards goals which [we] see, but they may not, is to deny their human essence, to treat them as objects without wills of their own, and therefore to degrade them. This is why to lie to men, or to deceive them, that is, to use them as means for [our], not their own, independently conceived ends, even if it is to their own benefit, is, in effect, to treat them as subhuman, to behave as if their ends are less ultimate and sacred than [our] own. … For if the essence of men is that they are autonomous beings – authors of values, of ends in themselves… - then nothing is worse than to treat them as if they were not autonomous but natural objects … whose choices can be manipulated…"

3.3 Intellectual Property Law

Intellectual property rights in human genetic material, and in particular, the obtainment of patents in cell lines shall be discussed in chapter 5. Although it does form part of the legitimacy issue, it mostly only does so in an indirect manner. For example: The intellectual property rights obtained in a cell line could be nullified if the original granting of those rights is deemed to be *contra bonos mores*. The intellectual property rights are dependant on the moral conceptions thereto, but do not dictate the legitimacy of stem cells in itself. Once the moral objections to property and intellectual property rights have been clarified, the challenges faced when patenting a cell line can be discussed.

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[317] 65 of 1983.

[318] "Human Experimentation and Human Rights" as published in Tomossy & Weisstub (eds) 225 at 239.

Intellectual property rights find its primary application in the assessment of the private sector's involvement in stem cell research. Through intellectual property rights private investors are able to obtain a certain measure of security in the positive results that their research may deliver. It has also been a source of great controversy due to the fact that some scholars are of the opinion that the granting of intellectual property rights in human genetic material amounts to unethical practices of conferring "ownership" of one human to another. Although the discussions pertaining to the ethics involved in stem cell research, that are discussed in this chapter, finds relevance to intellectual property rights, there are a number of other issues that also deserve mention, as have been done in chapter 5.

3.4 Common Law

3.4.1 Contractual and delictual principles pertaining to stem cells

In almost any case of human interaction the possibility of contractual or delictual liability is present.[319] Stem cells are no exception to this rule, for example: a couple decides to have the umbilical cord stem cells of their child stored directly after the birth of that child. A number of years later the child develops a disease that is curable through the use of the stored stem cells, but when the couple asks for the cells from the stem cell bank they are informed that something went wrong in the storing process and the cells are unusable. This situation poses a number of questions which includes:

- Can the parents (or sick child him/herself) sue the stem cell bank for a repayment of the storage costs that was paid over the years?
- Is it possible for the parents to claim their child's future medical costs from the stem cell bank?

[319] In a discussion of the contractual liability that could flow from research being conducted, Stauch, Wheat & Tingle *Sourcebook on medical law (2nd ed)* (2002) 580 distinguishes between the sponsor's (for instance a drug manufacturer or stem cell bank) obligations to the investigator and the obligations to the research subject. Cognisance should be taken of the fact that there could be different levels of contractual relations relevant to any specific situation.

- Would the stem cell bank be able to succeed with a claim of its liability being negated through a clause that excludes them there from, even if their storing practices are deemed to be grossly negligent?
- Can the parents claim the costs of rearing another child that was conceived, through the use of PGD and IVF,[320] with the sole purpose of providing the ill child with matching stem cells derived from this second child's umbilical cord blood?

Some guidelines are provided in case law as to the answers to the questions posted above. One such case is the one of *Administrator Natal v Edouard,*[321] in which the respondent (this is a decision by the Appellate Division) succeeded in being awarded monetary damages following the birth of a fourth child due to the fact that a doctor neglected to perform a sterilization operation on the respondent's wife. The court reiterated that the amount awarded in no way relieved the respondent of his obligation to support the child, but at most enabled the respondent to fulfil that obligation. This case could form the basis from which the medical costs and even the costs of rearing another child following PGD and IVF treatment could be claimed. The case is important for another reason, namely the fact that it confirmed the fact that only patrimonial loss can be claimed in contract and that any non-patrimonial loss needs to be claimed in delict.[322]

Providing important insight into the question as to the exclusion of liability through the use of an exemption clause[323] is the case of *Afrox Healthcare v Strydom.*[324] The respondent in this case (it is also a decision by the Appellate Division) neglected to read through a contract that excludes the hospital from liability, even for negligent conduct, before signing it. The respondent held that

[320] For a complete discussion of IVF and PGD treatment, see chapter 2.

[321] 1990 (3) SA 581 (A).

[322] *Administrator Natal v Edouard* 1990 (3) SA 581 (A) at 595-596.

[323] See a discussion hereof in Carstens & Kok "An assessment of the use of disclaimers by South African hospitals in view of constitutional demands, foreign law and medico legal considerations" (2003) *SA Public Law* 430.

[324] 2002 (6) SA 21 (HHA).

the enforcement of such a contract is contrary to the *boni mores* as well as unconstitutional. The court reaffirmed the principle of contractual freedom and reversed the decision made by the Transvaal Provincial Division. Of primary importance is the fact that the court stated that, even though the respondent did not rely on it, gross negligence on the part of the appellant's nursing staff could have restricted (but not invalidated) the exemption clause.[325] The decision as to whether a stem cell bank was grossly negligent in its storing procedures, and thus provided an injured party with the possibility to claim damages, despite the existence of an exemption clause, rests in the hands of the court.

The abovementioned questions, as well as issues surrounding causality, are but a few of the situations that would have to be addressed by the court. It is clear that the principles pertaining to the Law of Contract and Delict will be at the centre of such a discussion. A further point that cognisance should be taken of is the agreements that would have to be drawn up between different stem cell facilities working on a national level if a network of stem cell banks are to be set up. In a discussion that can be directly applied to stem cells, Hirtle[326] assesses the workings of DNA banks, the consent requisites and the further use of genetic material. Contractual relationships between such facilities would greatly depend on whether the samples are identified or anonymous and whether the appropriate protective measures have been taken to ensure donors confidentiality. Any mishaps when dealing with genetic information on such a large scale could lead to contractual and delictual liability.

In conclusion it would suffice to reiterate the fact that any contractual agreements should embrace the principles of informed consent as well as

[325] *Afrox Healthcare v Strydom* 2002 (6) SA 21 (HHA) at 35.

[326] "International Policy Positions on the Banking and Further Use of Human Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 149.

endeavour to address not only the procedure in which stem cells are derived, but any other related issues as well.[327]

3.4.2 Property rights in human tissue and stem cells[328]

When dealing with human materials, there has to be some sort of proprietary right vesting in the persons handling the materials. It costs money to store stem cells and once any monetary issues are involved the inevitable outcome is often actions for damages based on negligence, breach of contract or any other reason. In terms section 36 of the Human Tissue Act[329], the person acquiring human materials (including stem cells) receives "exclusive rights" therein. The section reads as follows:

> "Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of this Act, shall, subject to any restrictions in terms of this Act or any other law and provided he uses the body, tissue, blood or gamete for the purposes for which it has been donated, handed over or supplied to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof."

It is clear that there are certain rights present, even if it is simply one of possession. What is needed is to establish exactly which rights vests in human materials, especially stem cells and foetal tissue. This could play a key role in the determination of intellectual property rights on cell lines derived from embryos, umbilical cord blood or foetal tissue obtained by a prospective patent holder.[330]

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[327] For instance, the vesting of intellectual property rights if any patents are obtained because of the cells of the contracting cell donor.

[328] A further discussion of the proprietary interests in human material is provided in Klinkradt & Schwellnus "The legal and ethical implications of somatic tissue donation: the proprietary rights in respect of human tissue" (2000) 21 *Obiter* 200 as well as Lupton "Advances in medical technology and the ownership of human tissue" (2001) *Tydskrif vir die Suid-Afrikaanse reg* 567.

[329] 65 of 1983.

[330] Chadwick "Informed consent and genetic research" as published in Doyal & Tobias (eds) *Informed consent in medical research* (2001) 204 at 208-209 identifies the question as to whether a person is allowed to insist upon receiving part of the financial profit that was made following research on that person's genetic material. Unfortunately, the author does not provide an answer to the question, but merely states that it is increasingly discussed.

The derivation of stem cells does not fall within the ambit of donation by a deceased person. This means that chapter 2 of the Human Tissue Act[331] is applicable. Chapter 2 sets out the payments for import and exportation, the facilities that may acquire the materials and for which purposes these materials may be used, but neglects to state exactly which rights in the materials it is that are being obtained. A facility that is storing human materials may certainly not deal with it as it pleases.

The legal status of embryos and foetuses has been under scrutiny ever since the start of the abortion debate. It has been well established that a foetus is alive for the purposes of acquiring property,[332] but these economic interests that befall a foetus does not describe the proprietary rights vesting in the foetus itself. In a discussion of the status of genetic material in Canada, Litman and Robertson[333] states that the emerging trend is for *ex utero* embryos and gametes to be characterised as *sui generis*.

Another point that often creates confusion is the inability by some to distinguish between property rights and intellectual property rights. Patents do not confer "ownership" of the material onto the patent holder. In a discussion of DNA and gene patenting, Crespi[334] clarifies this distinction through stating that a patent holder holds the right to restrain another through a court order from infringing on his intellectual property in a patent. Such a patent is enforceable against the original unauthorised manufacturer and any other party in the chain leading to the actual sale of the patent holder's product. In

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Also see Braswell "Federal funding of human embryo stem cell research: advocating a broader approach" (2003) *Chicago-Kent Law Review* 423 at 437.

[331] 65 of 1983.

[332] See Davel & Jordaan 11-21 for a complete discussion of the *nasciturus*-fiction, as well as the case of *Pinchin v Santam Insurance Co Ltd* 1963 (2) SA 254 (W).

[333] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 55.

[334] "Patenting and ethics – a dubious connection" (2003) *Journal of Patent and Trademark Office Society* 31 at 34.

reality this means that the patent holder does not claim to have ownership in the patented product, but that he has the power to approach a court to stop others from infringing on his right to handle the patented product as he pleases.

Sometimes the relationship between the donor of material and the recipient is worthy of protection, but this still does not establish the extent of the rights vesting in the material itself. Litman and Robetson discuss a good example of this:[335]

> "This relationship-based approach is illustrated by the famous case of *Moore v Regents of the University of California*. In this case, Mr. Moore asserted a claim to a share of money generated by a patented cell line derived from bodily tissue taken from his diseased spleen. His spleen had been removed as part of his treatment for leukemia. Mr. Moore alleged that his cells and tissue were used to develop the cell line without his knowledge and consent. The various defendants in the case brought an action to strike out Mr. Moore's claim on the theory that even if all the facts he alleged were proved, there was no basis in law for recognizing his claim. This defence prevailed at first instance and Mr. Moore's action was struck out. However, on appeal, the California Court of Appeal ruled in favour of Mr. Moore and reinstated his action; this was affirmed on further appeal to the Supreme Court of California. That court held that when seeking a patient's consent for a medical procedure, a doctor has a fiduciary duty to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgement." *As we discuss later, the majority of the Supreme Court refused to accept that Mr. Moore could maintain an action based on property law.* However, because of the setting in which the case arose and, in particular, the existence of a doctor-patient relationship, Mr. Moore was able to use non-property law concepts (informed consent and fiduciary obligations) to ground his claim." [Own emphasis]

The legal concept of property does not refer to tangible objects itself, but rather to the rights of control over those objects.[336] This is an extremely

[335] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 55-56. Also see the discussion of this case in Boyd (2003) *North Carolina Journal of Law & Technology* 417 at 444-447.

[336] A further example of the fact that proprietary rights refer to the control vesting in an object or legal concept is the fact that certain states in the United States of America have even granted property rights in human genetic information. See Hildebrand, Klosek & Krzastek

important concept to take cognisance of. If the focus is merely placed on the human product itself, and not on the legal rights vesting therein, it could lead to an objectification of human material that undermines human dignity.[337] This could lead to a reduction of respect[338] and protection for the human body.[339] On the other hand, if property is viewed in terms of control over genetic materials it enhances the concept of dignity. The emphasis is placed upon the limits that a particular person has in the material under discussion. There are certain boundaries that cannot be crossed without proper regulation, for instance one cannot simply sell a foetus as one would a bicycle.[340]

Some scholars have placed the rights in human material as being quasi-property. This form of property is extremely weak, with limited possessory rights and very little else vesting in the material. Possession is one of the key concepts of property. To state that there are possessory rights but no property

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"Toward a unified approach to protection of genetic information" (2003) *Biotechnology Law Report* 602 at 604.

[337] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 59; Beyleveld & Brownsword "Human dignity, human rights and human genetics" as published in Brownsword, Cornish & Llewelyn (eds) *Law and human genetics – Regulating a revolution* (1998) 69 at 70.

[338] On the concept of respect for human embryos, see Steinbock "Respect for human embryos" as published in Lauritzen (ed) *Cloning and the future of human embryo research* (2001) 21.

[339] For more advantages and disadvantages to a property approach to human genetic material, see Hildebrand, Klosek & Krzastek (2003) *Biotechnology Law Report* 602 at 605-606.

[340] The proprietary interest in human material also finds relevance with regard to the future possibility of providing people with compensation for their tissue and other genetic material. Unfortunately the only legal model that can be seriously contemplated other than the current status quo of large scale non-recognition of proprietary interest is one in which one would allocate property rights in the human body. Such a large leap from one extreme to the next would not be possible, but at least one author has suggested a model in which a hybrid model of financial reward be used, in which people still donated their biological materials through the normal altruistic market, but that donors of tissue from which significant utility benefits are gained are compensated monetarily. This correlates with the arguments surrounding the *sui generis* nature of the proprietary interest in human material as well. See Harrison (2002) 28 *American Journal of Law and Medicine* 77 at 78.

rights in the material would be a contradiction of the terms. For that reason the concept of quasi-property is a very attractive one that strikes a middle ground between no rights and full ownership in the human materials.[341] Another option that is available is to characterise human material (stem cells in this instance) as being *sui generis*. This can be moulded to fit the rights needed in a certain object. In practice, however, it is clear that there are certain proprietary characteristics that befall stem cells even if they is classified as being *sui generis*, with the result that the distinction between *sui generis* and quasi-property, for purposes of stem cells, becomes very narrow.

A number of cases in the United States of America have dealt with the question as to whether embryos and gametes are property.[342] The two most influential of these are *Davis v Davis*[343] and *Hecht v Superior Court (Kane)*.[344] The *Davis*-case involved a custody dispute between divorcing parties over their cryogenically stored embryos left over after a successful IVF procedure. The trial court originally concluded that the embryos were completely constituted persons and thus awarded the custody on the basis of "the best interest of the child". The Court of Appeal rejected the trial judge's view of embryos as persons, but at no point referred to it as property. The case went even further, to the Supreme Court of Tennessee, where the Court of Appeal's decision was reaffirmed. The court then stated the position in such a way that the opinion of embryos being *sui generis* was reaffirmed: "Pre-

[341] Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 67-68.

[342] Also see Blackbeard "Therapeutic cloning – ok?" (2002) 35 *De Jure* 318 at 324 for a discussion of a number of cases surrounding the nature of ownership in human genetic material, including the American case of *Kass v Kass* 663 NYS 2d 581(1997) in which the court clearly stated that pre-embryos should be awarded "a status greater than that given to mere property, but not equivalent to a human being."

[343] 842 SW 588 (Tenn. 1992) as referred to in Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 78. The case is also discussed in Stauch, Wheat & Tingle 387-388.

[344] 20 Cal. Rptr. 2d 275 (Ct. App. 1993) as referred to in Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 79.

embryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life."[345]

The *Hecht*-case[346] dealt with cryogenically stored sperm that had been deemed to form part of a deceased's estate. The court noted that the value of sperm lies in its potential to create a child following fertilisation, and that that particular interest is similar to ownership.[347] Take note that the court was very careful not to specifically describe the interest as being full ownership, but rather similar to it. This again portrays the *sui generis* nature of human material, and could also be directly linked to the nature of stem cells.

Hirtle discusses two alternative approaches to the establishment of proprietary rights in the human body.[348] The first being a so-called "three-tiered legal structure" and the second being the theory of gradual distancing. The three-tiered legal structure allocates property rights to new products depending on the amount of labour performed on the human tissue. The first part of the system observes the living human body as a whole and allocates property rights to that person in his or her own body. The second tier of this system is activated once a physical component is removed from the body. This body part is then classified as being a *res nullius*, and ownership would go to the first person that takes possession of it.[349] It further states that in

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[345] As cited in Litman & Robertson "The Common Law Status of Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 51 at 79. Also see Steinbock "Respect for human embryos" as published in Lauritzen (ed) 21.

[346] 20 Cal. Rptr. 2d 275 (Ct. App. 1993).

[347] Boyd (2003) *North Carolina Journal of Law & Technology* 417 at 447-448.

[348] Hirtle "Civil Law and the Status of Human Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 85 at 108-112.

[349] A similar reference to the obtainment of ownership through the taking of possession of human materials can be observed in Strauss 164, when the question as to whether the remains of a non-viable foetus may be destroyed is discussed:

> "Judged in the light of general principles, it would seem as though non-viable foetal remains would definitely not qualify as human bodies and should therefore simply be dealt with on the basis of being a tissue removed from the mother's body. It is therefore submitted that a foetus may lawfully be destroyed in a

transplantation cases (and surely when stem cells are derived and stored as well) those persons in temporary possession of the tissue such as doctors or the storage facilities do not gain ownership of the tissues, but only keeps it in trust until the real recipient takes possession of it. The third tier states that tissue that is permanently removed from the human body (and would not be transplanted in its original form) is characterised as being *res communes omnium*. The reasoning behind this is that the only way in which to prevent tissue from becoming a marketable commodity is to characterise it as being the common property of all humans. Then, once labour and technology have been used to transform the tissue into something else[350] the final product will be susceptible for the allocation of property and intellectual property rights thereto.[351]

This three-tiered legal structure is open to criticism. Although it would prevent the possibility of donors later claiming they have property rights in their tissue which makes them party to expensive intellectual property rights created through the use of that tissue,[352] it could seriously undermine the process of obtaining informed consent. It could create a situation in which a researcher could simply take possession of, and obtain the resultant ownership in, each foetus that is aborted at a specific facility. The consent of the mother is not needed because of the fact that the foetus would be regarded as being a *res nullius*. If the foetus were characterised as rather being *res communes omnium*, the researcher would obtain property rights therein once the cells are derived from the foetus. Again it would confer the possessory rights therein away from the original donor thereof.

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hospital incinerator, *unless the woman has before removal or shortly afterwards laid claim to it."* [Own emphasis]

[350] For instance, when intricate techniques are used to create a cell line from foetal tissue germ cells.

[351] Hirtle "Civil Law and the Status of Human Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 85 at 110.

[352] As was the case in *Moore v Regents of the University of California* 793 P.2d 479 (Cal. 1990).

The second approach, the theory of gradual distancing, provides for a slightly different manner in which the allocation of proprietary rights in human material is calculated. Hirtle[353] explains the theory thoroughly with the following words:

> "…since fundamental civil law principles prohibit alienation of human persons, these body parts must be considered objects susceptible of alienation. Consequently, this provision changes the nature of the removed parts that are no longer "parts of persons" but have become things. These new things are treated with respect because their alienation must always be gratuitous. This respect is not so extensive, however, as to confer a sacred character to these new things that may, with certain constraints, be objects of commerce available for appropriation.
>
> At the third level of distancing, Goulet maintains that as the distance increases between the removed body part on the one hand, and the human body and person as an entity from whom the part originated on the other, the restrictions imposed on the circulation of the body will decrease accordingly. […] According to this approach, having the legal status of a thing, body parts are governed by the general rules of property law and ownership. For example, under property law, abandonment of things may not be presumed as it 'implies the owner's desire to stop owning the thing.' *If, for example, a woman's placenta following birth is to be treated as an abandoned thing, there must be either proof of the woman's informed consent or factual proof as to her absence of interest in her body part.*" [Own emphasis]

This approach to the question of property rights is more consistent with the current South African legal framework. It provides for the accommodation of informed consent before any further allocations of a person's genetic material can be made.

In conclusion it is clear that the legal characteristics of human genetic material including stem cells are *sui generis* in nature, although it possesses various proprietary legal aspects. The best approach in assessing the amount of legal rights that a particular entity possesses in the genetic material at hand would be to follow the guidelines provided by the theory of gradual distancing. This assessment has to be proceeded by a thorough fulfilment of the entire medico legal principles pertaining to any type of medical procedure, for instance, the

[353] Hirtle "Civil Law and the Status of Human Genetic Material" as published in Knoppers, Caulfield & Kinsella (eds) 85 at 111-112.

assurance that informed consent is given by a stem cell donor. Included in such an assessment would be the more ethically inclined debates. In a discussion of the Choice on Termination of Pregnancy Act,[354] Van Oosten[355] provides a measure of insight into the value allocation provided to an unborn embryo or foetus in South Africa. Even though he did not directly discuss the proprietary value of an embryo, the amount of respect awarded to it is noteworthy:[356]

> "And to add insult to injury (although in these days of high ideology, political correctness and similar forms of intellectual slavery, it may be the height of folly to proclaim this audibly), there even used to be the odd woman (of disloyal disposition and of the lunatic fringe, it goes without saying) who considered the life of an unborn embryo or foetus a legal interest which was, in principle at least, worthy of protection. […] As a non-human or non-person for legal purposes, a human embryo is evidently not entitled to any protection afforded to humans by the criminal law. It is simply a member of the pregnant woman's body and, in that capacity, subject to her right to 'security in and control over' her body, which includes the right to have her embryo killed."

Once the measure of proprietary interest in human material has been established as well as the requirements that have to be met before these materials (stem cells) can be obtained, it is necessary to assess the moral side of the stem cell debate. As was discussed in the beginning of this chapter, stem cells are not simply a human material that can be derived *in vacuo* to the *boni mores* prevailing at that point in time. The scientific possibilities have to be carefully weighed against the current public opinion thereto, in order to avoid any future obstacles in the application of stem cell technology.

3.5 Ethics and the Constitution: Establishing the *boni mores* concerning stem cells in the South African law

3.5.1 Introductory remarks

Any ethical considerations are inextricably intertwined with the constitutional principles that have been promulgated in the Constitution of the Republic of

[354] 92 of 1996.

[355] (1999) 116 *The South African Law Journal* 60 at 64.

[356] Also see Steinbock "Respect for human embryos" as published in Lauritzen (ed) 21.

South Africa.[357] The reason for this is the fact that chapter 2 of the Constitution, the Bill of Rights, establishes certain measures that protect the very roots of human nature. It touches on many of those aspects of a person's private being that deserves protection, for instance, the right to bodily and psychological integrity[358] and privacy.[359]

One of the key aspects that are also protected is that of freedom of religion, belief and opinion.[360] This fundamental human right also finds prominence in the stem cell debate. Religious viewpoints, especially with regards to the use of aborted foetuses and embryos in the derivation of stem cells, play an essential role in establishing the *boni mores*. Cognisance must again be taken of the fact that South Africa is a multicultural society in which it could prove to be difficult to balance the various interests in such a manner as to find an equitable middle ground between science and religion.[361]

The Legal Philosophy is, to a large extent, the key to incorporating the South African legal, religious and other interests into a working system. Whereas feministic perspectives could shed light on the concerns faced by women when addressing the stem cell debate, postmodernism and deconstruction could provide insight into the method in which the current legislative framework could be reinterpreted so that it accommodates the majority of the parties involved.

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[357] Act 108 of 1996.

[358] Sec 12(2).

[359] Sec 14.

[360] Sec 15.

[361] Strauss 194 states the hard task that lies before a jurist in making decisions concerning genetic manipulation and all other genetic procedures under the topic of "Ideological considerations." He reaffirms the fact that each procedure has to be judged on its own merits and that the jurist have to be guided by both the scientist with regards to the field of natural science and the *boni mores* in reaching a legally justifiable conclusion.

The abovementioned and other related issues are examined with regard to the application of stem cell technology in practice.[362]

3.5.2 Human Rights

Before a discussion of the constitutional applicability of stem cells can be made, it has to be stated that not all the sections of the Bill of Rights are applicable to private persons. In other words, the Bill of Rights has both a horizontal and a vertical application, but the horizontal application is subject to the nature of the right as well as the nature of the duty imposed by the right.[363]

The Bill of Rights does not only find direct application, but can also be applied indirectly.[364] It is a good set of norms expounding the values that should be respected in the South African setting. For that reason the Bill of Rights forms an intricate part of the examination into the *boni mores* of a particular factual situation and can be used effectively in the stem cell debate. The Constitutional Court is often charged with the task of identifying and applying these ethical considerations, that forms part of the Bill of Rights, to factual circumstances.[365] Langa[366] presents an example of the method employed by the Constitutional Court in establishing the *boni mores* pertaining to a certain question of law by using the example that it was the court that had to assess the public opinion on the abolishment of the death sentence in the *Makwanyane*[367] case, the public opinion at the time being very much against

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[362] A good overview of the types of philosophical arguments, including a discussion of some feminist perspectives, that are found in literature pertaining to biomedical advances can be found in Lee & Morgan *Human fertilisation & embryology – Regulating the reproductive revolution* (2001) 27-37.

[363] Brand *et al Human Rights 220 (MRT 220) Workbook 2003* (2003) 21. There is also a distinction made between direct and indirect horizontal application of the Constitution. See Van der Walt "*Progressive* indirect horizontal application of the Bill of Rights: Towards a co-operative relation between Common-law and Constitutional jurisprudence" (2001) 17 *South African Journal on Human Rights* 341.

[364] Brand *et al* at 22.

[365] Langa "The vision of the Constitution" (2003) 120 *The South African Law Journal* 670.

[366] "The vision of the Constitution" (2003) 120 *The South African Law Journal* 670.

[367] *S v Makwanyane* 1995 (3) SA 391 (CC).

the abolishment, and yet an application of the Bill of Rights was followed that rather reflects the ideal that the Court envisions the public opinion to be.[368] It would prove to be an interesting case if the Constitutional Court were to be charged with a problem relating to the public opinion on stem cell research at present. The very nature of stem cell research warrants a different approach to the application of public opinion in the interpretation of the law. At present the public opinion or *boni mores* have to be established through different means such as open debates within legal discourse, but the question of the approach that the Constitutional Court would have taken thereto remains an interesting one.

Human Rights as a field is not unique to South Africa and much can be learned from the methods in which it has been applied globally to similar areas of concern. Internationally there has been growing tension between the search for fundamental ethical principles in the formation of policies on biomedical research, and the need for respect of diverse moral perspectives.[369] This growing tension has led to the creation of a number of bioethical committees throughout the world, with the mandate to assess the ethical and moral objections to biomedical advances, and to provide for methods in which these assessments can be introduced into the respective legislative frameworks. For example, the creation of the International Bioethics Committee in 1993 and its establishment as a permanent committee of UNESCO in 1998, following the adoption of the Universal Declaration on the Human Genome and Human Rights in 1997, created a feeling of progression towards a truly international understanding of Human Rights concerns in biomedical research. Unfortunately the International Bioethics Committee has struggled to produce a substantial document addressing the issues. It has, however, produced a draft report on the possibility of creating a universal instrument on bioethics that will contribute and support international efforts that are made in providing

[368] See a full discussion on the role of the Constitutional Court in the assessment and often rejection of public opinion in Du Plessis "Between apology and utopia – The Constitutional Court and public opinion" (2002) 18 *South African Journal on Human Rights* 1.

[369] Plomer *The law and ethics of medical research: International bioethics and human rights* (2005) 13.

ethical guidelines in matters related to biomedicine.[370] This report only reaffirms the fact that countries have to establish their own methods in which to address stem cell research and other biomedically controversial applications. South Africa has its own resource of Human Rights principles in the Constitution.[371] Based on this it is believed that any concerns, albeit medical, ethical or legislative in nature, can be judged in such a way as to find a morally defensible approach thereto. Whether this is possible can only be established through an examination of the application of the Constitutional principles on biomedical issues itself, as is done hereunder.

3.5.2.1 Bodily and psychological integrity

Section 12(2) of the Constitution reads as follows:

> "Everyone has the right to bodily and psychological integrity, which includes the right-
> (a) to make decisions concerning reproduction;
> (b) to security in and control over their body; and
> (c) not to be subjected to medical or scientific experiments without their informed consent."

In a discussion of the abovementioned section, De Waal, Currie and Erasmus[372] identify some of the situations in which it would find prominence. Unfortunately they do not discuss the full application of the section in practice, but certain components are noteworthy:

- Section 12(2)(b) provides for two components of "individual inviolability" over one's body. "Security" refers to protection against interference by the state and "control" refers to general bodily autonomy against interference. It provides for a measure of protection against unwarranted intrusion by external parties.
- Section 12(2)(c) has two elements that have to be addressed. The first being the principle of "medical or scientific experiments." Medicine is not an exact science and sometimes the distinction between day-to-day care and experimental medicine becomes blurred. At present,

[370] Plomer (2005) 14.

[371] The Constitution of the Republic of South Africa, Act 108 of 1996.

[372] *The Bill of Rights Handbook (4th ed)* (2001) 261-264.

> stem cell based applications could still be deemed as being experimental in nature, but the more often it gets applied, the better the chances are that it would not be deemed experimental. The more contemporary a research endeavour becomes, the larger the likelihood of it not being condoned by the general public, with resultant difficulty in continuing such an endeavour. The second element identified in sec 12(2)(c) is that of informed consent. This has been discussed earlier in this chapter, but it is noteworthy that the Bill of Rights makes specific mention thereof with regards to medical experimentation.

Section 12(2)(a) allows a person to make his or her own decisions concerning reproduction.[373] This does not only focus on pregnancy in itself, but also on the termination thereof.[374] As has been identified earlier in this chapter, this section is also applicable to stem cell based endeavours. The right to make decisions concerning reproduction can even be interpreted as to include the decision about the donation of foetal tissue following a termination of pregnancy or to reproductively clone a human being. However, the primary stem cell related application of this section is where a parent is forced into having a second child in order to derive stem cells from the umbilical cord blood following a PGD and IVF procedure,[375] in order to treat another sick child. Although it is unlikely that this would happen in the near future, it is principles such as these that have to be clarified beforehand. The limitation clause[376] in the Constitution[377] could be used to limit the section 12(2)(a) rights of a parent in favour of a child.[378]

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[373] Jordaan (2002) 119 *The South African Law Journal* 294 at 296-300 describes the effect that this right has on reproductive cloning and its effect on genetic diversity.

[374] Davis, Cheadle & Haysom *Fundamental rights in the Constitution – commentary and cases* (1997) 87.

[375] See chapter 2 for a discussion of these procedures.

[376] Sec 36.

[377] The Constitution of the Republic of South Africa, Act 108 of 1996.

[378] Blackbeard (2002) 35 *De Jure* 318 at 326 is of the opinion that sec 12(2)(a) is only applicable to reproduction in the traditional sense of the word, and not to cloning and other forms of genetic manipulation. It is an interesting observation that might have to be clarified

In order for section 36 of the Constitution, the limitation clause, to be applicable, certain criteria needs to be met.[379] Subsection (1) provides for these criteria, namely that the limitation must be in terms of a law of general application and it must be reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom. Brand *et al*[380] provides for a list of legal rules that would most likely qualify as rules of law under section 36, namely:

> "[A]ll original legislation (national, provincial and local government legislation); all subordinate legislation (regulations); rules of the common law; rules of customary law."

Without having to delve into other laws of general application, the Constitution itself provides for rules of law that could be subjected to section 36 limitations. If, for example, the situation posed above is taken in which a sick child needs stem cells to be cured, it could lead to a weighing up of the parents interests with that of the child. Section 12(2) allows the parents to make their own decisions as to reproduction. On the other hand, section 28(2) states that:

> "a child's best interests are of paramount importance in every matter concerning the child."

If stem cell technology is developed to such an extent that the curing of the sick child is almost guaranteed, it would surely be in the best interest of the child that the parents go through the process of having another child in order to derive the umbilical cord stem cells from the birth. Such an extreme limitation of rights would first have to be justified in terms of the list of factors provided in section 36(1)(a-e).[381] A factor that would play a leading role is

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by the courts. If a person's section 12(2)(a) reproductive rights include cloning procedures, it could provide pro-cloning groups with a strong leg to stand on.

[379] A full discussion of sec 36 does not form part of the scope of this dissertation, but can be found in Rautenbach *General provisions of the South African Bill of Rights* (1995) 86 and Davis, Cheadle & Haysom 303-320.

[380] 43.

[381] The factors mentioned in the section 36 are the following:

(a) the nature of the right;

(b) the importance of the purpose of the limitation;

section 36(1)(e) in which it has to be assessed whether there are other, less restrictive means of achieving this purpose. The only other method that could possibly be applicable is if SCNT[382] is used to create an embryo identical to the sick child, and then derive the stem cells needed from that embryo. Unfortunately "genetic manipulation" is illegal in terms of section 39A of the Human Tissue Act,[383] with the result that SCNT would also be illegal.[384] On the other hand, it would be a less intrusive measure to take to have section 39A of the Human Tissue Act[385] limited, rather than section 12(2) of the Constitution.[386]

It is clear that the different rights are a close knit and have to be carefully weighed in order to provide a well-balanced solution, without severely limiting one person's rights in favour of another. The National Health Act,[387] as will be seen in the next chapter, will also play a cardinal role in the evaluation of a person's right to bodily integrity.

3.5.2.2 Privacy

The right to privacy,[388] as stated in section 14 of the Bill of Rights, reads as follows:

(c) the nature and extent of the limitation;

(d) the relation between the limitation and its purpose; and

(e) less restrictive means to achieve the purpose.

[382] See chapter 2 for a complete discussion of Somatic Cell Nuclear Transfer (SCNT).

[383] 65 of 1983.

[384] (2002) 119 *The South African Law Journal* 294 at 303 is of the opinion that sec 39A does not prohibit cloning, even reproductive cloning, by means of SCNT due to the section becoming inapplicable for vagueness. The ultimate decision of its application to stem cell research and therapeutic cloning procedures rests in the hands of the court.

[385] 65 of 1983.

[386] Act 108 of 1996.

[387] 61 of 2003.

[388] The right to privacy is also explicitly guaranteed in the Universal Declaration of Human Rights, The International Covenant on Civil and Political Rights, The European Convention on Human Rights and the American Convention on Human Rights. See Van Wyk, Dugard, De Villiers & Davis (eds) *Rights and constitutionalism – The new South African legal order* (1994) 242; Davis, Cheadle & Haysom *Fundamental rights in the Constitution – commentary*

> Everyone has the right to privacy, which includes the right not to have-
> (a) their person or home searched;
> (b) their property searched;
> (c) their possessions seized; or
> (d) the privacy of their communications infringed.

De Waal, Currie and Erasmus[389] identified three related concerns that the right to privacy seeks to protect, namely: certain aspects of one's life in respect of which one is entitled to be left alone including one's body, certain places (such as one's home) and certain relationships (such as marital, sexual or other intimate relationships). The second concern that a right to privacy aims to protect is the opportunities for an individual to develop his or her personality. This extends to certain forms of individual and personal self-realisation or self-fulfilment. The third concern that the right to privacy seeks to protect is the ability of individuals to control the use of their own private information.[390]

It is in particular the first and third concern that are applicable to stem cell related interventions. The right to be left alone (privacy in one's body) relates back to the protection provided by section 12(2) of the Constitution.[391] The protection of private information about an individual is also of extreme

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and cases (1997) 91-95 and Cachalia, Cheadle, Davis, Haysom, Maduma & Marcus *Fundamental rights in the new constitution* (1994) 42. The discussion of privacy in this dissertation forms only a small part of the tip of an iceberg. There are a number of sources that discuss the concept of privacy, but one of the more comprehensive ones with regard thereto in biotechnology is Laurie *Genetic privacy – A challenge to medico-legal norms* (2002).

[389] 270-271.

[390] Other authors have identified four similar interrelated components of genetic information, namely: access, use, disclosure and security. If any one of these components are breached it results in a breach of privacy to the individual concerned. See Hustead & Goldman "Genetics and privacy" (2002) 28 *American Journal of Law and Medicine* 285 at 286 for a further discussion on how these components of privacy interact.

[391] The Constitution of the Republic of South Africa, Act 108 of 1996.

importance~~,~~ in the light of possible discrimination based on, for example, HIV status.[392]

As the field of genetics becomes more defined and accessible to the general public, so too has the fear of exploitation based on a persons genetic information.[393] Because of the fact that this could be a valuable predictor of a person's future health, the fear is that it could be used negatively by employers[394] and insurance companies.[395] In an article on the topic, Hildebrand *et al*[396] describes the different angles of application that have traditionally been taken by the legislators in the United States of America in dealing with genetic information, and states that such legislation has generally taken one of two approaches:

> "it has either focused on categorizing genetic information as something that is private to the individual and therefore cannot be disclosed without the individuals' consent, or it has focused on labelling genetic information as something that is proprietary to the individual and thus not capable of being taken or used in the absence of the permission of, and perhaps payment to, the individual owner."

Whichever angle from which it is approached, genetic information needs to be protected.[397] This protection is granted not only through section 14 of the

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[392] Van Oosten § 174 provides the example of a doctor performing a secret HIV test or genome analysis on a blood sample that was obtained with the patient's consent. This type of violation of privacy has to be distinguished from cases in which a doctor breaches his duty of confidentiality. (See for example the case of *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A))

[393] See Powers "Privacy and Genetics" as published in Burley & Harris (eds) 364 at 368 for an explanation of privacy, as well as how genetic information sometimes merits higher standards of protection (so-called genetic exceptionalism); Schneider & Wardle "Genetics and artificial procreation in the U.S.A." as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) 55 at 65 and Smith *Human rights and biomedicine* (2000) 146-164; Laurie 92.

[394] Mason & McCall-Smith *Law and Medical Ethics (5th ed)* (1999) 178; Laurie 150-165.

[395] Mason & McCall-Smith 175; Laurie 130-137.

[396] (2003) *Biotechnology Law Report* 602 at 602.

[397] Mason & McCall-Smith (1999) 167-186 provides a comprehensive discussion on genetic information and the law.

Constitution,[398] but in other legislation as well. For example, in section 7(5) of the Choice on Termination of Pregnancy Act[399] the confidentiality of a woman undergoing a termination of pregnancy is ensured, and in section 33 of the Human Tissue Act[400] the publication of certain facts about a donor is prohibited. If it can be ensured that the publication of genetic information is done through a system of informed consent, most issues of interference of privacy would be addressed, although it could still leave other areas of possible breaches in privacy unattended to. Once that person provides consent for his information to be used, to what extent is he guaranteed that the information will not be dispersed further than originally agreed upon? Especially in light of the development of the World Wide Web, the ease of access thereto, and speed with which information can be obtained, has dramatically increased.[401] Privacy concerns are addressed in the legislative provisions posted above, but the unfortunate reality is that a breach of privacy often precedes legislative action being taken and once privacy is breached, the damage caused cannot simply be undone.

3.5.2.3 Socio-economic rights

Section 27 of the Constitution[402] reads as follows:

> (1) Everyone has the right to have access to-
> *(a)* health care services, including reproductive health care;
> *(b)* sufficient food and water; and
> *(c)* social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
>
> (3) No one may be refused emergency medical treatment.

[398] The Constitution of the Republic of South Africa, Act 108 of 1996.

[399] 92 of 1996.

[400] 65 of 1983.

[401] See Hustead & Goldman (2002) 28 *American Journal of Law and Medicine* 285 at 303-307 for a discussion on the impact of the Internet on genetic privacy.

[402] The Constitution of the Republic of South Africa, Act 108 of 1996.

This section places the focus on the public sector of medical intervention, and is discussed thoroughly in the next chapter.[403] Cognisance must be taken of the fact that the rights provided in section 27(1) are subject to availability of resources by the state.[404] The question that arises is whether it is possible for the state to even attempt the conducting of research in the stem cell field, when the money to be used is needed for other medical interventions?[405]

3.5.2.4 International Human Rights instruments[406]

Section 39 of the Constitution of the Republic of South Africa provides for the interpretation of the Bill of Rights and reads as follows:

> (1) When interpreting the Bill of Rights, a court, tribunal or forum-
> *(a)* must promote the values that underlie an open and democratic society based on human dignity, equality and freedom;
> *(b)* must consider international law; and
> *(c)* may consider foreign law.
>
> (2) When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.
>
> (3) The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.

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[403] It is interesting to note, however, that the difficulties that would be faced by the organs of state in realising these rights as well as in distinguishing between a right and a mere directive principle of law have been identified early on in South Africa's constitutional system and still proves to be challenging today. See Van Wyk, Dugard, De Villiers & Davis (eds) 625.

[404] Sec 27(2).

[405] See Bollyky "R if C > P + B: A paradigm for judicial remedies of socio-economic rights violations" (2002) 18 *South African Journal on Human Rights* 161 as well as Bilchitz "Towards a reasonable approach to the minimum core: Laying the foundations for future socio-economic rights jurisprudence" (2003) 19 *South African Journal on Human Rights* 1.

[406] A very comprehensive discussion on the application of International Human Rights is provided in Priso-Essawe "The protection of international human rights law in the South African legal system" (2001) 34 *De Jure* 549.

The fact that International Law must, and Foreign Law may be considered, would play a leading role in the way in which the Constitutional principles find application in stem cell related affairs.[407] Current international trends could also find relevance in the assessment of the *boni mores* in South Africa as well as the refinement of our stem cell related practices, for instance, through the establishment of certain criteria that has to be met before a facility may obtain and store stem cells.

In November 1996, the Council of Europe adopted, and in April 1997, signed the Convention on Human Rights and Biomedicine (hereafter known as the Bioethics Convention).[408] This convention's primary goal is to establish a direct relationship between bioethics and Human Rights.[409] It enlarges and builds upon the concept of respect and dignity that have been identified by Article 1 of the Universal Declaration of Human Rights.[410] The focus on dignity is so strong that the Bioethics Convention states that cloning of any type would amount to the instrumentalisation of human beings. It further states that the creation of embryos for research purposes is prohibited.[411]

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[407] Chirwa "The right to health in International Law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine" (2003) 19 *South African Journal on Human Rights* 541 describes the application of a number of international instruments to South African law.

[408] As found in Smith 12, Plomer 16-21 and Cox "The failure of 'rights talk' in the field of bioethics: The European Convention on Human Rights and Biomedicine" as published in Junker-Kenny (ed) *Designing life? Genetics, Procreation and Ethics* (1999) 23 at 23. Also see Strydom "The human rights side of the human genome" (2003) 1 *Tydskrif van die Suid-Afrikaanse Reg* 37 at 49. This convention was first know as the Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Bioethics, but the name was changed during the final version thereof presented in June 1996.

[409] Zigalvis "The European Convention on Human Rights and Biomedicine, and its Protocols" as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) 3 at 4.

[410] As referred to in Smith 13. Also see Beyleveld & Brownsword "Human dignity, human rights and human genetics" as published in Brownsword, Cornish & Llewelyn (eds) 69 in which the entire article in dedicated to an analysis of the concept of human dignity and its different forms of interpretation and application.

[411] Article 18.

Many of the European countries were against a comprehensive ban. On the other hand, the measures taken by the Bioethics Convention seems to be on par with the global disposition towards bioethics. UNESCO's Universal Declaration on the Human Genome and Human Rights[412] draws the attention back to the concept of human dignity on numerous occasions. In adopting the Universal Declaration, UNESCO attempted to establish a standard from which national legal frameworks and, over time, international conventions could be drafted.[413] As will be seen further on in this chapter, the concept of human dignity, as well as the protection against the instrumentalisation of human beings, lies at the centre of many religious and philosophical discussions. Although many of the international instruments prohibit reproductive cloning, they are mostly silent about cloning for the purpose of stem cell research. It would appear as if the international community is waiting for more clarity about the potential medical applications of stem cells before a decision is made as to the use of SCNT to create embryos for the sole purpose of being used in research. In a discussion of UNESCO's Universal Declaration on the Human Genome and Human Rights, Strydom[414] mentions that the weighing up of fundamental rights with freedom of research is further defined in the third part of the Declaration. Here the declaration determines that research, and its possible applications concerning the human genome, cannot outweigh the fundamental rights of individuals or groups of people. The Declaration only speaks out against human cloning for reproductive purposes, stating that it is impermissible because it is contrary to human dignity, but remains silent on cloning for the purpose of stem cell research.

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[412] As referred to in Smith 14. Also see the discussion thereof by Simon "Human Dignity as a Regulative Instrument for Human Genome Research" as published in Mazzoni (ed) *Ethics in law and biological research* (2002) 35 at 40.

[413] Similar to the Universal Declaration of Human Rights of 1948 and the resultant human rights covenants of 1966. See Strydom (2003) 1 *Tydskrif van die Suid-Afrikaanse Reg* 37 at 40.

[414] (2003) 1 *Tydskrif van die Suid-Afrikaanse Reg* 37 at 42.

This silence on cloning for the purpose of stem cell research appears to have been done deliberately upon the examination of a further provision allowing "the application of research concerning the human genome when it is aimed at offering relief from suffering and at the improving of the health of individuals and humankind as a whole."[415] This provision is broad enough in scope to allow for scientific processes involving human cloning for the purpose of stem cell research and is a welcoming sign that the international community is embracing the potential that stem cell research has to offer.

Once the National Health Act[416] and the regulations that are yet to be promulgated under it are in force, the courts will start to redefine the South African position. The international instruments and its foundation, which is grounded in Human Rights, will take centre stage in the evaluation of permissible and impermissible stem cell related practices. Some authors have already started to draft proposals of conventions with global application, for example the proposed Convention on the Preservation of the Human Species by Annas, Andrews & Isasi[417] that will outlaw reproductive cloning altogether as well as compel parties thereto to implement further legislation regulating the other aspects of biomedicine such as sufficient informed consent procedures, safety and conformity to universal ethical standards.

Opponents to stem cell research allege that research on human embryos amounts to a violation of human dignity as well as a violation of the embryos' right to life. Once these opponents to stem cell research are questioned on the precise scope of these violations of human dignity, it becomes clear that even amongst the critics of stem cell research there is disagreement on the nature of the ethical violations.[418] These disagreements reflect much deeper theoretical disagreements on many different philosophical and religious perspectives to stem cell research. For example, utilitarian and deontological

[415] *Ibid*.

[416] 61 of 2003.

[417] "Protecting the endangered human: Toward an international treaty prohibiting cloning and inheritable alterations" (2002) 28 *American Journal of Law and Medicine* 151at 154.

[418] Plomer 68.

theories are built on fundamentally different philosophical perspectives, and provide for different ethical approaches to matters concerning the nature of human life. These different approaches then leads to the conclusion that the ethics in genetics, so to speak, is not a concept that can ever be fully defined, but rather one that must constantly be refined with regard to the views of a pluralistic society. Human rights is one of the many factors determining the definition of ethics within the larger debate on how to balance different legal and ethical principles pertaining to biotechnology in general, and stem cell research in particular. The work below attempts to further refine the definition of ethics within stem cell research through an assessment of the primary philosophical approaches thereto.

3.5.3 Ethics – legal philosophical and religious approaches

Whilst the positivistic legal principles have been established, it is vital to evaluate the moral objections of stem cell endeavours. These objections often correlate with religious viewpoints thereto and play a key role in the assessment of the current *boni mores* on stem cell research. The discussions on stem cells always tend to speak of the "moral objections" thereto, whilst at the same time stating the positive law that regulates the position. It is interesting to note that these two always seem to be separated from each other. A valid question to ask is why the legal position does not resemble the current *boni mores* in the first place?[419] That is where the legal philosophical perspective comes into play. The post-modernistic strive towards the so-called "Other" describes the philosophical attempt at reconstructing the current legal position into one that provides the best possible justice available.

In order to apply the legal philosophical principles, it is necessary to first establish the playing field of moral objections that are made against stem cells. Firstly, the two primary categories into which the opinions can be dealt,

[419] In that regard, it is even possible to criticize the concept of legitimacy as well. Legitimacy in the traditional sense of the word only focuses on the positivistic legal principles, whilst the moral objections are only seen as by-products of principles that are unrelated to hard law.

namely utilitarianism and deontology, are discussed. Thereafter some of the religious viewpoints and finally the legal philosophical assessments are made.

3.5.3.1 Deontology versus utilitarianism

The deontological and utilitarianistic schools of thought resemble the different extremes when it comes to the moral approaches where embryos and foetuses are to be used in research. Whilst utilitarianism focuses on the "greater good" and how the embryo holds great potential for future applications, the deontological approach is concerned with the status of the embryo as a human being.[420] Certain religious viewpoints embrace either more, or less of these two approaches. The most effective method in which to differentiate between utilitarianism and deontology is through the use of an embryo-based example. Momeyer[421] describes the different positions on the moral status of the embryo as follows:

> "1. The embryo should be thought of as having full moral status. It has a full, unique human genome and the potential, in the normal course of events, to become a child and then an adult human being. In these most important respects it is already a unique human life and should be treated with the respect due any human being. Failure to show full respect for embryonic life threatens to de-value all human life.
> 2. A second position is that the embryo has some moral status as human life, but not full moral standing. Full moral standing comes as the result of a gradual process of development culminating with birth. Legally, this is where protection traditionally begins, and morally it is the appropriate place for full moral status.
> 3. The embryo-the pre-implantation embryo-should be thought of as having no moral standing at all. The embryo satisfies none of the reasonable criteria for having intrinsic moral status: it has no personhood, no consciousness, no self- consciousness, no sentience, and no interests. It is an object that may have great value, but no moral value in itself."

The first point describes the deontological perspectives on the human embryo reasonably accurately. They are of the opinion that the embryo is fully human from the point of conception, and needs to be treated with the same amount of

[420] Also see the discussion of deontological and utilitarian perspectives by Warnock "Experimentation on human embryos and fetuses" as published in Kuhse & Singer (eds) 390 at 393.

[421] (2003) *Capital University Law Review* 93 at 94.

respect as one would treat any fully developed human being.[422] This approach is not without its criticism. For instance, why have the deontological supporters not made more objections to IVF practices? There are countless embryos cryogenically stored that would simply be discarded after a contractually agreed upon time. Why has the issue of using embryos, even those created for the sole purpose of being destroyed for research purposes, suddenly become such a big problem? The answer to this lies in the concepts of dignity[423] and respect.[424] The deontological approach constantly warns of the dangers of the instumentalisation of human life and how the loss of respect for potential life is the first step on the slippery slope towards reproductive cloning.[425] There are also a number of extreme deontological viewpoints available in the legal literature. McDonald[426] presents such an approach in a discussion of the thirteenth amendment in the United States of America, which placed a ban on slavery. She states that an embryo possesses the full genetic code of an individual and should thus be treated like any other human being. McDonald then comes to the conclusion that the use of embryos in research is

[422] Strydom (2003) 1 *Tydskrif van die Suid-Afrikaanse Reg* 37 at 44 also refers briefly to this and other views on the status of the embryo.

[423] Dignity plays a very important part in many of the debates surrounding stem cell research. This concept of dignity is enhanced through other means as well, including international documents such as the Convention on Human Rights and Biomedicine which have direct references to dignity as a trait worthy of protection. References to the inherent dignity of the human person are also found in the preamble to the Charter of the United Nations, the UN Declaration of Human Rights, the International Covenant on Civil and Political Rights and the International Covenant of Economic, Social and Cultural Rights. See a further discussion of dignity in stem cell research in Plomer 68-77 as well as in Macklin 196.

[424] For a brief overview of this concept within moral decision-making, see Chapman *et al* (1999) *American Association for the Advancement of Science and Institute for Civil Society* 8-9.

[425] This is reasserted in a discussion of religion and bioethical advancement by Mckenny "Religion and Gene Therapy: The End of One Debate, the Beginning of Another" as published in Burley & Harris (eds) 287 at 289 as well as Parens "On the Ethics and Politics of Embryonic Stem Cell Research" as published in Holland *et al* (eds) *The human embryonic stem cell debate: science, ethics and public policy* (2001) 37 at 45.

[426] "Patenting human life and the rebirth of the thirteenth amendment" (2003) *Notre Dame Law Review* 1359.

a form of slavery because it amounts to the possession of one human being by another.

The third point that is described by Momeyer[427] above best resembles the utilitarian perspective on the human embryo. No matter which methods are used in obtaining the stem cells, as long as the results are positive, the method is justified. This again moves into a dangerous area. Even if a deontologically approved amount of respect is shown to the embryo, the embryo itself could still have been obtained through otherwise unsavoury practices.[428]

A further interesting observation that is made about the two approaches includes the possibility that no matter whether a deontological or utilitarianistic approach is followed, the result would still be that submission to therapeutic cloning[429] will result in reproductive cloning practices. The reasoning behind it reads as follows:[430]

> "1. Utilitarian View
> Reproductive cloning of humans will be pursued provided that utilitarian values are met because there is no outside measure that would absolutely prohibit the action and prevent the slide. The reasoning behind this is that it is not conduct, but ends, that drives the decision. As long as reproductive cloning is medically unsafe, the end of happiness cannot be achieved. Therefore, the conduct of reproductive cloning will be condemned. […] Once safety is no longer a scientific issue, will a uniform agreement to ban evaporate and emerge as a uniform agreement to permit? It seems likely for several reasons. Once therapeutic cloning is accepted, only a thin line separates it from reproductive cloning - the biologic content is the same; the process is the same. The difference is only a matter of human will that either chooses to destroy the "therapeutic" clone

[427] (2003) *Capital University Law Review* 93 at 94.

[428] Also see Ryan "Creating embryos for research: On weighing symbolic costs" as published in Lauritzen (ed) 50 at 57.

[429] In other words the use of SCNT in order to create an embryo that is identical to the donor, with the result that stem cells that match the genetic make-up of the donor can be derived from the embryo.

[430] Makdisi "The slide from human embryonic stem cell research to reproductive cloning: ethical decision-making and the ban on federal funding" (2003) *Rutgers Law Journal* 463 at 504.

> or chooses to implant the "reproductive" clone. The semantic difference lies not in the clone, but in the human action that determines its fate. As soon as safety issues are resolved, the before-condemned conduct may become a desired goal. […] Additionally, the American value of reproductive choice [as will the South African constitutionally protected right to reproductive choice] will likely create a merging of medicine and business, with the ethics of business guiding the ethics of medicine. In circular fashion, choice may well be manipulated by creating demand through advertising, as in the IVF business. Unlike other areas, where peer scientists or companies dictate rules, reproductive law has taken shape around its consumers.
>
> 2. Deontological View
> Once safety issues have been resolved, an identical result (acceptance of reproductive cloning) will occur by application of an ethical position that refrains from instrumentalizing embryonic life. The same arguments that condemn the destruction of a human embryo to harvest its stem cells operate to promote implantation once a new life has begun, whether through fertilization, SCNT, or whatever process is employed to create the human embryo. Because there is no biological difference between a laboratory clone created for purposes of therapeutic research and a laboratory clone created for purposes of implantation, the same rights would be accorded to each. Most fundamental among these is the right to be valued, at each stage of development, as an end and not as an instrumental means toward another's end. The practical application of this right necessitates implantation and gestation until birth. A natural consequence of adherence to a principle-based argument thereby dovetails with the natural consequences of a utilitarian argument. Adherence to either view would advance the acceptance of reproductive cloning once embryos were safely created in the laboratory."

This is an alarming observation that is made by Makdisi and reaffirms the fact that legal instruments, both nationally and internationally, should be in place to prohibit reproductive cloning.[431] It is now possible to evaluate the different religious viewpoints on the use of embryos and foetuses in research and to establish where these viewpoints lie within deontology and utilitarianism.

[431] On the other hand, there are some authors that pose very convincing arguments as to why reproductive cloning should be allowed. See Green "Much ado about mutton: An ethical review of the cloning controversy" as published in Lauritzen (ed) 114 at 115-116.

3.5.3.2 Religious viewpoints[432]

There are sometimes only small differences between different religions' perspectives on the field of genetics, and in particular, stem cells. On the other hand, there could also be vast differences of opinion within a particular religious denomination, with the result that the viewpoints expressed thereto in legal literature should merely serve as an indication thereto and not as the only possible interpretation.

Judaism[433] sees physicians as the agents of God in the act of healing, with the result that even if a particular therapy is created rather than found in nature, the legitimacy thereof does not get affected.[434] On the other hand it is important to take notice of the fact that all human beings are created in the image of God and are to be valued as such. Before one can establish whether researchers are allowed to conduct research on and derive stem cells from aborted foetuses, the status of abortion within Judaism needs to be addressed. For the most part of the pregnancy a foetus is simply seen as "the thigh of its mother."[435] No person may amputate their thigh, because that would do damage to the image of God. On the other hand, if the foetus is diseased or the pregnancy would endanger the woman's life, a termination of pregnancy is justified. As long as a foetus is aborted for legitimate reasons

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[432] There are only a handful of religious viewpoints discussed in this dissertation, but information on other religious approaches is available in the following sources: Hamida "Islam and bioethics", Martin "Buddhism and the right to respect of the person in the face of risks associated with progress in biotechnologies" and Caillavet "Agnostic thought and human bioethics" as published in European Network of Scientific Co-operation on Medicine and Human Rights *The human rights, ethical and moral dimensions of health care* (1998) 81, 93 and 99 respectively.

[433] Even within religious denominations there can be different perspectives on a particular subject. See for instance another approach to Judaistic perceptions in Zoloth "Born again: Faith and yearning in the cloning controversy" as published in Lauritzen (ed) 132 and Guigui "Jewish morality with respect to medicine and biotechnology" as published in European Network of Scientific Co-operation on Medicine and Human Rights 73.

[434] Dorff "Stem Cell Research – A Jewish Perspective" as published in Holland *et al* (eds) 89 at 89.

[435] *Ibid* at 90.

under Jewish law, that foetus may be used to preserve the life of others.[436] Take note of the fact that a foetus does not have the status of a normal person, but only as a part thereof.

Since stem cells can be derived not only from foetuses, but from embryos as well, it is interesting to note that for the first forty days after implantation into a woman's womb they aren't even seen as being part of a human being.[437] This does not mean that an abortion can be undergone within the first forty days for any particular reason. As long as the mother or embryo's health is not abnormally affected, the fact that the implanted embryo can potentially become a human being warrants protection. Embryos that are created *in vitro* and not implanted into a woman's body have no legal status in Jewish law and can be discarded or used for research purposes without any problems.[438]

The Roman Catholic perspectives are not quite as well defined as those of the Judaistic scholars. The overwhelming sentiment seems to be one in which the possible benefits that can flow from stem cells can be utilised without having to do damage to the inherent dignity that befalls a human being.[439] In an article on the subject, Farley[440] provides a comprehensive discussion of the different Roman Catholic views, and states that a case can be made both against and

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[436] As a matter of fact, Judaism mandates a person to utilise measures that can be used if it can save a life. See Zoloth "The Ethics of the Eighth Day: Jewish Bioethics and Research on Human Embryonic Stem Cells" as published in Holland *et al* (eds) 95 at 100.

[437] Dorff "Stem Cell Research – A Jewish Perspective" as published in Holland *et al* (eds) 89 at 91; Levy *The human body and the law: Legal and ethical consideration in human experimentation (2nd ed)* (1983) 41.

[438] Zoloth "The Ethics of the Eighth Day: Jewish Bioethics and Research on Human Embryonic Stem Cells" as published in Holland *et al* (eds) 95 at 100.

[439] See Miller (2003) *Catholic University Law Review* 437 for a further evaluation of the Catholic perspectives. This article focuses on the very deontological opinion that human life must be protected from the moment of conception. Also see Levy 41 and Sgreccia "The Catholic Church and the exercise of the medical profession" as published in European Network of Scientific Co-operation on Medicine and Human Rights 59.

[440] "Roman Catholic Views on Research Involving Human Embryonic Stem Cells" as published in Holland *et al* (eds) 113 at 115.

for such research, each dependent on different interpretations of the moral status of the embryo and the aborted foetus.

Firstly, significant numbers of Catholics make the case *against* research on embryos. They hold that human embryos must be protected on a par with human persons, at least to the extent that they ought not to be either created or destroyed merely for research purposes.[441] Moreover, the use of aborted foetuses as a source of stem cells, although not in one sense different from harvesting tissue from any human cadavers, nonetheless should be prohibited as it offers a possible incentive for elective abortion.[442] Part of the case against embryo stem cell research also rests on identifying alternatives, including the use of adult stem cells.[443]

Another viewpoint suggests that a case *for* human embryo stem cell research can be made on the basis of positions developed within the Roman Catholic tradition. Growing numbers of Catholic moral theologians, for example, do not consider the human embryo in its earliest stages[444] to constitute an individualised human entity with the settled inherent potential to become a human being.[445] In this view the moral status of the embryo is therefore not that of a person, and its use for certain kinds of research can be justified. Since it is, however, a form of human life, some respect is due, for example, it should not be bought and sold. Those who make this case prefer to return to

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[441] Also see the article by Mendiola, in which this concept of the embryo as a person and its effect on stem cell research is discussed in more detail. Mendiola "Human Embryonic Stem Cells: Possible Approaches from a Catholic Perspective" as published in Holland *et al* (eds) 119.

[442] If the foetuses in question were spontaneously aborted, however, some opening is allowed for their use in this research.

[443] One can also presume that the case against embryonic stem cell research includes a case against cloning, if and insofar as this research incorporates steps involved in procedures for cloning, such as SCNT.

[444] Before development of the primitive streak 14 days after conception or implantation. See Ryan "Creating embryos for research: On weighing symbolic costs" as published in Lauritzen (ed) 50 at 57.

[445] Much like the proposed judaistic views.

the centuries-old Catholic position that a certain amount of development is necessary in order for a foetus to warrant personal status. From this viewpoint concerns about cloning may be partially addressed by insisting on an absolute barrier between cloning for research and therapeutic purposes on the one hand, and cloning for reproductive purposes on the other.

What is interesting to note is how many of the principles mentioned by the religious viewpoints are already incorporated into current law. For instance, the remark by the Catholic perspective that an embryo should not be bought and sold is representative of the *sui generis* nature of human material with regards to the proprietary rights vesting therein. So too are objections to reproductive cloning clearly addressed in the various documents that define International Law.

In an evaluation of general Protestant considerations on stem cell research, Meilaender[446] states that it always seems like whenever a new type of endeavour is discussed, it appears to lead back to the abortion debate.[447] This always amounts to a conflict between the interests of the mother and those of the foetus. This type of conflict is also evident in the examination of the human embryo and focuses on the honouring of the dignity of even the smallest of human being. Only once the dignity of the embryo is respected as one would respect the dignity of any fully developed human being, can society force itself to look for other possible ways in which to achieve the same goals. These other possibilities may include the deriving of original methods in which umbilical cord stem cells, following live births, can be effectively utilised.[448]

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[446] "Some Protestant Reflections" as published in Holland *et al* (eds) 141 at 142.

[447] See a further discussion on the Protestant viewpoints in Collange "Bioethics and Protestantism" as published in European Network of Scientific Co-operation on Medicine and Human Rights 67.

[448] Stevens "Embryonic stem cell research: Will President Bush's limitation on federal funding put the United States at a disadvantage? A comparison between U.S. and international law" (2003) *Houston Journal of International Law* 623 at 632 aslo makes mention of this emphasis that is sometimes placed on the *alternatives* to the current method of destroying embryos in the derivation of stem cells.

The majority of Protestant writers do not approve the use of embryos, even excess embryos following IVF procedures, and neither aborted foetuses. The focus on respect for the embryo and foetus takes centre stage in the evaluation of any question surrounding its application in research.[449]

Although there are aspects of utilitarianism that feature in some of the religious viewpoints, the primary focus still seems to lean towards a deontological approach to stem cells. This further explains why many religious groups still oppose the termination of pregnancy well after the implementation of the Choice on Termination of Pregnancy Act.[450] In some regards it is an indication of the legal position sometimes being established contrary to what the *boni mores* dictates. It is this difference in moral and legal opinion that legal philosophical writers attempt to address and rectify. In a field that develops as quickly as stem cell research does, is it not necessary for the law to conform to the moral objections that are founded in well established religious opinions in stead of the these moral objections being ignored for the sole purpose of pursuing scientific advancement?

3.5.3.3 Certain legal philosophical observations of the ethical critique to stem cell research

In a discussion of informed consent in the early 1980's, Barber[451] relates the balance between law and morality in a way that is still applicable today:

> "On the whole, the values and laws of a social system have some tendency to be consonant with one another, arising out of common moral roots. This may certainly be so in the long run, though in the short run there may be all sorts of inconsistencies, discrepancies and conflicts. That is inevitable, especially in changing social systems. In situations of change, new values and norms arise in new social situations; and their holders press for their incorporation

[449] Also see Peters "Embryonic Stem Cells and the Theology of Dignity" as published in Holland *et al* (eds) 127, Lebacqz "On the Elusive Nature of Respect" as published in Holland *et al* (eds) 149 and Mazzoni (ed) 36-40 for a discussion on the dignity and respect that have to be granted human genetic materials and how it affects the use thereof in research.

[450] 92 of 1996.

[451] 33.

> into and enforcement by statutory, administrative or judicial law. The law often lags; it contains old principles and rules that no longer have moral support but have not yet been extruded. Sometimes the law is ahead of established values, or at least a minority of the society is successful in making an appeal to some principle of the law for adjudication of a new problem when a majority of the population still has moral objections to seeing it applied."

This bringing together of law and the values that are intrinsic to ~~the~~ society[452] is one of the objectives of legal philosophy. It is a difficult task to harmonise law and medicine because the one is usually a step ahead of the other. Whereas the law often places its focus on the concrete legal principles, medical ethics is much more focussed on the context of a particular case.[453]

Feminist writers assist in reminding other legal scholars of the fact that the role of the woman should not be seen lightly in biomedical applications. It could easily happen that the focus is placed upon the source of stem cells to such an extent that sight is lost of the fact that the cells are to be derived from embryos or foetuses donated by women.[454] In a discussion on feminist and medical ethics, Sherwin[455] focuses on the use of context in ethical discussions. She refers to research that has been conducted in which the different patterns of reasoning between male and female participants in problem solving have been analysed. It showed that in male reasoning the participants pursued universal rules in the search for a fair result (a so-called ethic of justice), whereas the female participants focussed on the actual feelings of those involved (an ethic of care).[456] The difference in reasoning patterns can easily be seen in the current legal system and this could be one

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[452] The *boni mores*.

[453] Compare for instance any book on medical ethics with that of a legal book. The medical ethics often work on a case-by-case basis in explaining how a particular patient was helped whereas legal principles are seldom shaped around each individual case.

[454] Holland "Beyond the Embryo: A Feminist Appraisal of the Embryonic Stem Cell Debate" as published in Holland *et al* (eds) 73 at 73.

[455] "Feminist and Medical Ethics: Two Different Approaches to Contextual Ethics" as published in Shogan (ed) *A Reader in Feminist Ethics* (1992) 39.

[456] Sherwin "Feminist and Medical Ethics: Two Different Approaches to Contextual Ethics" as published in Shogan (ed) 39 at 41.

of the reasons why so many religious and other groups debate the justifiability of certain principles. For example: The implementation of the Choice on Termination of Pregnancy Act[457] followed the affirmation of choice in reproductive health in the Constitution.[458] This was mainly justified on concrete legal principles without truly examining the context specific elements that play a role. Many doctors are still struggling to harmonise their religious beliefs with the burden that is placed before them in terminating a pregnancy.

Other philosophical theories are also focussed on context to a certain degree, for instance the Kantian theory.[459] This theory "demands an interpretation of context in order to determine which maxim applies in a given case. But Kantian theory does assume that the maxims, once identified, will be universal […]."[460] It falls back on the premise that there can be universal boundaries that regulate all behaviour in a just manner. Once these boundaries have been established through the promulgating of legislation or setting of a president in case law, the danger of a modernistic approach to all cases arises. Such a focus on the concrete could lead to an unjustifiable justice being dealt. Legal applications that were deemed to be just twenty years ago would in many cases currently be seen as degrading and out of place.

When the law is examined in this manner it becomes clear that it is necessary to constantly re-evaluate the legal principles pertaining not only to new technologies such as stem cells, but to evaluate the legal system across the board.[461] This re-evaluation and interpretation based on context specific

[457] 92 of 1996.

[458] Sec 12(2)(a) of the Constitution of the Republic of South Africa, Act 108 of 1996

[459] See Jordaan (2002) 119 *The South African Law Journal* 294 at 301 where a quick discussion is made on Kantian theory and its reference to human dignity.

[460] Sherwin "Feminist and Medical Ethics: Two Different Approaches to Contextual Ethics" as published in Shogan (ed) 39 at 43.

[461] There has been mention that any type of re-evaluation of legal principles pertaining to stem cells can only occur through open public debate. Even though the last number of years have created the illusion that there have been public debate on stem cells and that during these debates headway have been made in establishing a form of public collective concerning the ethical considerations in stem cell research, these "public debates" have not

assessments finds prominence in postmodernistic legal writing, and in particular, in the deconstructive school of thought.[462]

In a discussion of postmodernism, Le Roux and Van Marle[463] state that:

> "Ethical postmodernism equally remains committed to law as a normative enterprise, but do so by highlighting the impossibly paradoxical or aporetic nature of justice, the only normative available to law."

The "paradoxical nature of justice" that is referred to above finds application in almost all writings of postmodernism through the use of the concept of the "Other".[464] The Other represents the ultimate justice that law has to strive to obtain. The Other always stands at the opposite side of a door that the law will never be able to go through. This is the aporetic nature thereof, the constant strive towards a true reflection of justice without ever reaching it. The goal of postmodernistic writings is to reinterpret the legal principles so that it becomes the truest reflection of the Other that is possible for that particular time and situation.[465] But one must not forget the fact that it is not only the legal

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provided a true reflection of public opinion. It has simply been discussions amongst the elites of biomedicine claiming that experience in conducting research in other fields of medicine now allocates them a form of legitimacy in relaying ethical interests. This argument have been delved into more comprehensively by Wolpe & McGee "'Expert bioethics' as professional discourse: The case of stem cells" as published in McGee (ed) (2003) *Pragmatic Bioethics (2nd ed)* 181.

[462] Le Roux & Van Marle *Regsfilosofie 311* (2002) 129. See Lenta "Just gaming" The case for postmodernism in South African legal theory" (2001) 17 *South African Journal on Human Rights* 173 for a brief overview, at page 174, of the criticism that post modern writers face, as well as a reply to the criticism within the South African law.

[463] "Postmodernism(s) and the Law" as published in Roederer & Moellendorf *Jurisprudence* (2004) 354 at 373.

[464] Douzinas & Warrington "A Well-Founded Fear of Justice" Law and Ethics in Postmodernity" as published in Leonard (ed) *Legal studies as cultural studies – a reader in (post) modern critical theory* (1995) 197 at 199.

[465] Lyotard *The Postmodern Condition: A Report on Knowledge* (1984) 81 describes the duty of the postmodernist as follows (take notice of the fact that although no reference is made to the Other, the author still deals with concepts that represent a strive towards the unattainable):

frameworks themselves that needs constant re-evaluation. Stem cell research itself has a wide scope that has led to numerous debates on its ethical considerations. For post-modernistic legal scholars to be able to reinterpret the legal position on biomedical advances and to bring it closer to the unattainable "Other", this "Other" needs to obtain a certain level of stability. Philosophical writings, in general, not only redefines the legal principles pertaining to new applications, but it redefines the ethical considerations that they are attempting to include in the legal principles themselves.

This is the beauty of what philosophical writings strive to achieve. In stem cell debates one would benefit to take cognisance of legal philosophical writings, especially feminism and the deconstruction theory within postmodernism, to create a regulative framework[466] that is not only reminiscent of the current *boni mores* thereof, but that is flexible enough to be reinterpreted as technology further develops.

3.5.4. Closing remarks on ethical considerations

Douzinas and Warrington[467] poses the question: "Is the law law because it is just or is the law just because it is the law?" When the focus is placed on the foundations of the current legal principles within Human Rights and the assessments of legal philosophical scholars taken notice of, one reaches the conclusion that the law is the law due to its justness. Stem cell research has healthcare potential unlike any medical technology of its time. Both religious and other scholars recognise this potential. The important fact remains that cognisance must be taken of the warnings posed by all parties; warnings of

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> "A postmodern artist or writer is in the position of a philosopher: the text he writes, the work he produces are not in principle governed by pre-established rules, and they cannot be judged according to a determining judgement, by applying familiar categories to the text or to the work. Those rules and categories are what the work of art itself is looking for. The artist and the writer, then, are working without rules in order to formulate the rules of what will have been done. […] Finally, it must be clear that it is our business not only to supply reality but to invent allusions to the conceivable which cannot be presented."

[466] Even though the creation of a fixed regulative framework to regulate this field seems to be a more modernistic approach to the matter.

[467] "A Well-Founded Fear of Justice, Law and Ethics in Postmodernity" as published in Leonard (ed) 197 at 198.

the instrumentalisation of a human life, of the slippery slope towards reproductive cloning, and the encouragement of abortive practices for the sake of research, to name but a few.

Although contemporary, stem cell technology can be successfully balanced within the legislative framework to give both researchers and opposing parties an equitable share thereof. At present, public policy might dictate a careful approach in which, for example, the use of SCNT is prohibited to create embryos for the derivation of stem cells. It is the task of not only legal philosophical writers, but of all legal and religious scholars to identify the time at which it would be acceptable to take further steps in the development of stem cell technology within South Africa.

3.6 Conclusion – the balancing of interests

Upon taking all of the legal and ethical principles that currently have relevance to stem cell research into consideration, it becomes clear that to establish legitimacy is not a simple task. The concept of legitimacy itself is open to scrutiny as was discussed in the beginning of this chapter and could undoubtedly lead to a number of philosophical debates.

What is of importance is the fact that the Human Tissue Act[468] is currently sufficient in the regulation of the first era of stem cell research. Certain factors, however, need to be re-examined, for instance, the use of umbilical cord blood in the derivation of stem cells as well as the exact scope of the ban on “genetic manipulation.”[469] Consent is of primary importance, but if a thorough informed consent process can be established it ought not to provide too many obstacles. Of course aspects such as financial incentives in the obtainment of stem cells would have to be clearly stipulated, but the current system is more than capable of ensuring an open and thorough process that still protects the privacy of the genetic information of each individual donor.

[468] 65 of 1983.

[469] Sec 39A

The current legislative framework, including the Constitution,[470] is reasonably representative of global developments in the field of genetics. Furthermore, legal philosophical scholars seem to be directing the focus of research on human subjects in the right direction. Although many religious and other groups oppose the derivation of stem cells from practices that are deemed to be immoral,[471] there still appears to be enough room for the research to begin to find applications through the use of embryos left over after IVF therapy has been completed, as well as through the use of umbilical cord blood following a successful birth. The resultant effect is that, although partially qualified, there does not seem to be anything wrong with the legitimacy of stem cell research in South Africa at present.

The question that arises, however, is whether the National Health Act,[472] once completely in force, would be able not only to re-establish this legitimate stance, but to also strengthen it. Since a large number of the intricate areas of stem cell research will only be dictated through regulation, it becomes essential that the regulations, once promulgated, keeps the South African position alive within the international community. Legitimate and comprehensive practices for obtaining consent, protecting privacy, storing, and the availability of cells need to be established, and in order to do so it may be necessary to follow the lead of countries such as the United States of America and the United Kingdom in which the debate has been fought for ages.

Not only can incomplete regulations cause damage to the concept of legitimacy, but so too can the South African public and private sectors if a balance is not struck between them. One of the key elements that needs to be considered is whether it is even possible for the public sector (the state) to attempt pursuing such an expensive field whilst basic areas of healthcare are already being neglected. This further raises questions about the constitutionality of any prohibitions for conducting research that might be

[470] Constitution of the Republic of South Africa, Act 108 of 1996.

[471] For instance the use of aborted foetuses as well as the creation of embryos for the sole purpose of it being used in research.

[472] 61 of 2003.

placed on individual researchers by the public sector. If only private researchers can afford to pursue this field, would the state be allowed to prevent a researcher that presents a comprehensive and legitimate proposal for conducting research from doing exactly so? These are amongst some of the many concerns that need to be addressed before a comprehensive stem cell research base can be established in South Africa.

As will be seen in the next chapter, the ineffective application of stem cell research in practice, no matter how solid the legislative and ethically justified foundation thereof, can cause damage to the legitimacy of an otherwise legitimate practice.

Chapter 4

The impact of the National Health Act

4.1 Introduction

In the previous chapter it has been established that stem cell research, although qualified to a certain extent due to ongoing debates surrounding reproductive and therapeutic cloning practices, is legitimate. There are, however, certain factors that can affect the legitimacy thereof without having formed part of the foundational assessment that was made of this field of biomedicine in the previous chapter.[473] These factors include ineffectiveness, the lack of resources to pursue stem cell related objectives, and the veto of private researchers by the public sector through not granting licences and permits thereto.

Although the Human Tissue Act[474] is capable of regulating basic stem cell related endeavours, it becomes evident that the new legislation, the National Health Act,[475] will have to accommodate the best possible methods in which to apply stem cell research in South Africa. As the research develops further, the use of SCNT to create embryos that match the genetic profile of the donor thereof might not only become important, but ethically incumbent. If healthcare technology that is capable of healing a person, who would otherwise be doomed to a sickly demise, is refused simply because of a ban on "genetic manipulation,"[476] the refusal could be seen to be contrary to basic humanitarianism.

A further possible situation reveals itself: a patient has some or other disorder that can only be cured through the use of stem cell technology. The procedure costs vast amounts of money, but the patient is willing to fund it. If no government hospital is able to effectively conduct the procedure, can the

[473] See chapter 3 for a complete discussion of the legitimacy of stem cell research.

[474] 65 of 1983.

[475] 61 of 2003.

[476] Sec 39A of the Human Tissue Act 65 of 1983.

public sector still refuse a private practitioner the licence and approval to go ahead with the procedure? Would a patient's constitutional right to access to healthcare services[477] include stem cell research, if that were the only healthcare procedure that can save the patient? Can a patient who is willing to undergo treatment be refused that treatment based on policy considerations because the public sector wants to prevent the financial gain thereof from going to the private sector?

These are just some of the questions that need to be answered before stem cell research and its healthcare applications can be fully incorporated into the South African legal system. There are a number of benefits and disadvantages, depending on whether stem cell research falls more into the public or private sector. While the public sector provides for more oversight mechanisms, the private sector is willing to invest large sums of money in this research. Some guidance in finding the correct balance between the public and private sectors can be taken from the legislative frameworks of other countries such as the United States of America and the United Kingdom.

Before one can fully evaluate the application of stem cells on a national level, it is necessary to discuss the proposed legislative framework, namely the National Health Act, intended to regulate this research and its healthcare applications.[478]

4.2 The National Health Act – Regulation or limitation?

Before an assessment of the legislative provisions pertaining specifically to umbilical cord stem cells, foetal tissue germ cells and embryonic stem cells can be made, it is necessary to evaluate some of the provisions that are applicable to stem cells in general. Upon first glance it becomes evident that the National Health Act[479] is much more in tune with the advances that have been made in healthcare over the last number of years. On the other hand, a

[477] Sec 27(1)(a) of the Constitution of the Republic of South Africa, Act 108 of 1996.

[478] 61 of 2003.

[479] *Ibid*.

large part of the Act still needs to be refined through regulations. There are numerous references to whichever medical interventions are under discussion as having to be "in accordance with prescribed conditions."[480] Without the regulations being promulgated, it becomes a difficult task for legal scholars to provide accurate explanations about new judicial requirements to prospective stem cell researchers.

4.2.1 Provisions pertaining to stem cells in general

Whereas the Human Tissue Act[481] does not provide definitions for either embryos nor zygotes, the National Health Act[482] does so; a zygote being the product of the union of a male and female gamete and an embryo being a zygote within the first eight weeks from conception.[483] Furthermore, the definitions of an organ as well as tissue[484] do not include stem cells and blood or blood products from which such cells can be derived. Although the definition of tissue does refer to body fluid, it is submitted that this does not include stem cells derived from any type of bodily fluid.

The National Health Act[485] makes provision for informed consent[486] and the confidentiality[487] of patient information. These requirements have already

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[480] See for example sec 55.

[481] 65 of 1983.

[482] 61 of 2003.

[483] Sec 1.

[484] The definition of tissue reads as follows: "'tissue' means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete."

[485] 61 of 2003.

[486] In sec 6-8, which reads as follows:

> "6 User to have full knowledge
> (1) Every health care provider must inform a user of-
> *(a)* the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
> *(b)* the range of diagnostic procedures and treatment options generally available to the user;
> *(c)* the benefits, risks, costs and consequences generally associated with each option; and
> *(d)* the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

been discussed in chapter 3 and will only be touched on lightly in the following pages. Chapter 8[488] of the National Health Act[489] is the cornerstone in the

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(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

7 Consent of user

(1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless-

(a) the user is unable to give informed consent and such consent is given by a person-

(i) mandated by the user in writing to grant consent on his or her behalf; or

(ii) authorised to give such consent in terms of any law or court order;

(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;

(c) the provision of a health service without informed consent is authorised in terms of any law or a court order;

(d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or

(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) For the purposes of this section 'informed consent' means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

8 Participation in decisions

(1) A user has the right to participate in any decision affecting his or her personal health and treatment.

(2) *(a)* If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.

(b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.

(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest."

[487] In sec 14, which reads:

"14 Confidentiality

(1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

(2) Subject to section 15, no person may disclose any information contemplated in subsection (1) unless-

(a) the user consents to that disclosure in writing;

(b) a court order or any law requires that disclosure; or

(c) non-disclosure of the information represents a serious threat to public health."

[488] Sec 53-68.

[489] 61 of 2003.

stem cell debate, providing the bulk of the provisions needed to facilitate its implementation into the South African legal system.

Section 55 of the Act states that no tissue, blood, blood product or gametes may be removed from the body of another living person without having obtained the written consent thereto from that person. This consent is to be given "in accordance with the prescribed conditions," with the result that further ministerial regulation thereof may very well occur in the future. The removal consented to in section 55 refers only to purposes that are envisaged in section 56. These two sections are very similar to sections 18 and 19 of the Human Tissue Act.[490] Section 56(2)(a)(I-iii) deals with the removal of tissue, blood, blood products and gametes from mentally ill persons and minors. It prescribes similar conditions as are found in the Human Tissue Act[491] and will not be discussed again. What is very important, however, is section 56(2)(a)(iv) and 56(2)(b). It reads as follows:

> "(2) *(a)* Subject to paragraph *(b)*, the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):
>
> (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.
>
> *(b)* The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph *(a)* and may impose any condition which may be necessary in respect of such removal or withdrawal."

Section 56(2)(a)(iv) of the National Health Act[492] places a prohibition on the removal of stem cells and the tissue from which stem cells can be derived. The only method in which to proceed with such research would be to obtain ministerial authorisation thereto in terms of section 56(2)(b) of the Act.[493] Questions surrounding appeal processes and the enforceability of arbitrary ministerial decision-making come into play. For instance, what can a

[490] 65 of 1983.

[491] *Ibid*.

[492] 61 of 2003.

[493] For a further discussion of these two sections, see paragraph 4.2.1 hereunder.

researcher do in a case where his application to conduct stem cell research is simply rejected without reason? The answer thereto forms part of the Administrative Law and unfortunately does not fall within the scope of this dissertation. It is, however, already worthy of mention that the scope of the ministerial power granted in terms of the National Health Act[494] may very well become subject to Constitutional scrutiny. The decision-making powers vesting in the Minister in terms of the National Health Act[495] are unnervingly legislative in nature.

Section 60 has similar conditions as can be found in section 28 of the Human Tissue Act,[496] namely that only an authorised institution may receive remuneration for the import- or exportation of blood or blood products. Section 60(4), however, adds the following:

> (4) It is an offence for a person-
> *(a)* who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and
> *(b)* to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.

This effectively takes away the future likelihood of possible financial incentives given in the obtainment of human materials for stem cell purposes. As has been discussed in the previous chapter, such a prohibition has both positive and negative qualities. Although it would ensure the survival of the altruistic donor market, it also creates an opportunity for black market trading in which any amount offered would be an incentive for donors to sell their materials. This limitation on financial rewards given to donors has to be distinguished from section 68(2) in which the minister may make regulations relating to the payment of persons and institutions who obtain, import, export and store human materials.

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[494] 61 of 2003.

[495] *Ibid*.

[496] 65 of 1983.

It is noteworthy to mention the fact that if an institution was given licences and permits to continue with stem cell research in terms of the Human Tissue Act,[497] those provisions would still be enforceable in terms of the National Health Act.[498] There are furthermore research oversight committees in place. Each institution that proposes to conduct research (including stem cell research) has to have a health research ethics committee,[499] which is registered with the National Health Research Ethics Council.[500] This will hopefully provide a certain measure of oversight when dealing with such contemporary issues such as reproductive cloning.

The application of the National Health Act with regard to umbilical cord stem cells, foetal tissue germ cells and embryonic stem cells is discussed hereunder.

4.2.2 The application of the National Health Act to umbilical cord stem cells

Umbilical cord stem cells are some of the least ethically problematic cells to obtain. The reason for this is the fact that it is derived from umbilical cord blood following the successful birth of a child. This blood would have been discarded in general medical practice in any case, with the result that any further benefit that can be gained through its use leaves little to object to.

Under certain circumstances an institution that deals with human material has to be designated as an "authorised institution" in terms of section 54 of the National Health Act.[501] Although the section mainly deals with the use of tissue obtained from living or deceased persons, subsection (2)(d) specifically refers to blood products as being one of the substances that an authorised institution may deal with. It becomes necessary to establish whether umbilical cord stem cells would fall under this definition of blood products. The definition

[497] *Ibid*.

[498] 61 of 2003, sec 93(2).

[499] Sec 73.

[500] As established through sec 72 of the National Health Act 61 of 2003.

[501] 61 of 2003.

of a blood product in section 1 includes umbilical cord progenitor cells. At first glance this could be interpreted as to include umbilical cord stem cells or cord blood in general. However, further on in the Act[502] specific reference is made to umbilical cord stem cells, which leads to the conclusion that umbilical cord progenitor cells cannot be interpreted widely as to include umbilical cord stem cells. The definition of a blood product, however, remains wide enough to include these stem cells,[503] with the effect being that any institution dealing with umbilical cord stem cells has to be designated as an authorised institution in terms of section 54 of the National Health Act.[504]

Even though, when examining the abovementioned definition of blood products in section 1 and the reference made thereto in section 54, one can gather that umbilical cord stem cells derived from umbilical cord blood would amount to a blood product. There is one other aspect that could seriously affect the application of the National Health Act,[505] namely the reference that is made to both blood products and stem cells in section 68. The relevant subsections of section 68 read as follows:

> "(1) The Minister may make regulations regarding-
>
> *(c)* the removal of donated tissue or cells from persons, tissue or cells obtained from post mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons;
>
> *(f)* the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
>
> *(g)* the importation and exportation of tissue, human cells, blood, blood products or gametes;
>
> *(k)* the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;

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[502] Sec 57(2).

[503] The use of the word "any" in the definition leads to the conclusion that the definition of blood products can be interpreted as to include umbilical cord stem cells. The definition reads as follows: "'blood product' means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells."

[504] 61 of 2003.

[505] *Ibid*.

> *(p)* the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose;
> *(r)* any other matter relating to regulating the control and the use of human bodies, tissue, organs, gametes, blood and blood products in humans."

If, during the entire National Health Act,[506] no reference is made to stem cells as a separate human material except in cases that specifically deal with its use in reproductive and therapeutic cloning,[507] why would the legislator suddenly refer to it as well as blood products in section 68? If the objective was to exclude stem cells from the definition of blood products, it would also have a dire effect on the working of section 56. Section 56(2)(a)(iv) places a ban on the removal of placenta, embryonic or foetal tissue, stem cells and umbilical cord from a living person. On the other hand, section 56(2)(b) allows the Minister to:

> "authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph *(a)* and may impose any condition which may be necessary in respect of such removal or withdrawal."

If the interpretation of section 68 leads to the conclusion that stem cells do not fall within the definition of blood products, then the minister does not have the authority to allow the removal of stem cells from a living person in terms of section 56(2)(b) either. Why the legislator felt it necessary to distinguish between stem cells and blood products is a question that can only be speculated about at present. For the purposes of this dissertation it is assumed that even though a distinction is made between stem cells and blood products in section 68 of the National Health Act,[508] it does not affect the fact that (at least umbilical cord) stem cells also fall within the ambit of blood products.

The section that is of particular importance to stem cells is section 57. Although much still has to be addressed through regulation, this section

[506] 61 of 2003.

[507] Sec 57.

[508] 61 of 2003.

provides for the requirements that have to be met in order for a person to conduct research on stem cells. Subsection (6) distinguishes between therapeutic and reproductive cloning:

> "(6) For the purpose of this section-
> *(a)* 'reproductive cloning of a human being' means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose; and
> *(b)* 'therapeutic cloning' means the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues."

The section amounts to little more than a focus on the purpose for which research is conducted. Despite all the criticism to the use of the words "genetic manipulation" in section 39A of the Human Tissue Act,[509] it would seem that the legislators decided not to disengage from the use thereof in the National Health Act.[510] In this case the legislator provides an example of what is included under the scope of genetic manipulation, namely nuclear transfer.[511] The result is that if a researcher decides to clone human embryos with the purpose of implanting such an embryo into a woman's womb, it would fall under the definition of section 57(6)(a), and if the researcher merely clones the embryo in order to use it in further research it falls under the ambit of section 57(6)(b).

Section 57(1) prohibits reproductive cloning, whilst section 57(2) allows for therapeutic cloning using umbilical cord stem cells. This permission to proceed with therapeutic cloning has to be done with ministerial consent, and under such conditions as the minister may deem fit. One would hope that the conditions posed by the minister would ensure for thorough oversight mechanisms, seeing as the jump between therapeutic and reproductive cloning is separated only by the aim of implanting a cloned embryo. There is a fine and/or imprisonment not exceeding five years that could befall persons

[509] 65 of 1983.

[510] 61 of 2003.

[511] For a discussion of nuclear transfer (SCNT) see chapter 2.

who contravenes section 57.[512] Although its not a huge penalty if compared to the global impact that reproductive cloning would have, at least it is slightly more than the previous penalties in terms of the Human Tissue Act.[513] The fact that each institution that proposes to conduct research has to have a health research ethics committee[514] that is registered with the National Health Research Ethics Council[515] provides for a measure of security in allowing researchers to continue with such precarious handiwork. Part of the council's work entails the setting of norms and standards for conducting research on humans,[516] as well as advising the national and provincial health departments on ethical issues surrounding research.[517] There is a large responsibility resting on the shoulders of the council and the committees in order to ensure that no fallouts with Human Rights groups that could hamper the research occur, especially in light of the fact that according to the legislation the only difference between reproductive and therapeutic cloning being the purpose for which the genetic material under hand is manipulated.

One of the interesting aspects of the National Health Act[518] is the fact that the Act mostly only addresses cases in which stem cells are collected for the purpose of being used in research. It neglects to mention the storage of stem cells by private companies that only derive it from umbilical cord blood without conducting further research thereon. The only reference thereto is section 68 in which the Minister can make further regulations pertaining to stem cells. One would assume that, once in place, the regulations that are yet to be promulgated would establish a proper system of licence acquisition and oversight mechanisms.

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[512] Sec 57(5).

[513] 65 of 1983.

[514] Sec 73.

[515] As established through sec 72 of the National Health Act 61 of 2003.

[516] Sec 72(6)(c).

[517] Sec 72(6)(g).

[518] 61 of 2003.

4.2.3 The application of the National Health Act to embryonic stem cells

The majority of the legislative provisions pertaining to stem cells have already been discussed in the paragraphs above. There are, however, certain principles in the National Health Act[519] that are only applicable to embryonic stem cells.

Section 57(4) allows for the Minister of Health to approve research on stem cells and on zygotes[520] that are not more than fourteen days old.[521] This is subject to the researcher documenting his research for record purposes as well as the obtainment of consent from the donor of the stem cells or zygotes. The reason for the fourteen days cut-off point during which to conduct research is because of the fact that this is the time at which the primitive streak appears on the embryo. It is at this critical time period that many humanitarian groups argue that the embryo starts to warrant protection. The fact that the researcher only has to document his research appears not to affect the allocation of any intellectual property rights that may be gained through the research. What is important, however, is the fact that there appears to be no ban on using zygotes that are created only for research purposes. As long as the researcher has ministerial and donor consent, it does not matter whether the source of the stem cells are left over embryos following IVF procedures or embryos created only for research purposes.

This can provide for difficulty once the National Health Act[522] comes into force. Since a large number of religious groups and even certain international documents support a prohibition on the use of embryos created solely for research purposes due to reasons of the instrumentalisation of human life, a public outcry against stem cell research in general cannot be negated. If the

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[519] *Ibid*.

[520] See the definition of a zygote in sec 1 of the National Health Act 61 of 2003.

[521] Section 57(4) reads as follows:

> "(4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if-
> *(a)* the applicant undertakes to document the research for record purposes; and
> *(b)* prior consent is obtained from the donor of such stem cells or zygotes."

[522] 61 of 2003.

public only place their focus on this method of stem cell derivation, it could hamper progress in all areas of stem cell advancement.

One assumes that the proposed regulations will address the concerns surrounding the use of embryos created only for research purposes by either placing a moratorium thereon for a fixed time, or providing the research ethics committees that have to oversee the research with more comprehensive guidelines in their assessment of the stem cell field in general.

4.2.4 The application of the National Health Act to foetal tissue germ cells

The final aspect of stem cell regulation in terms of the National Health Act[523] is the possible use of foetal material in the derivation of germ cells. Because the Choice on Termination of Pregnancy Act[524] has been implemented, this area could prove to hold the key to gaining access to an unlimited source of stem cells.

There appears to be no further provisions in the National Health Act[525] with regard to foetal tissue and its use in the derivation of stem cells except insofar as that ministerial authorisation is required to remove it from a living person in terms of section 56(2). Had the foetal tissue been removed through the normal termination of pregnancy procedures[526] without the primary goal thereof being the utilisation of the foetal tissue in the derivation of stem cells, it would appear as if no ministerial consent is necessary in terms of section 56(2).

Furthermore, section 57(4) only start to apply once the stem cells (germ cells) have been derived from the foetus and are to be used in research, resulting in a situation in which a researcher can obtain and derive as many stem cells as he wants from foetuses remaining after terminations of pregnancy without

[523] *Ibid*.

[524] 92 of 1996.

[525] 61 of 2003.

[526] In other words, in terms of the Choice on Termination of Pregnancy Act 92 of 1996.

having to obtain further ministerial consent thereto, as long as he doesn't commence research thereon.[527] The courts will most likely interpret section 56(2) differently, namely to have the requirement for ministerial consent apply from the moment which a researcher attempts to obtain the aborted foetuses for purposes of the derivation of stem cells, no matter what the original reason for the termination of pregnancy had been.

Throughout the explanation of the application of the National Health Act[528] to stem cell research it has been clear that there is much work to be done by the proposed regulations. For now it is sufficient to remark that some form of framework has been established through the Act, but without sufficient support from the regulations it will not withstand judicial scrutiny.

Although the National Health Act[529] provides for the legislative procedures that have to be followed, it does not present an accurate reflection of the different interests that have to be addressed in practice. The primary interests that are weighed up against each other are those of the private and public sector. A question that arises is whether the public sector is even able to propose the pursuit of stem cell related goals when all the financial considerations are regarded?

4.3 Financing the future – Public pursuits of private interests

4.3.1 Introductory remarks

Money is a universal incentive. Without investing financially in a field it is virtually impossible to reap the rewards there from. In a country such as South Africa millions of rands cannot simply be provided by the public sector to facilitate new areas of research, since the unfortunate reality is that an immense burden is resting on the shoulders of the healthcare system. This burden focuses the attention of most of the resources towards the provision of

[527] The exact scope of "research" for purposes of this section is unclear as well, since no definition thereto has been provided in the act.

[528] 61 of 2003.

[529] *Ibid*.

primary healthcare services[530] such as emergency medical treatment and the fight against HIV/AIDS.

It becomes necessary to establish the extent to which new technology such as stem cell research can expect to be supported through public funding. This again, has to be placed in perspective with the balance between public and private sources of research facilitation. Questions surrounding the impact of a privatised stem cell research sector, its implications on effective oversight mechanisms and the effect this would have on the ordinary man in the street are also identified and addressed below. But it is first necessary to establish what the scope of the available healthcare resources in South Africa is.

There are a number of constitutionally[531] protected socio-economic rights that can assist the assessment of the scope of healthcare resources.

4.3.2 Socio-economic constitutional principles

Section 27 of the Constitution[532] provides for the socio-economic rights that pertain to healthcare.[533] The section reads as follows:

> "(1) Everyone has the right to have access to-
> *(a)* health care services, including reproductive health care;
> *(b)* sufficient food and water; and
> *(c)* social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
> (3) No one may be refused emergency medical treatment."

[530] The definition of "primary health care services" is open to debate as well, but for purposes of this dissertation it can simply be interpreted as to mean health care aimed at addressing ailments that affect such a substantial amount of citizens that it cannot be ignored by the Department of Health.

[531] Constitution of the Republic of South Africa, Act 108 of 1996.

[532] *Ibid*.

[533] See a discussion hereof in Davis, Cheadle & Haysom *Fundamental rights in the Constitution – commentary and cases* (1997) 354-359.

The preamble to the National Health Act[534] also makes reference to section 27 of the Constitution.[535] Without having to refer to section 36, the limitation clause, it becomes evident that the access to healthcare services is subject to the resources available.[536] On the other hand, emergency medical treatment may not be refused a person.[537] The distinction between normal healthcare services as proposed by section 27(1)(a) and emergency medical treatment as envisaged by section 27(3) of the Constitution has been the subject of much debate. Whilst some authors believe that an emergency situation does not necessarily have to coincide with an element of unexpectedness and urgency, others feel that emergency situations only stretch up until a patient has been stabilised. This distinction is of primary importance to all areas of healthcare, for example: If a person is involved in a motor vehicle accident and suffers major trauma to his spine which paralysis him from the neck down, the general consensus would be that the stabilising of that patient in order to save his life would amount to emergency medical treatment, and is Constitutionally guaranteed.[538] If, however, that same patient start to lose organ function due to the paralysis and would inevitably die because of it, is given the chance of recovery through an expensive procedure in which stem cells are implanted into his spine, would this situation not also amount to an emergency in the eyes of the patient? Surely the reality of death is just as present to a patient who is paralysed compared to the one being rushed to the emergency room? It is at this point that the distinction becomes important. If the concept of emergency is measured according to the patient's perception, almost any

[534] 61 of 2003.

[535] Constitution of the Republic of South Africa, Act 108 of 1996.

[536] For a complete discussion of the influence of financial resources on constitutionally protected rights, see Van Oosten "Financial resources and the patient's right to health care: Myth and reality" (1999) 32 *De Jure* 1.

[537] Take note of the fact that simply because a person cannot be refused emergency medical treatment because of lack of funds, this does not entitle that person to free medical treatment. The cost of the emergency medical treatment can be recovered later. See Davis, Cheadle & Haysom 358.

[538] Although Constitutionally guaranteed, whether this right finds effective application in practice is another matter. See Bilchitz "Giving socio-economic rights teeth: The minimum core and its importance" (2002) 119 *The South African Law Journal* 484.

medical procedure will potentially amount to an emergency medical procedure that warrants Constitutional protection, no matter what the patient's financial position proves to be. If the stem cell implantation into the patient's spine is deemed to be a normal healthcare service, despite the inevitability of death without it, the public sector can refuse the treatment based on financial considerations.

This situation found application in the South African case of *Soobramoney v Minister of Health, Kwazulu-Natal.*[539] The facts of the case are set out quite well by Chaskalson P in the beginning of the case[540], a summarised version thereof being the following: The appellant was 41 years old and a diabetic suffering from ischaemic heart disease, cerebro-vascular disease and irreversible chronic renal failure. His life could be prolonged by means of regular renal dialysis, which was treatment he sought from the Addington State Hospital in Durban. He was not admitted to the dialysis programme of the hospital due to the hospitals policy to automatically admit to the renal dialysis programme those patients who have a possibility of being treated and remedied through dialysis. This policy was adopted due to insufficient resources to provide dialysis treatment to all patients suffering from chronic renal failure.

Patients suffering from *irreversible* chronic renal failure (as was the case with the appellant) were not admitted automatically to the dialysis programme but according to a set of guidelines, which made the primary requirement for admission a patient's eligibility for a kidney transplant. A patient who was eligible for a transplant would be provided with dialysis treatment until an organ donor was found and a kidney transplant had been completed. The guidelines further stipulated that patients were not eligible for kidney transplants unless they were free of significant vascular or cardiac disease.

[539] 1998 (1) SA 765 (CC). Also see the discussion of socio-economic rights and the method in which it were applied to the case in Scott & Alston "Adjudicating constitutional priorities in a transnational context: A comment on *Soobramoney's* legacy and *Grootboom's* promise" (2000) 16 *South African Journal on Human Rights* 206.

[540] *Soobramoney v Minister of Health, Kwazulu-Natal* 1998 (1) SA 765 (CC) 770-771.

Because the appellant suffered from ischaemic heart disease and cerebro-vascular disease, he was not eligible for a kidney transplant and was unable to receive dialysis for reasons of not being on a kidney transplant waiting list. In July 1997 the appellant, relying on sections 27(3)[541] and 11[542] of the Constitution,[543] made an urgent application to a Local Division of the High Court for an order directing the Addington Hospital to provide him with ongoing dialysis treatment and interdicting the respondent from refusing him admission to the renal unit of the hospital. The application was dismissed and the appellant appealed to the Constitutional Court.

The Appellant passed away shortly after the decision by the Constitutional Court. The decision focused strongly on the definition of emergency medical treatment and came to the conclusion that the situation had not been deemed to be an emergency for purposes of section 27(3).[544] The Court stated that the facts under discussion had not been a sudden or unexpected event that required immediate attention, but rather an ongoing state of affairs.[545] Although the Court had taken notice of the fact that such a situation may be perceived as an emergency by the patient, the final decision did not take cognisance of these contextual circumstances. Upon reading the decision, with all due respect, one gets the feeling that the Court had already "made up its mind" about there not being sufficient funds to treat these patients and were looking for a way in which to define emergency medical treatment so that it conforms to the health budget of South Africa.[546]

This decision also has dire implications to the stem cell related example posted above. The implantation of stem cells into a person's spine could cost hundreds of thousands of rands. This would not fall under emergency medical

[541] No-one may be refused emergency medical treatment.

[542] Everyone has a right to life.

[543] Act 108 of 1996.

[544] Of the Constitution of the Republic of South Africa, Act 108 of 1996.

[545] *Soobramoney v Minister of Health, Kwazulu-Natal* 1998 (1) SA 765 (CC) 774.

[546] Also see a critical analysis of this case in Van Oosten "Financial resources and the patient's right to health care: Myth and reality" (1999) 32 *De Jure* 1 at 11-17.

treatment with the result that even though a patient cannot be prevented from having the procedure done physically through not granting him access to a healthcare facility, that patient would have to pay for it out of their own pocket.

Although an unfortunate fact for many healthcare users, the decision in *Soobramoney v Minister of Health, Kwazulu-Natal*[547] conforms with the reality of public healthcare being stretched to its limits. In the end it amounts to a calculation of the maximum amount of patients that can be helped on a minimum amount of money.[548] There is one aspect of the case that is alarming however, namely that the Constitutional Court stated:[549]

> "The provincial administration which is responsible for health services in KwaZulu-Natal has to make decisions about the funding that should be made available for health care and how such funds should be spent. These choices involve difficult decisions to be taken at the political level in fixing the health budget, and at the functional level in deciding upon the priorities to be met. *A court will be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.*" [Own emphasis]

Is it not part of the court's duty in assessing these matters to critically examine the methods in which public funds are utilised?[550] There is no higher mechanism of oversight available than the court and it should not hesitate to step in when serious cases of mismanagement of funds occur.[551] This had been the case in *Minister of Health and Others v Treatment Action Campaign*

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[547] 1998 (1) SA 765 (CC).

[548] For a further discussion of the decisions that have to be made regarding financial burdens and medical interventions, see Mason & McCall-Smith *Law and Medical Ethics (5th ed)* (1999) 301.

[549] On page 776 of the judgement.

[550] See Langa "The vision of the Constitution" (2003) 120 *The South African Law Journal* 670 at 672 in which the role of the judiciary is explained.

[551] This does not suddenly mean that the court should simply take on the role of legislator and executive arms of government as well, but the court should take the lead in addressing cases where the Constitutionally guaranteed rights are not met. See Van Oosten (1999) 32 *De Jure* 1 at 17 as well as Newman "Institutional monitoring of social and economic rights: A South African case study and a new research agenda" (2003) 19 *South African Journal on Human Rights* 189 at 204.

and Others (No 2).[552] In this case the court had stated clearly that it had the competence to order the state to change their healthcare policies in circumstances where the state had not lived up to its Constitutional obligations.[553] In this case the state had only supplied Nevirapine, a drug that can help prevent the transmission of HIV/AIDS between mother and child, to certain clinics. The court had found that in not supplying the drugs to more clinics, the state had not adequately complied with the provisions of section 27 of the Constitution[554] and ordered it to change its policies as to conform to the Constitutional standards.[555]

These cases of medical treatment provide a view into the financial burdens that are placed upon the public purse. It indicates a situation in which the health budget can ill afford the financial strain that high profile stem cell research would place upon it.[556] On the other hand, such research could lead to highly lucrative intellectual property rights being granted on the cell lines that are derived. The public sector would have this possibility in mind when the research takes off. It invariably comes down to a weighing up of interests: The

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[552] 2002 (5) SA 721 (CC).

[553] In a similar case – *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC) - on the application of socio-economic rights principles, this time with regard to adequate housing, it is reiterated that the only way in which these rights can result in real improvement in the quality of life of the poor is if they precipitate concrete changes in the current social policies. See Liebenberg "The right to social assistance: The implications of *Grootboom* for policy reform in South Africa" (2001) 17 *South African Journal on Human Rights* 232 at 233 as well as Bilchitz (2002) 119 *The South African Law Journal* 484 and Scott & Alston (2000) 16 *South African Journal on Human Rights* 206.

[554] Constitution of the Republic of South Africa, Act 108 of 1996.

[555] See Bollyky "R if C > P + B: A paradigm for judicial remedies of socio-economic rights violations" (2002) 18 *South African Journal on Human Rights* 161 for a full discussion of the application of socio-economic rights principles by the Constitutional Court as well as Bilchitz "Towards a reasonable approach to the minimum core: Laying the foundations for future socio-economic rights jurisprudence" (2003) 19 *South African Journal on Human Rights* 1.

[556] See Morrow & Bryant "Measuring and valuing human life: cost-effectiveness, equity and other ethics-based issues" as published in Bankowski & Bryant (eds) *Poverty, vulnerability, and the value of human life – A global agenda for bioethics* (1994) in which examples are given of the methods in which health care allocations are calculated.

interests of a health budget that is thinly stretched, with the potential profits and other benefits to be made thereof if the budget is stretched even thinner, as well as a balancing of interests between the private and public sector in trying to secure the maximum amount of benefits that the research has to offer.[557] The potential influence that both of these sectors have on each other are discussed below.

4.3.3 Public and private equilibrium

Financial considerations plays a vital role in the assessment of whether stem cell related advances will be able to find application in private and public institutions. It has been seen above that the definition of an emergency for purposes of section 27(3) of the Constitution[558] have, to a certain extent, also been moulded around the availability of funds. In a country with a markedly higher health budged compared to the number of citizens, the definition would have most likely been sculpted as to include a larger array of medical interventions.[559]

The question being faced now is whether this definition of emergency medical treatment automatically becomes wider once the financial considerations are

[557] Certain propositions for finding a working agreement between private and public researchers includes the establishment of a national stem cell donor bank which allows for individuals to donate adult stem cells, umbilical cord stem cells and placental stem cells to a reserve that is similar to the American national bone marrow registry. Such a stem cell bank could potentially benefit private- and publicly funded researchers and provide for effective oversight over stem cell research in general. For a further discussion hereof, see Miller "Promoting life? Embryonic stem cell research legislation" (2003) *Catholic University Law Review* 437 at 477-478. A similar national stem cell bank has been proposed in the United Kingdom as well, and a national stem cell bank advisory committee have been established to research the feasibility thereof. See Monachello "The cloning for biomedical research debate: do the promises of medical advances outweigh the ethical concerns?" (2003) *Tulsa Journal of Comparative and International Law* 591 at 610.

[558] Constitution of the Republic of South Africa, Act 108 of 1996.

[559] See Chirwa "The right to health in International Law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine" (2003) 19 *South African Journal on Human Rights* 541 for a discussion on the minimum core that socio-economic rights applications have to meet in term of international law.

removed? If, for example, a patient arrives at the door of a private institution stating that he has some or other life threatening disease that can only be cured through the use of highly expensive stem cell related applications, can that patient still be refused that treatment? At a private institution it might well be the case based on the fact that the doctor still has a relative margin of freedom in accepting a mandate from a patient. However, if this same patient is to arrive at a public hospital demanding to be helped, and stating that he'd finance the procedure out of his own pocket, the situation becomes more complicated.

Even if such a procedure does not fall within the ambit of an emergency, section 27(1)(a) of the Constitution[560] becomes applicable. This section states that everyone has the right to have access to healthcare services, including reproductive healthcare. This right to access to healthcare services is qualified in section 27(2) through the availability of state resources.[561] If a patient arrives at a public health facility proclaiming that he will fund any costs relating to a stem cell related procedure, the facility might be forced to provide the patient with the necessary medical assistance. On the other hand, section 27(2) does not state explicitly that the available resources have to be financial in nature. A public health facility could well be warranted in refusing to provide such a patient with medical assistance based on the fact that it lacks the human resources to partake in such endeavours. The result being that a patient who is willing to pay for a stem cell based procedure could face a situation in which nobody is willing, or able to help him.

If, however, a private practitioner decides to assist the patient in a stem cell related procedure, one of the key aspects becomes whether that practitioner can be refused by the Minister to do so in terms of the National Health Act.[562] The scope of regulatory authority invested in the Minister of Health in terms of section 68 of the abovementioned Act includes the authority to make

[560] Constitution of the Republic of South Africa, Act 108 of 1996.

[561] Also see Newman (2003) 19 *South African Journal on Human Rights* 189 for a discussion on the methods in which socio-economic rights applications are being monitored in practice.

[562] 61 of 2003.

regulations pertaining to the "the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose."[563] This means that the Minister has the authority to dictate the extent to which, and the identity of practitioners who may, engage in stem cell related applications. This regulatory authority vesting in the Minister stands in stark contrast with the right to access to healthcare services,[564] with the definition of healthcare services surely including the utilisation of stem cell related applications. If a healthcare practitioner meets the standards that are set by the relevant health professions councils as well as any other requirements that needs to be met in order to practice his profession, that practitioner must surely also meet the standards for being able to conduct stem cell related procedures? The ministerial regulations will dictate the extent to which stem cell procedures in the private sector will be affected, but it is interesting to note that if the regulations are too inhibitory in nature, it could become subject to Constitutional scrutiny.

The impact of stem cell technology on healthcare in general does not only extend to the individual practitioner and patient wanting to engage in stem cell applications. It is still in the initial phase of development with the result that a large amount of money and human resources are needed to conduct research on the development of stem cell applications. This research could include the use of left over embryos following IVF procedures, embryos created for the sole purpose of research, cloned embryos created through SCNT, foetuses following abortions, and umbilical cord blood, to name but a few. The extent to which the different legislative provisions address the use of these materials in research have been discussed both in this chapter with reference to the National Health Act,[565] and in the previous chapter concerning the Human Tissue Act.[566] The application of the National Health Act[567] seems to be

[563] Sec 68(1)(p).

[564] In terms of sec 27(1) of the Constitution of the Republic of South Africa, Act 108 of 1996.

[565] 61 of 2003.

[566] 65 of 1983.

[567] 61 of 2003.

drafted as to include the interests of both the private and public sectors concerning stem cells.

One of the aspects that it does not clearly address is whether there are any mechanisms in place to further regulate the private sector.[568] Although it might not be necessary at present, if stem cell technology falls primarily within the scope of the private sector, the oversight mechanisms that are in place could prove to be ineffective in regulating the field. If a private company decides to conduct stem cell research, the oversight mechanisms have to be able to ensure that there is no unethical conduct such as reproductive cloning procedures present. The monitoring bodies pertaining to stem cell research that are created in the National Health Act[569] are the National Health Research Ethics Committee,[570] which relays research concerns directly to the Minister of Health, the National Health Research Ethics Council[571] which relays information to the National Health Research Ethics Committee, as well as the normal Health Research Ethics Committees,[572] working on ground level in relaying ethical and other research concerns back to the council and ensuring that individual research projects are conducted in an ethical manner.

These monitoring mechanisms will ultimately dictate whether stem cell research takes steps forward whilst staying in line with global and local ethical concerns, or whether the private sector will reign free under ineffective

[568] These other areas of the private sector that needs to be addressed further includes issues surrounding the fact that, due to the cost of stem cell and any other procedures such as genetic enhancement, only the wealthy will be able to afford it. This could lead to a new form of discrimination between those able to purchase their way towards tissue sculpted around the traits necessary to excel in specific areas of life against those who cant. Although it might seem far-fetched at present, there are some authors who express great concern for such happenings in the future. See, for instance, Mehlman & Rabe "Any DNA to declare? Regulating offshore access to genetic enhancement" (2002) 28 *American Journal of Law and Medicine* 179 at 181-185.

[569] 61 of 2003.

[570] Established in terms of sec 69(1) of the National Health Act 61 of 2003.

[571] Established in terms of sec 72(1) of the National Health Act 61 of 2003.

[572] Established in terms of sec 73(1) of the National Health Act 61 of 2003.

oversight and make a blind dashes towards financial gain. In order to evaluate the effectiveness of the structure of these monitoring mechanisms, it becomes necessary to compare it to the structures of other countries that have proven to be capable of balancing the private and public concerns with regard to stem cell research where the financial markets dictate its progression.

4.4 Comparative analysis of the South African regulatory framework with reference to the international arena.

The impact of stem cell research has taken on global proportions, particularly because of its close ties to other fields of genetic advancement such as reproductive cloning. Although each country has a different approach thereto based on its legal background and assessment of other areas in healthcare, there is still a level of consensus amongst all legal scholars that can guide South Africa during its own addressing of these issues; an international form of *boni mores*.

Without going into the legislative position in too much detail, a number of European developments are discussed below, with particular emphasis being placed on the German[573] and United Kingdom's frameworks. The United Kingdom was chosen based on its pro-active legislative position that has proven to be extremely effective in addressing both public and private interests. Thereafter the regulatory frameworks within the United States of America are discussed.

Although the bulk of the dissertation is made up of South African and United States legal material, with the United States arguably being the leader in world genetic advancement at present, the scope of stem cell research justifies an examination of the methods in which other countries are also addressing the issues. A comparison between the Foreign Law regulatory frameworks and that of South Africa is drawn as the discussions thereof progress.

[573] The German position has been chosen, thanks to the fact that the author had been able to spend some time in Germany during the completion of this dissertation.

4.4.1 European regulations pertaining to stem cell research

As has been made clear in the earlier chapters, there are a number of different fields of biomedicine that are affected by stem cell research and its possible applications. Amongst these are embryo research, reproductive and therapeutic cloning, abortion and PGD. Some of these fields will be discussed below, with reference to the German[574] and United Kingdom's legislative positions.

4.4.1.1 Embryo research

In Germany, the *Embryonenschutzgesetz* (Embryo Protection Act)[575] states that it is an offence to fertilise a human egg for any purpose other than to start a pregnancy in the woman who produced the egg,[576] to fertilise an embryo for any purpose other than to oversee its healthy development[577] or to separate and use totipotent cells of an embryo for research.

However, in July 2002, the German Federal Cabinet issued regulations for new embryonic stem cell research law, which allows researchers to use imported embryonic stem cells (created before January 1, 2002), but only if no other alternatives to these cells can be found.[578] Contravention of the abovementioned principles could lead to imprisonment.

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[574] Although the discussion of the German position is set out extremely briefly hereunder, a detailed assessment of their legislative position with regard to embryonic stem cells, umbilical cord stem cells and others can be found in Deutsche Forschungsgemeinschaft *Forschung mit humanen embryonalen Stamzellen – Standpunkte/Research with human embryonic stem cells – positions* (2003) 91-117.

[575] Of 13 December 1990.

[576] Sec 1(2).

[577] Sec 2(1).

[578] Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 622; Rhodes "The difficulty of regulating reproductive and therapeutic cloning: Can the United States learn anything from the laws of other countries?" (2003) *Penn State International Law Review* 341 at 354-355; Stevens "Embryonic stem cell research: Will President Bush's limitation on federal funding put the United States at a disadvantage? A comparison between U.S. and international law" (2003) *Houston Journal of International Law* 623 at 642-643.

The United Kingdom, on the other hand, permits research on embryos in terms of the Human Fertilisation and Embryology Act.[579] In order to conduct such research, however, one has to obtain a licence thereto and can only conduct the research up to the appearance of the primitive streak, or fourteen days after fertilisation, whichever is the earliest.[580] The Act goes further by permitting the creation of embryos specifically for use in research,[581] but such research has to be conducted with the purpose of promoting advances in the treatment of infertility, congenital disease, miscarriage, conception or chromosome abnormalities.[582]

It is already evident that the United Kingdom is much more open to the concept of research on embryos, including research that would lead to the destruction thereof in the derivation of stem cells. On the other hand, the legislation does not present researchers with complete freedom. The institution of a fourteen-day cut-off point for research is very much in tune with the date at which a majority of Human Rights groups argue that embryos can start to feel pain.[583] Furthermore, the European Convention on Human Rights and Biomedicine could affect the application of the Human Fertilisation and Embryology Act because of article 18 of the convention, stating that "adequate protection" of the embryo should be ensured when research is conducted. The

[579] Of 1990.

[580] Secs 1(3)(a) and 1(4), as referred to in Haker & Beyleveld (eds) *The ethics in genetics in human procreation* (2000) 228.

[581] Haker & Beyleveld (eds) (2000) 228.

[582] See a further discussion hereof in Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 606-607.

[583] Similar provisions are found in the legislation of Finland, Spain and Sweden. Other countries such as Ireland do not allow for any embryo research whatsoever, with the life of an embryo even provided with constitutional protection equal to that of its mother. See Haker & Beyleveld (eds) (2000) 229.

process of licence applications and approval would most likely be sufficiently "adequate" for purposes of the convention.[584]

4.4.1.2 Therapeutic and reproductive cloning

The German *Embryonenschutzgesetz*[585] again proves to be prohibitive in nature, stating in section 6 that it is an offence to create an embryo that is genetically identical to another embryo, foetus, or any living or dead person. The Act does not provide a definition of the term "genetically identical" with the result that a wide interpretation is used. This means that the use of SCNT procedures in research is also prohibited.

The United Kingdom, in terms of the Human Fertilisation and Embryology Act,[586] states that licences are required for the nuclear substitution of an embryo[587] and for the creation of an embryo outside of the body.[588] A researcher could, theoretically, have previously commenced reproductive cloning procedures under this legislation[589] due to a loophole that had been formed in the original 1990 Act. The Human Fertilisation and Embryology Act,[590] which was originally intended to ban reproductive cloning, only applied to embryos created by the union of sperm and egg.[591] Since SCNT procedures develops an embryo through the injection of a somatic cell, it did not fall within the scope of the Act and researchers could have theoretically commenced with reproductive cloning through SCNT without facing penalties.

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[584] Haker & Beyleveld (eds) (2000) 230. Also see Zigalvis "The European Convention on Human Rights and Biomedicine, and its Protocols" as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) *Biomedicine, the Family and Human Rights* (2002) 3 at 9.

[585] Of 13 December 1990.

[586] 1990.

[587] Sec 3(3)(d). This would amount to SCNT procedures.

[588] Sec 3(1)(a), as referred to in Haker & Beyleveld (eds) (2000) 232. Also see the discussion of the United Kingdom's position on therapeutic cloning in Blackbeard "Therapeutic cloning – ok?" (2002) 35 *De Jure* 318 at 325.

[589] Haker & Beyleveld (eds) (2000) 232; Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 606-610.

[590] 1990.

[591] See Kennedy & Grubb (2000) Chapter 10.

Parliament quickly adopted emergency legislation to correct the problem and banned any form of reproductive cloning.[592] Even though it is not clearly stipulated in the Human Fertilisation and Embryology Act[593] itself, it is submitted that the approval of a licence application to conduct therapeutic cloning will be allowed, although it will be subject to very strict control mechanisms.[594]

Upon examination of the abovementioned legislation, it is clear that South Africa's National Health Act[595] is much more inclined towards the position as it stands in the United Kingdom. This is good news for researchers because the recent history has shown that the United Kingdom is making large inroads into the field of stem cell research. One difference, however, is the role that the Human Fertilisation and Embryology Authority plays in the United Kingdom. The licensing procedures followed are fairly well administered, both during the application process and afterwards, and includes an evaluation of research practices following successful applications. The scope of the mandate given to the health research ethics committees that are established in terms of section 73 of the National Health Act,[596] combined with the National Health Research Ethics Council,[597] needs to be drastically redefined. Although the health research ethics committees have to review and approve research proposals and protocols to ensure that research conducted by the relevant institution meets the ethical standards of that health research ethics committee,[598] the scope of these "ethical standards" with regard to therapeutic cloning is unclear. It is details such as these that have to be dealt with prior to the commencement of application processes to the committees and other oversight mechanisms by prospective researchers.

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[592] Rhodes (2003) *Penn State International Law Review* 341 at 351-352.

[593] 1990.

[594] Also see Stevens (2003) *Houston Journal of International Law* 623 at 638-639 for an overview of the position in the United Kingdom.

[595] 61 of 2003.

[596] *Ibid.*

[597] As established in terms of sec 72 of the National Health Act 61 of 2003.

[598] Sec 73(2).

The legislative and regulatory mechanisms addressing stem cell related research in the United States of America are discussed below.

4.4.2 American regulations pertaining to stem cell research

The background surrounding federal funding for stem cell research has already been discussed in chapter 1, and will not be repeated in this chapter.[599] It is noteworthy that the primary method in which the United States government attempts to address ethical issues in stem cell research is through prohibiting federal funding from being used to conduct such research. One would expect measures to be taken that would address these issues in both the public and private sectors, and not simply shift it into the private sector where financial objectives often overshadow ethical considerations.[600]

There are a large number of different councils, boards and institutions that participate in the granting of licenses and other forms of approval in the United States of America. It is sometimes a difficult task to establish exactly which committees are responsible for the monitoring of stem cell research and its related applications, and which committees simply provide others with guidelines on current ethical and other issues pertaining to the research.[601]

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[599] Further discussion on the attempts by the United States senate to pass bills on human reproductive and therapeutic cloning can be found in Makdisi "The slide from human embryonic stem cell research to reproductive cloning: ethical decision-making and the ban on federal funding" (2003) *Rutgers Law Journal* 463 at 497-503 as well as in Monachello (2003) *Tulsa Journal of Comparative and International Law* 591 at 603-605 and Rhodes (2003) *Penn State International Law Review* 341 at 348-351.

[600] See Kincaid "Oh, the places you'll go: The implications of current patent law on embryonic stem cell research" (2003) *Pepperdine Law Review* 553 at 567-571 for a discussion on how the federal funding debates not only affects the perception of stem cell research in the United States negatively, but actually leads to benefits for other countries with less restrictive and complicated regulatory systems, such as the United Kingdom.

[601] See Schneider & Wardle "Genetics and artificial procreation in the U.S.A." as published in Meulders-Klein, Deech & Vlaardingerbroek (eds) 55 for a full discussion on the intricate legislative position surrounding biotechnology in the United States of America.

One of the oversight mechanisms in place is the Food and Drug Administration (FDA). It requires the reviewing of all research on human subjects, whether conducted in private or public institutions, by independent review committees known as Institutional Review Boards (IRBs).[602] This is very similar to the health research ethics committees that are established in terms of section 73(1) of the National Health Act[603] in South Africa, by every institution, health agency and health establishment at which health research is conducted.

The IRBs have to review new research proposals in order to ensure that the studies, and their protocols, are scientifically correct as well as ethically legitimate.[604] Before FDA approval by a company can be obtained for a new food, drug or medical device, it must complete preliminary studies that are approved by an IRB.[605] In order to accelerate the review and approval of new research protocols, many biotechnology companies have established their own, private IRBs.[606] This, again, is similar to the health research ethics committees that have to be established in terms of section 73(1) of the National Health Act.[607] Every research establishment that falls within the scope of section 73 has to have access to these committees or establish one

[602] Resnik "Privatized biomedical research, public fears, and the hazards of government regulation: Lessons from stem cell research" as published in Tomossy & Weisstub (eds) *Human experimentation and research* (2003) 591 at 593; Maloney *Protection of human research subjects – A practical guide to federal laws and regulations* (1984) 48.

[603] 61 of 2003.

[604] Murphy *Case studies in biomedical research ethics* (2004) 90 provides a further explanation of the different responsibilities that rest on the shoulders of these review boards when examined from the perspectives of the board members themselves or from the research subjects. The IRBs also have a responsibility towards the identification of conflicts of interest amongst researchers and the companies they work for. See Goldner "Dealing with conflicts of interest in biomedical research: IRB oversight as the next best solution to the abolitionist approach" as published in Tomossy & Weisstub (eds) (2003) 557 at 568.

[605] Blackbeard (2002) 35 *De Jure* 318 at 323; Maloney 81-94.

[606] Resnik "Privatized biomedical research, public fears, and the hazards of government regulation: Lessons from stem cell research" as published in Tomossy & Weisstub (eds) (2003) 591 at 593.

[607] 61 of 2003.

of its own.

Interestingly enough, however, these private IRBs have been subject to a vast amount of well-founded criticism. The criticism being that private IRBs are not subject to the same type of stringent openness rules that apply to public IRBs and do not normally operate under the same potential threat of public scrutiny as do other IRBs. Also, private studies of new drugs or biomedical applications that are not submitted for FDA approval may never be brought out into the open.[608] This, combined with the possible role that financial incentives given to private IRBs could play, provides for a potential conflict of interests in which the legitimacy of such research can be seriously affected. Decreased openness and increased financial pressure make private IRBs a less than ideal method for promoting scientific and ethical standards in research on, and about human subjects.[609] The possibility of undue influence being exerted by a company on its private IRB, or in the case of South Africa its private health research ethics committee, need to be weighed against the reality of a lack in resources to successfully oversee all research proposals by a single, publicly instituted, review board. Private IRBs, despite the possibility of undue influence being asserted, are in the best position to thoroughly evaluate the complexities of proposed research by its instituting company within the larger scientific, legal and ethical domain. The best way in which to ensure that no undue influence is asserted by companies on their private IRBs, or private health research ethics committees in South Africa, is to have an efficient body that overseas the IRBs itself. The National Health Act[610] has established such a body in section 72, namely the National Health Research Ethics Council, but ultimately only time will tell whether this Council can effectively address any stem cell related issues identified by the Health

[608] Resnik "Privatized biomedical research, public fears, and the hazards of government regulation: Lessons from stem cell research" as published in Tomossy & Weisstub (eds) (2003) 591 at 593.

[609] *Ibid* at 594.

[610] 61 of 2003.

Research Ethics Committees.[611]

Similarly to the National Bioethics Advisory Commission (NBAC) and the Recombinant DNA Advisory Committee (RAC) in the United States of America, the South African National Health Research Ethics Council should incorporate open debates about issues such as stem cell research into its processes of establishing norms and standards for conducting research.[612] The NBAC and the RAC complements other regulatory mechanisms such as the FDA through insight into the ethical considerations of current biomedical advances. Through time these advisory committees have acquired a degree of legitimacy amongst private and public researchers because of their focus on incorporating the current ethical considerations into their recommendations.[613] One of the goals of the National Health Research Ethics Council must be to obtain a similar degree of legitimacy through the constant adaptation to new biomedical advances, whilst maintaining a firm grasp on the ethical considerations pertaining thereto.

4.5 Conclusion

There are remarkable similarities between the South African, American and United Kingdom's legislative positions. Recent history has shown that, despite the influence of federal funding disputes, the proposed model is effective.

[611] Notice should be taken of the fact that the IRBs in the United States of America have been subject to accusations of being uninformed about the scope of research being conducted under their watch, and simply focussing on smaller areas such as the structure of consent forms in research. An ineffective monitoring committee at ground level could seriously hamper the functioning of the national monitoring system as a whole and care should be taken to ensure the competence of these personnel. See Noah "Informed consent and the elusive dichotomy between standard and experimental therapy" (2002) 28 *American Journal of Law and Medicine* 361 at 384 as well as Macklin *Double standards in medical research in developing countries* (2004) 150-152.

[612] See sec 72(6)(a), (c) and (g) of the National Health Act 61 of 2003, in which the National Health Research Ethics Council's functions are specified.

[613] Chapman, Frankel & Garfinkel (1999) "Stem Cell Research and Applications – Monitoring the Frontiers of Biomedical Research" Produced by the *American Association for the Advancement of Science and Institute for Civil Society* 28.

Having entry-level review boards in the form of Health Research Ethics Committees is a good way in which to maintain control over the scope of both public and privately instituted research endeavours.

It is evident that the legislative framework established through the National Health Act[614] has the potential of providing an effective base from which stem cell research can be conducted in South Africa. Chapter 3 identified that the legitimacy of stem cell research can possibly be affected by the ineffective regulation thereof, and it has become clear that the legislative framework created would be able to carry the debate successfully. This framework is exactly that, the primary structure to which a number of other regulations should still be added. The creation of the National Health Research Ethics Council, and the Health Research Ethics Committees working underneath it, is a positive step towards the successful implementation of stem cell research in South Africa. The true test for the legislation, however, lies in the assessment of whether the Council and its Committees are able to effectively administer the research that will be conducted under its watch.

Upon examining the current international position on stem cell research it becomes clear that private companies spend large amounts of time and money in facilitating the research. These companies are not simply conducting the research for free, but are looking for ways in which to obtain financial gain there from. One of the primary incentives for these companies is the possibility of obtaining intellectual property rights on any new technology that they hope to develop. Although it seems straight forward, there are a number of concerns regarding the granting of patent rights in biomedical inventions. It is very important that these concerns are addressed, since any problems in the obtainment of patent rights could discourage private investors from further developing the field of stem cell research.

A *capita selecta* of intellectual property rights in stem cell related advances are discussed in the following chapter.

[614] 61 of 2003.

Chapter 5

Capita selecta of Intellectual Property Law – Who owns whom?

5.1 Introduction

The development of stem cell technology and its healthcare applications is an expensive field to invest in.[615] This has already been made clear in the previous chapter and can be seen in the vast amounts of money that are being put into it through federal funding in the United States of America. If the public sector is not able to fund continuous research on stem cells, private institutions will surely take up the task. These institutions demand some sort of guarantee that their investment would be safe once any breakthrough is made in the stem cell field. The guarantee that they are looking for comes in the form of intellectual property rights.

There are a number of aspects of Patent Law that have to be clarified before it can be applied to this case. For instance, any question surrounding the fact that it is human material that is being patented and whether this could lead to a situation in which a person literally owns someone else. Once the basics of Patent Law[616] is understood, it becomes clear that the patenting of biomedical advances is nothing out of the ordinary.

One of the key aspects that deserve attention is the fact that the granting of patent rights to a particular object does not confer ownership thereto.[617] This

[615] In 1996 it was estimated that, through intellectual property law, the biotechnology industry in the United States of America spends upwards of $100 million annually simply to recoup its developmental expenses. See Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) *Contemporary issues in law, medicine and ethics* (1996) 237 at 238.

[616] The better term would rather be the law of inventions because patenting only makes out a part of this field of law. Klopper & Van der Spuy *The Law of Intellectual Property* (2003) 268.

[617] Such a right to an invention is a patrimonial right due to its monetary value and can be ceded and inherited as well. Also see Brom "The expressive-communicative function of bio-patent legislation: the need for further public debate" as published in Baumgartner & Mieth

basic premise of Patent Law is frequently misunderstood and has often in the past led to a perception that individuals obtain ownership over others. Ossorio[618] clarifies the concept well in the following words:

> "Unfortunately, literature discussing the ethics of patenting human-derived materials frequently incorporates the assumption that patents confer ownership of the item or process patented. The analysis then focuses on whether owning people, or parts of people, is ethically acceptable. While the question of owning people is an old and well travelled ethical debate, it is not particularly relevant to the ethics of patenting human DNA or cell lines. Analysis of the ethics of patenting should examine whether the right to exclude which is conferred by patents undermines other rights, conflicts with particular interests, conflicts with important values, or interferes with utility maximization."

These rights merely allows for the patent holder to prohibit any other person to make use of that particular object without his consent.[619] This monopoly that the patent holder has over the invention lapses after a certain number of years with the result that the public in general can then gain benefit thereof.[620] The provision of legally enforceable rights in an invention further ensures that inventors and researchers disclose their work, which in turn ensures that these inventions find application in the community.[621]

A major controversy surrounding Patent Law and stem cell research started only after the first patent on a stem cell line had been awarded. This is known as the so-called "806" patent and was granted to the University of Wisconsin's

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(eds) *Patente am Leben? Ethische, rechtliche und politische aspekte der biopatentierung* (2003) 117 at 121.

[618] "Legal and Ethical Issues in Biotechnology Patenting" as published in Burley & Harris (eds) *A Companion to Genethics* (2002) 408 at 411.

[619] According to Klopper & Van der Spuy 289, with reference to sec 45 of the Patents Act 57 of 1978, the patent holder has exclusive rights to manufacture, apply, exploit, import and assign the invention.

[620] Twenty years from the date of the patent application.

[621] Klopper & Van der Spuy 272.

Wisconsin Alumni Research Foundation following the research conducted by Dr James Thomson, a developmental biologist at the University.[622]

5.2 Aspects of Patent Law

Before the specific aspects pertaining to Patent Law and stem cells can be addressed, it is necessary to present an overview of Patent Law in general.[623]

5.2.1 General principles of Patent Law

The law protects the idea of a particular invention, and not the physical invention itself.[624] This does not mean that a person can, for instance, just go and obtain the patent rights on a flying car simply because he thought of it. Generally there is distinction between three types of patents, namely: design patents, plant patents, and utility patents. A utility patent is the type that is granted most frequently in the field of biotechnology. Generally, utility patents protect the structure or function of the invention, including the workings and usability thereof, and is normally sought when an inventor seeks protection over how the invention operates. A utility patent can be issued to any person for a process, machine, manufactured article, composition of matter, or any new and useful improvement to the aforementioned types of inventions.[625] The Patents Act[626] requires a full description of the invention itself. If another person or researcher that is knowledgeable in that area cannot use the

[622] The full reference number of the patent is 6200806 of 1998. See Kincaid "Oh, the places you'll go: The implications of current patent law on embryonic stem cell research" (2003) *Pepperdine Law Review* 553 at 571-572.

[623] Also see Caulfield, Cherniawsky and Nelson "Patent Law and Human DNA: Current Practice" as published in Knoppers *et al* (eds) *Legal rights on human genetic material* (1996) 117 for a good overview of the patent law field as well as Hasskarl (ed) *Europäisches Gentechnikrecht/European Genetic Engineering Law – Regulations, Directives, Decisions* (2002) 338-350 for a discussion on the directive of the European Parliament on the legal protection of biotechnological inventions. This provides a view into the international regulations pertaining to biomedical patenting.

[624] Klopper & Van der Spuy 273.

[625] Kincaid (2003) *Pepperdine Law Review* 553 at 556-557.

[626] 57 of 1978.

description to create a working model of the invention, the patent rights cannot be granted thereto.

The meaning of an invention is found in section 25(1) of the Patents Act[627] and reads as follows:

> "A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture."

From the wording of section 25 it becomes clear that there are three requirements that an invention must meet in order to be patentable, namely that it must be new (novelty), involve an inventive step, and be capable of being used or applied.[628] The basic elements of these requirements will be discussed below. Attention must however be drawn to the fact that certain creations are specifically excluded as patentable inventions. These include:[629]

- A discovery. The reason for the non-patentability hereof is the fact that it is a *res communes* as part of the existing laws of nature. The exclusion of the patentability of a discovery has led to many authors arguing that stem cell technology, as being part of the expanding knowledge of the human body, is not patentable either;
- A scientific theory;
- A mathematical method or theory;
- Musical, dramatical, literary or artistic works;
- The presentation of information;

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[627] *Ibid*.

[628] Klopper & Van der Spuy 277. Some sources claim that there are in fact a fourth requirement that needs to be met, namely an "adequate disclosure of the invention". Although this is indeed a part of the patent application process in South African law, it is not another requirement for purposes of sec 25 of the Patents Act 57 of 1978. See Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 241. American patents law does, however, have a fourth requirement of disclosure that has to be met. For a discussion on the requirements of American patent law as well as thorough references to their patents legislation, see Kincaid (2003) *Pepperdine Law Review* 553 at 557-558 as well as McDonald "Patenting human life and the rebirth of the thirteenth amendment" (2003) *Notre Dame Law Review* 1359 at 1365.

[629] *Ibid* at 275.

- An invention which would encourage promiscuous or offensive behaviour;[630]
- An invention of a method of medical treatment of a human or an animal body, or the diagnosis thereof. This exclusion too, has led to many authors questioning the patentability of stem cell technology.

5.2.1.1 Novelty

Novelty is defined in section 25(5) of the Patents Act,[631] namely that:

> "An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention."

The priority date that is referred to is the date on which the application for a provisional patent is lodged at the patents office.[632] In establishing what the state of the art is with regard to a particular invention, cognisance is taken of all other similar inventions contained in patents and patent applications, products, processes and information both inside and outside the Republic of South Africa. These include written and oral descriptions of inventions used either secretly or commercially in South Africa.[633]

The method, in which novelty is tested against the state of the art, comprises of both a quantitative and a qualitative element. Klopper and Van der Spuy[634] describes the test in the following words:

> "As far as *quality* is concerned, the test is whether the existing matter which allegedly destroys the novelty of the invention, forms part of "the state of the art". If not, such matter cannot be used to prove that the invention lacks novelty. The quantitative element means that the invention must not be substantially identical to

[630] It is interesting to note that the European Patent Convention, although not applicable to South Africa also excludes inventions which are contrary to morality from patentability. See Van Owerwalle "Legal and ethical aspects of bio-patenting. Critical analysis of the EU Biotechnology Directive" as published in Baumgartner & Mieth (eds) (2003) 145 at 146.

[631] 57 of 1978.

[632] Sec 33(1) of the Patents Act 57 of 1978.

[633] Klopper & Van der Spuy 278.

[634] 278.

> anything which forms part of the state of the art, because that will negate the novelty of the claim."

5.2.1.2 Inventiveness

Inventiveness is defined in section 25(10) of the Patents Act and reads as follows:

> "Subject to the provisions of section 39(6), an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8))."

The test for inventiveness amounts to establishing whether a person skilled in the art and who is knowledgeable within the field of the invention, with due consideration of the state of the art, does not consider the invention as obvious. This means that the invention should not be an inevitable or an evident step in the process.[635]

The courts have formulated certain steps and guidelines when determining the inventiveness of an invention. These include the following:

- Skill cannot be equated to inventiveness;
- Improvement of existing craftsmanship does not amount to inventiveness;
- The improvement of size, gauge or strength only rarely amount to inventiveness;
- The change in form or exchange of parts is not inventive, unless the change brings about unforeseen results.[636]

5.2.1.3 Application in trade, industry or agriculture

This requirement amounts to exactly what the title says, namely that it must be capable of being applied in trade, industry or agriculture. There are certain inventions which cannot be used in this way, including education systems and

[635] Klopper & Van der Spuy 280.

[636] *Ibid* 281-284.

systems of government.[637] This requirement is sometimes know as the "utility" element of patenting. Although it seems clear cut, there have been a number of debates surrounding the scope of the utility element. If a researcher only describes the structure of a particular cell line, this requirement will not be met, but if a researcher also provides a disclosure of how the cell line, isolated from its natural state, can be used, this requirement will be met.[638] It is clear that a fairly wide definition of utility is followed in the examination of biomedical patent applications.

It now becomes possible to evaluate the application of stem cell related inventions within Patent Law and the methods in which any obstacles that may have surfaced are being addressed.

5.2.2 The patentability of stem cell related advances

Stem cell research offers potentially lucrative opportunities for private companies to invest in.[639] The lucrative potential of stem cell research, however, stretches only as far as its patentability is willing to take it. If a private company was not guaranteed that, once a breakthrough is made, his investment would be secured through intellectual property rights, that company would not provide funding for research to continue.

The two primary reasons why an application for patent rights in a cell line could be refused is that it is deemed to be a "discovery" and is therefore unpatentable, or that the application is refused based on reasons of morality. These two grounds are discussed hereunder.

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[637] *Ibid* 285.

[638] Kincaid (2003) *Pepperdine Law Review* 553 at 562.

[639] See for example the world wide web site of Lazaron Biotechnologies at www.lazaron.co.za.

5.2.2.1 Discovery

Before one can assess the impact of discovery on the patentability of a product, it is necessary to grasp the scope of the concept of discovery. Crespi[640] provides a comprehensive definition thereof namely:

> "To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters and it is "new" in the absolute sense of having no previously recognised existence, then the substance per se may be patentable."

The exclusion of discovery for purposes of patenting is due to the belief that nothing that occurs freely in nature should be subjected to a patent application.[641] Numerous reasons for this exclusion from patentability have been given, including the fact that it would be inappropriate to offer a monopoly to someone who has simply stumbled upon something that turns out to be important.[642] Another argument states that a product of nature is the property of all mankind and should therefore not befall only certain individuals, albeit for a limited amount of time. Different countries approach the concept from different angles, but the result is always the same, namely that discoveries are unpatentable.[643]

Fortunately for the biotechnology industry this exclusion from patentability is not applied too strictly in practice. The different patents offices throughout the world have established a number of qualifiers that go hand in hand with this

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[640] Crespi "Patenting and ethics – a dubious connection" (2003) *Journal of Patent and Trademark Office Society* 31at 39.

[641] Freedman *Legal issues in biotechnology and human reproduction: Artificial conception and modern genetics* (1991) 16; Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 242.

[642] Laurie *Genetic privacy – A challenge to medico-legal norms* (2002) 305.

[643] American case law merely states that such a subject is not new and therefore not patentable, whilst the European case law focuses on whether there has been an element of manufacturing involved in the process by the patentee. See Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 242.

exclusion. One such qualifier being that the process to isolate, purify or produce a naturally occurring entity is patentable.[644] It is based on this qualifier that stem cell researchers often succeed in a patent application on a new stem cell line. Although the stem cells are products of nature, the process through which they are derived is worthy of protection.[645] The question as to whether a certain product is an invention or a discovery is addressed best through an examination of whether the inventor has gone further and identified a genuine practical application for the isolated material, which serves some useful purpose.[646]

5.2.2.2 Morality

One of the exclusions to patentability is if the product would encourage offensive or promiscuous behaviour.[647] Upon the examination of the stem cell debate in general one can clearly see that, for example, the use of aborted foetuses in the derivation of germ cells could be deemed to encourage promiscuous behaviour.[648] This is where the writings of legal philosophical scholars as well a clear legislative position regulating such practices finds application. If the general public can be assured that any research conducted on aborted foetuses is strictly separated from the abortive practice itself, for instance, through means of timely consent procedures after the abortion has been finalised, the *boni mores* on the immorality of stem cell research can be guided in a positive direction.

The current position has developed dramatically in the last number of years. Only thirty years ago it was still debatable about whether the patenting of any

[644] Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 243.

[645] Kincaid (2003) *Pepperdine Law Review* 553 at 555.

[646] Crespi (2003) *Journal of Patent and Trademark Office Society* 31at 38.

[647] Laurie 305.

[648] Crespi (2003) *Journal of Patent and Trademark Office Society* 31at 45-47 directs a lot of criticism towards the European authorities for side-stepping many of the issues surrounding stem cells by simply approving patent applications on cell lines derived from left over IVF embryos, whereas patent applications on cell lines developed from aborted foetuses are rejected.

living matter should be allowed. United States case law proved to be a guiding factor in that regard, following the court's decision in the then controversial case of *Diamond v Chakrabarty.*[649] The case had involved a patent application for certain bacteria that had been created using genetic engineering. These bacteria had the unique ability to break down multiple compounds of crude oil, and had been used successfully in the prevention of major environmental catastrophes following oil spills. In allowing the patent application the court not only opened the door for the patenting of other living materials, but delivered a clear statement that the role of patents are to secure financial returns and to encourage scientific progress.[650]

There have been a number of other cases of patenting disputes surrounding living materials,[651] but the clear message through the last number of years has been, that given the right circumstances, the patentability of human genetic or other material is not beyond the scope of the world's patent and trademark offices. Arguably, the most influential case of its time surrounding patent disputes and proprietary interests in human genetic material was the case of *Moore v Regents of the University of California.*[652] The facts of the case have already been discussed in chapter 3 concerning the proprietary value of human material. Mr Moore had failed to establish any proprietary interests in his cells, with the result that the cased failed based on that presumption. He did, however, succeed with his action due to a failure by the respondent to obtain informed consent prior to using his cells to conduct research and patent a cell line. The case did not, however, establish clear guidelines on the scope of the exclusion due to morality in patenting. This lack

[649] 447 US 303, 65 L Ed 2d 144, 100 S Ct 2204 (1980) (as referred to in Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 251).

[650] Kincaid (2003) *Pepperdine Law Review* 553 at 560; McDonald (2003) *Notre Dame Law Review* 1359 at 1366.

[651] For example *Johns Hopkins University v. CellPro, Inc* 152 F.3d 1342 (1998) in which the dispute resolved around the derivation of blood stem cells, which is needed in the treatment of a number of diseases, from bone marrow.

[652] 793 P.2d 479 (Cal. 1990).

of guidance is a source of concern amongst legal scholars because the interpretation of a concept such as morality is something that, according to many, should not be left to a body such as the patent and trademark office.[653]

Although the morality issue in patenting is constantly the source of debate,[654] it seems as if none of the parties involved have been able to reach an agreement concerning the impact and scope of morality in stem cell patenting. Certain scholars approach the argument from a financial perspective, stating that monetary incentives with regard to human genetic material is unwarranted, whilst others still oppose the general idea of patents being granted to any living material.[655] The effect of the inconclusiveness of these debates is that researchers are unsure about whether their work could be rejected on grounds of morality. Such uncertainty could prove to be counterproductive in situations where the researchers have to balance the time and money involved in the development of a new cell line with the possibility of their patent application being rejected due to moral objections.

5.3 Monitoring mechanisms regulating biomedical research

One aspect of Patent Law that cognisance has to be taken of is the fact that Patent Law itself has a largely retrospective application. In itself, Patent Law is little more than a guarantee given to a patent holder that no other entity is allowed to profit from his particular invention. Up to the point at which a patent application has been made, or a patent holder informed of some or other infringement in his rights, there are virtually no Patent Law related mechanisms in place to regulate the workings of the individual researchers.

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[653] Laurie "Biotechnology and Intellectual Property: A Marriage of Inconvenience?" as published in Mclean (ed) 237 at 254.

[654] One such an argument even claiming that the patenting of human genetic material and any products derived from embryos amounts to a form of ownership that infringes upon the American thirteenth amendment, which prohibits slavery. For a complete discussion hereof, see McDonald (2003) *Notre Dame Law Review* 1359 at 1382-1386.

[655] Kincaid (2003) *Pepperdine Law Review* 553 at 577.

This could prove to be a major concern for the oversight committees that have to evaluate the field and ensure that the boundary between therapeutic and reproductive cloning is not crossed by eager researchers. By the time that Patent Law finds application, any such event would have already occurred. This is particularly problematic when dealing with the private sector, due to the fact that the oversight mechanisms established to regulate their research is not as open to public scrutiny as those of researchers working in the public sector. It again places the emphasis on the legislative principles that have been enacted with regard to stem cell research. The National Health Act[656] has the responsibility of proactively dealing with possible reproductive cloning endeavours, without unnecessarily hampering other researchers that may be legitimately pursuing goals related merely to therapeutic cloning.

Although the National Health Act[657] has already been discussed in the previous chapter, the importance of oversight mechanisms that are able to effectively address issues of private sector involvement in stem cell research needs to be reaffirmed. The legislation is merely a piece of paper without the support of an effective and efficient oversight mechanism. This is the challenge posed to both the National Health Act,[658] and the proposed regulations thereto.

5.4 Conclusion

Although the issues surrounding the legitimacy of stem cell research have been discussed in earlier chapters, it is important to reaffirm the role that intellectual property rights plays in connection therewith. Patenting, especially because of its strong financial interests, is very much a device with which current public perceptions can be measured. The constant inclination towards the allowance of more specialised patents on living organisms has proven to be an indication of the *boni mores* surrounding genetically based medical advancement. The approval of patent rights in stem cells derived from

[656] 61 of 2003.

[657] *Ibid.*

[658] *Ibid*.

embryos left over after the completion of IVF treatment was simply the natural step in a process that would ultimately lead to the approval of stem cell lines derived from embryos created for the sole purpose of research through SNCT processes.

The challenge being faced by legal as well as scientific scholars is the establishment of a bridge between technological advancement and the current moral objections thereto. Building such a bridge can be possible, and would ultimately lead to a harmonisation of all interests that are casting their shadows on stem cell research. Such a harmonisation, however, can only be achieved with the support of a legislative framework that is able to address all of the scientific and moral concerns posed by stem cell research. The previous chapter has already outlined the structure of the National Health Act[659] and it's application to stem cell research. In the final chapter, a number of guidelines are proposed which could aid the implementation of stem cell research within the South African healthcare framework. These guidelines are subject to whether or not the proposed regulations yet to be published in terms of the National Health Act[660] proactively address the issues pertaining to stem cell research.

[659] 61 of 2003.

[660] *Ibid*.

Chapter 6

Closing remarks and regulatory recommendations

6.1 Introduction

Stem cells are proving to play a growing role in the way that previously unassailable medical problems are being approached. Stem cell technology not only stands to benefit the individual patient, but financially the prospects of benefit are immense. Although sometimes controversial, it is safe to assume that the patenting of these advances are proving to be one of the key factors in private investors' decision-making as to the funding of stem cell related projects.

The previous chapter has also identified the manner in which intellectual property rights not only solidify the impact of stem cell research financially, but also assist in sculpting the *boni mores* concerning the use of previously deemed controversial methods in conducting the research itself. Despite any arguments to the contrary, stem cells have enormous potential, which will ultimately be exploited to the fullest extent possible by any party able to fund its research. At the moment private researchers internationally are a step ahead of the public sector due to slow legislative procedures and disputes over the use of public funds to finance these incentives.[661] On a national level, a perfect balance between the private and public sectors, although achievable, is unlikely. The South African health budget simply cannot afford to fund this type of research with the current demands for primary healthcare.

On the short term, the only method in which stem cell research and its' potentially lifesaving applications will fall within the grasp of the ordinary man

[661] See for instance the discussion in chapter 1 surrounding the disputes over federal funding in the United States of America. Whilst those debates have been going on, the private sector had effectively vetoed researchers in the public sector from conducting any noteworthy research. The patent rights granted on the cell lines produced by the private sector have effectively placed the public sector under the control of privately driven market indicators.

in the street is if there are funding for research at a national level. Chapters 3 and 4 have outlined the constraints that the health budget is facing and it is clear that South Africa cannot afford to spend an enormous amount of money on spearheading new fields of research whilst, for example, HIV/AIDS numbers are reaching epidemic proportions. On the other hand, once stem cell researchers in the private sector have been able to conduct their research free from unnecessary constraint by the legislative and regulatory mechanisms in place, the products of their research could become household procedures. The current expensiveness of stem cell related applications should not become the deciding factor in prohibiting researchers from applying their knowledge in expanding the scope of stem cell technology even further. What can only be afforded by a select number of individuals at present, would ultimately enhance not only the stem cell field in itself, but medicine in general.[662] The criticism that stem cell research is currently facing is not unlike that of *in vitro* fertilisation[663] and other treatments that were deemed to be controversial at the time of their introduction into the global market. Although the use of aborted foetuses as well as the creation of embryos for the sole purpose of them being used in research are sensitive issues, proper legislative and regulatory oversight mechanisms can address these concerns in a constructive manner.

There are a number of minor changes that can be made to the legislative position that the National Health Act[664] is proposing to establish. These changes can ensure the effectiveness of the Act itself, although, as with all legislation, the effectiveness of the practical application thereof is something that can only be established retrospectively. Before the recommendations are to be made, it is first necessary to provide an overview of the current position on stem cell research as has been established in the previous chapters.

[662] See for instance chapter 2 for a discussion on the potential applications of stem cell research.

[663] IVF.

6.2 Legitimacy in retrospect

In the previous chapters it has been established that legitimacy is a concept that is context-specific. Specifically with regard to stem cell research, it is a concept that cannot be assessed through simply examining one field of law, but one in which a number of factors from different sources all have to be balanced. These factors include aspects of Medical Law, Intellectual Property, Common Law, Human Rights, Legal Philosophy, as well as additional ethical considerations. But even if the requirements set by these fields have been met, there is still another factor that could affect the legitimacy of stem cell research, namely the ineffective implementation of the legislative and other legal principles in practice. If the monitoring mechanisms that assess the permissibility of certain research proposals are not alert and efficient, the legitimate theoretical base that is set through the abovementioned fields of law becomes null and void.

The results of the abovementioned legal and ethical assessments are summarised below and acts as a guide to the proposed changes that can be made to the new legislation, the National Health Act,[665] in the legitimate and effective regulation of stem cell research within the South African law.

6.2.1 Current legal position of stem cell research

The examination of the legal position of stem cell research involves an assessment of the current legislation that regulates the field, namely the Human Tissue Act.[666] Although the Act is capable of dealing with stem cell research to a certain extent, it is evident that it had not originally been written with the regulation of these types of endeavours as its primary objective. The fact that the Act prohibits any type of genetic manipulation through section 39A is fairly inhibiting considering the current research setting in which the primary argument is not so much about whether genetic manipulation in the

[664] 61 of 2003.

[665] 61 of 2003.

[666] 65 of 1983.

form of therapeutic cloning should be allowed, but rather the scope of allowance thereto.

Still within the parameters of Medical Law, there is also the question of consent to stem cell research. Of particular interest is the procurement of consent from minors as well as the use of aborted foetuses for research purposes. External factors can affect the provision of consent by a prospective donor of stem cell related material. These factors include illiteracy as well as the effect that financial incentives could have on the provision of free and voluntary informed consent. In retrospect, the procuring of informed consent from stem cell donors does not provide for any insurmountable obstacles in the question of legitimacy, although its' ineffective application could introduce possible illegitimate practices once implemented.

Once stem cells have been obtained from donors, it becomes important to establish exactly what type of right the researcher obtains in the material under hand. The level of proprietary interest could affect later intellectual property rights as well as contractual obligations that the researcher might become party to. An examination of the Common Law properties of human material concluded that the proprietary interest therein is *sui generis* in nature, not providing a researcher with full proprietary interest, but still with a possessory interest worthy of protection. As research in genetic material progresses and the material is further separated from the original donor, the proprietary interest that a researcher possesses therein will therefore be strengthened in accordance with the theory of gradual distancing.

The discussion on the legitimacy of stem cell research then flows into one of ethics and the influence thereof in the South African law. This is assessed through the use of Human Rights as well as Legal Philosophy. Those findings are further discussed below.

6.2.2 Human Rights influences on stem cell research

Human Rights, and in particular the applicable provisions in the Constitution,[667] provides a number of principles that can be used in incorporating new areas of research, such as stem cell research, into the South African law. Of particular interest is a person's right to bodily and psychological integrity,[668] privacy,[669] as well as the effect that socio-economic rights[670] have on access to new advances in healthcare.

The assessment of one's right to bodily and psychological integrity proved that future advances in stem cell technology might lead to the reproductive rights of parents' being limited to only favour their ill children. The only method in which such a possible limitation can be avoided is through the use of therapeutic cloning procedures to obtain stem cells to cure the sick child. This situation proves that advances in healthcare applications also has its disadvantages.

The privacy of a stem cell donor is of vital importance and again the impact of thorough informed consent procedures is evident, since an efficient system of consent acquisition could minimise possible privacy violations. Genetic information in general is a subject that has provided for a vast amount of concern due to its potentially damaging influence on the private and professional lives of its holder. The discussion on the protection of genetic information touches on the nature of this type of information itself, but reaffirms that it is an area in which careful contemplation is needed, irrespective of the nature thereof.

In chapter 5, socio-economic rights are discussed to indicate the relevance thereof in establishing the scope of the public sector's ability to conduct stem cell research when considering aspects such as resource allocation. The

[667] Constitution of the Republic of South Africa, Act 108 of 1996.

[668] Sec 12.

[669] Sec 14.

[670] Sec 27.

discussion on International Law and its application to Human Rights and stem cell research reaffirmed the complexity of this area of research, as well as the struggle by international bodies to establish a universal document pertaining thereto.

6.2.3 Current ethical debates on stem cell research

The ethical debates surrounding stem cell research provide for a very interesting area of proposed regulation. The reason for this being that it is exactly that …a debate. The ethicists are so busy devising new methods of complicating the questions under hand, that it has become almost impossible to ascertain exactly what the scope of the current ethical dilemmas seems to be. The majority of the sources that present themselves as true reflections of the ethical considerations are so vague that they only refer to ethical issues, without ever stating clearly whether, for instance, the creation of embryos for the sole purpose of it being used in research is ethically accepted or not.

This led to an analysis of certain religious denominations and their assessment of stem cell research and the ethical issues pertaining thereto. The religious viewpoints are somewhat varied as well, but one of the areas of relative consensus is that research on embryos before the appearance of the primitive streak[671] is allowed. This is encouraging news considering the fact that the National Health Act[672] also has a provision that research on embryos may only be performed within the first fourteen days after fertilisation.[673]

Legal philosophical writers guide the ethical debates in a direction that would ultimately present itself to be ready for interpretation and maybe even incorporation into legislation. Post-modern writers set out to reinterpret the current legal principles in such a manner that the justifiability thereof becomes consistent with the current ethical position pertaining to, in this case, stem cell

[671] The primitive streak appears about 14 days after fertilisation and is the first signs of the development of the nervous system of the embryo.

[672] 61 of 2003.

[673] Sec 57(4).

research. It becomes clear that the current ethical position on stem cell research and its different areas of application is, as a matter of fact, unclear.

This had also been the position internationally, but the United Kingdom set a good example of how to deal with it. Their approach has been discussed in chapters 1 and 4, but entails a speedy incorporation of a regulatory framework that allows for stem cell research without unduly lingering on more controversial aspects such as reproductive cloning. This seems to be a similar approach currently followed in South Africa through the promulgation of the National Health Act.[674] It provides for therapeutic cloning practices to be allowed following ministerial consent, but alleviates the public concern of eugenic practices by prohibiting reproductive cloning.

The ethical position on stem cell research appears to correlate with the position that is presented by the National Health Act.[675]

6.2.4 Socio-economic concerns and oversight mechanisms on stem cell research

Socio-economic rights are provided for in the Constitution[676] and have been discussed in conjunction with the National Health Act[677] in chapter 4, and form part of the public sector of stem cell research and its healthcare applications. The impact of monetary considerations in the definition and provision of primary and emergency healthcare services in South Africa led to a re-evaluation of the case law and other principles underlying its implementation. The definition and scope of emergency healthcare services plays a cardinal role in assessing whether stem cell research applications will become accessible to the ordinary man in the street. This assessment led to the conclusion that stem cell research is not currently a field that can be effectively pursued by the public sector and should rather be left in the hands of private researchers.

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[674] 61 of 2003.

[675] 61 of 2003.

[676] Constitution of the Republic of South Africa, Act 108 of 1996.

[677] 61 of 2003.

These private researchers will only conduct their research if their own financial input could lead to possible monetary gain following the success of their research endeavours. The incentive through which financial input is justified for researchers is provided in the form of intellectual property rights on their biomedical inventions. The practical considerations when one is dealing with patents in human material as well as certain objections thereto that have surfaced in the past, such as the discovery versus invention debate, are discussed in chapter 5. The result of this evaluation of the Patent Law, as well as socio-economic rights applications, is that intellectual property rights provide a legitimate incentive for researchers in the private sector, which will ultimately lead to the advancement of all fields of healthcare.

The only areas of concern when stem cell research is shifted out of the public and into the private sector, is whether the oversight mechanisms that have been established though the National Health Act[678] are sufficient in addressing not only the physical research, but also that of the ethical concerns thereto. Chapter 4 provides an assessment of the Act and highlights its possible weaknesses, particularly with regard to incomplete definitions of concepts such as genetic manipulation and blood products. These weaknesses are addressed in the proposals made below, and are points of concern that can be fairly easily rectified. What is important, however, is the fact that South Africa has a satisfactory system of oversight in the National Health Research Ethics Council[679] and the Health Research Ethics Committees,[680] when compared to the oversight mechanisms regulating the field internationally. Taking the practical aspects of stem cell research regulation into account, these oversight bodies provide for the measure of legitimacy that is required in establishing the overall concept of legitimacy within stem cell research.

[678] 61 of 2003.

[679] Sec 72.

[680] Sec 73.

However, if these bodies of oversight are inefficient in their handling of further ethical and practical problems which may surface during the course of stem cell research, or if regulations promulgated by the minister fail to establish a defensible system of stem cell research principles (including a thorough consent procedure), it could affect the legitimacy of stem cell research.

6.3 Legislative and regulative recommendations

The legislative changes and regulative proposals suggested hereunder are the result of the legislative inconsistencies that have been identified in the National Health Act[681] as discussed in chapter 4. Notice is taken of other policy recommendations that have also been made previously, for instance those posed by Jordaan[682] with regard to reproductive cloning. Although the scope of this dissertation does not allow for an in-depth analysis of reproductive cloning within South African law, one is inclined to agree with Jordaan in establishing a moratorium thereon for a number of years[683] rather than the current prohibition in terms of section 57(1) of the National Health Act.[684] On the other hand, as has been discussed above, the current ethical debates seem to lean towards a ban on reproductive cloning and such a prohibition could take some of the pressure asserted by ethical groups off researchers that are currently conducting research using therapeutic cloning procedures.

The recommendations of proposed changes to the National Health Act[685] as well as the content of the future regulations thereto are as follows:

- Section 55 of the Act states that no tissue, blood, blood product or gametes may be removed from the body of another living person without having obtained the written consent thereto from that person. This consent is to be given "in accordance with the prescribed

[681] 61 of 2003.

[682] Jordaan "Human reproductive cloning: A policy framework for South Africa" (2002) 119 *The South African Law Journal* 294.

[683] *Ibid* at 303-304.

[684] 61 of 2003.

[685] *Ibid*.

conditions," these prescribed conditions then being established through further regulation. It is submitted that the conditions pertaining thereto establish a similar prescribed form to be filled out by the donor, whilst being overseen by the person collecting the genetic material, as can be found in annexure A and B of the Regulations under Choice on Termination of Pregnancy Act.[686] Such a prescribed form will establish a base level of information that has to be shared with the patient regarding stem cell research and would avoid possible disputes on the scope of consent in the future.

- Section 56(2)(a)(iv) of the Act places a prohibition on the removal of stem cells and the tissue from which stem cells can be derived. The only method in which to proceed with such research would be to obtain ministerial authorisation thereto in terms of section 56(2)(b). It is submitted that regulations be promulgated that establish an exact application process as well as the requirements that need to be met when ministerial authorisation for the removal of stem cells or the tissue from which stem cells can be derived, is sought. These regulations would also assist the health research ethics committees at later stages in evaluating stem cell research practices, since it would already establish a level of compliance that needs to be met in order to commence with research.
- The definition of "blood products" as provided in section 1 of the Act does not specifically include stem cells. On the other hand, a reading of section 56(2)(a)(iv) together with section 56(2)(b) is interpreted as to include stem cells under the scope of blood products, whilst sections 68(1)(f), (g) and (p) describe stem cells as falling outside the scope thereof. It is submitted that a correction be made to the definition of "blood products" in section 1 as to include stem cells. This inclusion will then render any further reference to stem cells in section 68 unnecessary and can be omitted, unless the legislator also inserts a section that is only applicable to stem cells and not to blood products in general. The current content of section 68 only appears to make

[686] 92 of 1996" as published in GN R168 in *GG* 17746 of 31 January 1997.

reference to stem cells in cases where reference is also made to blood products. However, a further clarification of section 68(1)(c) is necessary due to its reference to “cells” in general. It is unclear whether the legislator was referring only to the removal of stem cells, or all types of human cells.

- Section 56(6) of the Act provides for definitions of reproductive and therapeutic cloning. Within those definitions reference is made to the “manipulation of genetic material.” It is submitted that a definition of “genetic material” be inserted in section 1 of the Act in order to provide for a clear interpretation of the scope of the abovementioned cloning practices.
- Section 57(2) allows for therapeutic cloning using umbilical cord stem cells. This permission to proceed with therapeutic cloning has to be done with ministerial consent, and under such conditions as may be prescribed. It is submitted that a fixed set of base level conditions that have to be met before an application is made for consent to commence therapeutic cloning using umbilical cord stem cells be established through regulation. Such a set of conditions will provide guidance for prospective researchers as well as ensure that a certain level of legitimacy and oversight in the research practices is met.
- The Minister can make further regulations pertaining to stem cells in terms of section 68 of the Act. It is submitted that clear regulations be promulgated which indicate the route that private companies must take to obtain licences, import and export permits, as well as how to meet further obligations pertaining to their facilities in cases where they are simply proposing to obtain, store and supply umbilical cord stem cells for possible future use in medical endeavours.
- Although section 56(2) of the Act makes reference to the use of adult or umbilical cord stem cells in therapeutic cloning and section 56(4) allows for research to be conducted on embryos which are not more than 14 days old, no mention is made to the allowance or prohibition of practices in which embryos are created for the sole purpose of them being used in research. It is submitted that such a provision be added

to the Act in order to clarify any possible misconceptions surrounding the scope of possible therapeutic cloning practices.

- In terms of section 73(2), health research ethics committees have to review research proposals and protocols in order to ensure that "research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases" and grant approval for this proposed research in cases where research proposals and protocol "meet the ethical standards" of that health research ethics committee. Although it does not strictly fall within the scope of further legislative or regulatory action that can be taken, it is submitted that the health research ethics committees, in conjunction with the National Health Research Ethics Council, submit a document that stipulates the scope of these "ethical standards" that have to be met. It can only be in the best interest of both these oversight mechanisms as well as the individual researcher if the ethical criteria to which the research is subjected is public knowledge.

These proposed changes, regulative guides, and further comment on the National Health Act[687] attempt to address areas of concern that could have an effect on the successful application of stem cell research practices in future. It has already been stated earlier that the Act establishes a sound framework within which similar healthcare technologies can reach new levels of application whilst still being subject to effective oversight. However, upon examining the requirements for stem cell research in detail it becomes clear that the abovementioned recommendations are essential in settling not only legal, but also certain ethical concerns.

6.4 Conclusion

The conclusions of academic publications usually contain some or other witticism uttered by another author of similar persuasion, said witticism then

[687] 61 of 2003.

fully encompassing the importance of the innumerable previous pages as well as the effort that went into clarifying the concepts discussed therein. However, upon examining stem cell research, one is forced to concede that there are no appropriate quotes available that can describe the impact that stem cell research is already having, and still will have, on global healthcare.

Stem cell research and its possible areas of application is enormous in scope, not to mention the countless hours of joy provided to ethicists who seem to surround themselves with vague terminology whilst reasserting the fact that the moral objections to these types of endeavors are too grave to mention. The obstacles posed by ethicists are, to a certain extent, being re-evaluated by legal philosophical scholars and positioned as an ethically concise version of the *boni mores* pertaining to stem cells within the current legal framework. Similar to a bright beacon of light within an ocean of chaos, the National Health Act[688] establishes a firm position that protects both scientific and ethical interests whilst providing for clever legal oversight. The Act itself is attentive of international considerations pertaining to the field and also establishes regulatory bodies similar to those that have been proven to be effective in Foreign Law. Other areas of law, such as Intellectual Property, Human Rights, Legal Philosophy, further Medical Law aspects and the Common Law provide ample support in addressing any legal and ethical issues that may arise from stem cell research.

Baring certain modifications to the abovementioned legislation, it is relatively safe to conclude that stem cell research is legitimate in theory and that the application thereof in practice will cause no damage to that fact. The future is the only indicator of whether stem cell research will become a medically and financially lucrative enterprise within South Africa. Further advances in the field of stem cell research, as well as genetic engineering in general, will also determine the effectiveness of the current legal framework. With sufficient attentiveness to new developments in those areas, the scope for adaptation according to global and national ethical standards leaves enough room for a

[688] 61 of 2003.

just and legitimate approach thereto for many years to come.

Stem cell research is the new alchemy, but instead of turning lead into gold it is turning researchers into miracle workers, and redefining the boundaries of medical intervention. The excitement that is surrounding stem cell research is sometimes overwhelming, but becomes justified when compared to its incredible potential.

Glossary

Definitions and terminology[689]

Stem cell research is a fairly complex field of biomedicine. It is sometimes a hard task for legal persona to accurately interpret documents pertaining to stem cells without some sort of medical background. The following glossary is compiled from numerous documents addressing the issues. The majority of the definitions are medically related and universally accepted as being a just description thereof. With regard to legal definitions, referrals are primarily to the South African Law, unless otherwise indicated.

AAAS. American Association for the Advancement of Science. (United States of America)

Adult stem cell. Stem cells found in the adult organism (for example bone marrow and skin) that replenish tissues in which cells often have limited life spans. They are more differentiated than embryonic stem cells or embryonic germ cells.

Autologous transplant. Transplant using tissue from the same individual, or a twin.

Allogeneic transplant. Transplant using tissue from a donor individual not genetically identical to the recipient.

[689] Due to the complexity of the medical terminology involved, a large amount of the definitions has been borrowed from the following paper produced by the American Association for the Advancement of Science, working in conjunction with the Institute for Civil Society in the United States of America: Chapman AR, Frankel MS & Garfinkel MS (1999, November) "Stem Cell Research and Applications – Monitoring the Frontiers of Biomedical Research" Produced by the *American Association for the Advancement of Science and Institute for Civil Society* 31-33. The glossary provided for in Holland *et al* (2001) 243-245 provided some usefull insight into some of the principles as well. Furthermore use has been made of the definitions provided in the following South African legislation: the National Health Act, 61 of 2003, the Human Tissue Act, 65 of 1983, the Choice on Termination of Pregnancy Act, 92 of 1996, the Child Care Act, 74 of 1983, and the Mental Health Care Act, 17 of 2002.

Autoimmune diseases. A constellation of different diseases all characterised by the failure of the body to distinguish “self” from “non-self” causing the body to attack its own tissues.

Blastocyst. A pre-implantation embryo of 30 -150 cells. It consists of an outer layer of trophoblast to which is attached an inner cell mass.

Blastomere. One of the cells into which the egg divides after it is fertilised.

Blood product. Any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells (in terms of the National Health Act[690]).

Cell lines. Cultures of disaggregated tissue that can be maintained and propagated for use in research. The length of time cells will survive in culture varies. Some cell lines are immortalised; that is, they can be maintained essentially indefinitely, for one of a variety of reasons. Embryonic stem cells and embryonic germ cells are immortal because they express telomerase, one of the factors necessary for cells to propagate normally.

Child. Any person under the age of 18 years.

Chimera. An individual organ, or part of an organism consisting of tissues of diverse genetic constitution (for example the result of using animal egg cells and human sperm cells in the therapeutic cloning process).

Clinical trial. Research to test the safety and efficacy of new treatments or to compare the effects of different treatments in patients or healthy volunteers.

Communicable disease. A disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host.

Cryopreservation. The process of freezing biological materials in such a way that they can be stored for long periods of time, and then thawed for use.

Diploid cell. A cell containing two complete sets of genes derived from the father and mother.

[690] 61 of 2003.

Ectoderm. The outermost of the three primary layers of an embryo; produces the nervous system, the epidermis and epidermal derivatives, and the lining of various body cavities such as the mouth.

Ectopic tissue. Tissue that has formed abnormally temporally or spatially.

EG cells. Embryonic germ cells. These cells are found in a specific part of the embryo/foetus called the gonadal ridge, and normally develop into mature gametes.

Embryo. Organisms in the early stages of growth and development. In animals, embryos are characterised by the cleavage of the fertilised eggs to many cells, the laying down of the three germ layers, and formative steps in organ development. Although there is some discussion about the characteristics marking the switch from embryo to foetus, in human beings, "embryo" generally refers to the time from implantation to about eight to twelve weeks after conception. In terms of the National Health Act[691] it is only known as human offspring after the first 8 weeks from conception and not the first 12 weeks.

Embryonic stem cell research. See definition provided under "foetal tissue research".

Endoderm. One of the three primary layers of an embryo; it is the source of the digestive tract and other internal organs.

ES cells. Embryonic stem cells. Cells that are derived from the inner cell mass of a blastocyst embryo.

Eukaryotic. Organisms composed of cells that have a nucleus (i.e., the nucleus, where the genetic material resides, is separated from the rest of the cell, called the cytoplasm, by a complex membrane called the nuclear envelope).

Foetal tissue research. Research conducted in this manner is done on an embryo/foetus that is already dead, for instance during procedures using aborted foetuses. Distinguish this procedure from human embryonic stem cell research where the research conducted leads to the destruction of the embryo.

[691] 61 of 2003.

Foetus. Organisms in later stages of development. In human beings, approximately eight to twelve weeks after conception.

Gamete. General term describing either of the two generative cells necessary for human reproduction.

Gene therapy. The use of genetic material, usually DNA, to correct inherited or accumulated genetic damage.

Genome. The complete genetic code for any individual or species.

Germ cells. Cells comprising actual reproductive components of an organism (specifically, eggs and sperm, and their precursors).

Gonad. A human testis or human ovary.

Health research. In terms of the National Health Act[692] it includes any research which contributes to knowledge of-

(a) the biological, clinical, psychological or social processes in human beings;

(b) improved methods for the provision of health services;

(c) human pathology;

(d) the causes of disease;

(e) the effects of the environment on the human body;

(f) the development or new application of pharmaceuticals, medicines and related substances; and

(g) the development of new applications of health technology.

Haematopoietic stem cell. Refers to a particular kind of stem cell that can restore blood.

HERP. Human Embryonic Research Panel (United States of America).

Immortalized cell line. See Cell lines.

Informed consent. Autonomous authorisation of a medical invention or involvement in research based on substantial understanding. The two main pillars upon which informed consent rest are knowledge and appreciation of the specific procedure proposed.

In vitro. Refers to processes taking place in test tubes or similar containers.

In vivo. Refers to processes taking place in an organism.

[692] 61 of 2003.

IVF. In vitro fertilisation. A procedure during which male and female gametes are brought together outside of the human body to form an embryo.

Medical practitioner. A person registered as such under the Medical, Dental and Supplementary Health Service Professions Act[693].

Mental illness. A positive diagnosis of a mental health related illness in terms of accepted diagnostic criteria made by a mental healthcare practitioner authorised to make such diagnosis (as specified in the Mental Health Care Act[694]).

Mesoderm. One of the three primary layers of an embryo; produces muscle, bone, and other related tissues.

Mesenchymal stem cell. A particular kind of stem cell that may give rise to tissues of mesodermal origin, including muscle, bone, and related tissues.

Minor. Any person under the age of 21 years.

Monoclonal antibodies. Antibodies produced in the laboratory by specialised cells called hybridomas. The important features of these antibodies include their specificity of binding to a single antigen (protein), the ability to produce them in unlimited amounts, and their homogeneity. These antibodies have proven to be very useful in the detection of several diseases (including, but not limited to, cancer and various viral infections) and in therapy (for certain cancers).

National Health Council. The Council established by section 22(1) of the National Heath Act.[695]

National Health Research Committee. The Committee established in terms of section 69 (1) of the National Health Act.[696]

National Health Research Ethics Council. The Council established by section 72 (1) of the National Health Act.[697]

NBAC. National Bioethics Advisory Commission (United States of America).

NIH. National Institute of Health (United States of America).

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[693] 56 of 1974.

[694] 17 of 2002.

[695] 61 of 2003.

[696] *ibid.*

[697] *ibid.*

Oocyte. A developing human egg cell.

Organ. In terms of the National Health Act[698] it means any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete.

Pluripotent. Referring to cells able to give rise to virtually any tissue type, but not to a functioning organism.

Preimplantation embryo. An embryo before it has implanted in the uterus. The term is commonly used to refer to IVF embryos before they are transferred to a woman's uterus.

Primordial germline cells. The source of embryonic germ cells. In normal development, these are the cells that give rise to eggs or sperm (gametes).

Private health establishment. A health establishment that is not owned or controlled by an organ of state.

Provincial department. The department responsible for rendering health services within the provincial sector of government.

Recombinant DNA. Molecules that are constructed outside living cells by joining natural or synthetic DNA segments in such a way that they can replicate in a living cell (the replicative products are also considered to be recombinant DNA).

SCNT. Somatic cell nuclear transfer. Procedure through which spare embryos can be created. These embryos, however, are not genetically unique as is the case with embryos created through IVF.

Somatic cells. Refers to cells of the body excluding germ (reproductive) cells.

Stem cell. In general, a cell with the capacity to divide indefinitely, and to produce distinct differentiated tissue.

Termination of a pregnancy. The separation and expulsion, by medical or surgical means, of the contents of the uterus of a pregnant woman.

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[698] *ibid.*

Tissue. In terms of the National Heath Act[699] it means any human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete.

Trophoblast. The outer layer of cells of the mammalian blastocyst that gives rise to the placenta.

Totipotent. Refers to cells able to give rise to virtually any tissue type and, in some cases, as shown experimentally in mice, to a functioning organism.

Zygote. The product of the union of a male and a female gamete. This definition overlaps with that of the broader term “embryo” which will be more frequently used.

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