

Stem cell research

Is South African law locking progress?

By Yda van Aartsen

On 15 April 2013 it was reported that a researcher in the United States of America (USA), Dr Atala, announced that he had made a breakthrough in his research and is now able to grow an entire new organ requiring only a collagen frame filled with stem cells (Harold Maass 'Growing rat kidneys in a lab: Are human organs next?' (<http://theweek.com/article/index/242746>, accessed 31-1-2014)). Although this was achieved using a kidney from a rat, Dr Atala reported that this technique could be used to grow fully functional human organs from scratch. This scientific breakthrough may result in many lives being saved around the world, since there will, for example, be no need for dialysis patients to wait for a compatible organ to be donated and these organs would not be rejected by the body ('Lab-made rat kidneys raises hope for dialysis patients' *Reuters*, 5-4-2013, www.foxnews.com/health/2013/04/15/lab-made-rat-kidneys-raise-hopes-for-dialysis-patients/, accessed 31-1-2014).

Imperative to this scientific breakthrough is funding and legislation regulating the research and industry. Essential to be noticed is that legislation in South Africa is currently not capable of regulating the organ-growing research industry. The current National Health Act 61 of 2003 is not up to date with international developments and does not enable patients in South Africa to benefit from the advantages of the research.

In this article I will summarise the technique of organ growing, the ethical implications thereof, the formation of regulating legislation, the battle to obtain funding for the research, and the position in the USA and South Africa relating to this type of research and recent developments.

Organ-growth technique

The technique described by Dr Atala involves a rat kidney being washed of all cells, to leave only a residual collagen framework. This framework is then filled with embryonic stem cells (ESCs). ESCs are the fundamental cells in a fertilised embryo that can differentiate and grow into any human tissue (pluripotent ESC). Adult stem cells, however, are multipotent and are only capable of producing cells belonging to the specific tissue type that they form part of. The ESCs then grow inside the collagen framework to form a new functional kidney capable of producing rudimentary urine (see *Reuters* article above).

To have all these advanced developments in the organ-growing field made possible, funding and regulating legislation are needed.

Legislative regulation of the research internationally

Human stem cell research is a very controversial subject as some of the research methods used involve the destruction of human embryonic cells to create a human ESC line. This is also the reason why stem cell research is still a much debated issue, even in the USA where this regenerative research with stem cells has reached an advanced stage. Due to the fact that an embryo is considered an early aged human life, there are groups that are concerned about the ethical implications of the research and that it might be conceived as murder.

The creation of US legislation to patent these existing ESC lines for research and funding was an uphill battle, which was eventually won after ten years in 2012, when judgment was delivered in *JL Sherley and Others v K Sebelius and Others* (Cov. No. 1:09-CV-01575 (DDC)). In this case the appellants were researchers in the field of adult stem cells who opposed the use of federal funding for the development of embryonic stem-cell research, challenging it to be against the restrictions in the Dickey-Wicker amendment. (This amendment prevents federal funding for the creation of new stem cell lines by known methods.)

The defendant-scientists argued that researchers might not be free to create new lines of stem cells with federal funding, but President Obama's policy allows federal funding to be used for research involving existing stem cell lines, as well as any further lines created using private funds or state-level funding (Lucas Mlsna 'Stem cell based treatments and novel considerations for conscience clause legislation' (2010) 8(2) *Indiana Health Law Review* at p 471) (<http://journals.iupui.edu/index.php/ihlr/article/viewFile/2020/1894>, accessed 31-1-2014). This funding made the breakthrough in the organ-growing research field possible (Peter Aldhous 'Obama lifts research restrictions on embryonic stem cells' (2009) *New Scientist* (www.newscientist.com/article/dn16728-obama-lifts-research-restrictions-on-embryonic-stem-cells.html, accessed 31-1-2014).

This case was decided on appeal on 24 August 2012, where the appeal court for the district of the Colombia circuit decided that government funding may be used for this stem cell research because it involves the use of existing embryonic stem cell lines, and would not jeopardise or destroy any other embryonic stem cells or human life.

It was during President Bush's term in office that the Stem Cell Research Enhancement Act 2007 was passed. In 2009, President Obama removed the restriction on government funding for stem cell research. President Obama then signed the Omnibus Appropriations Act of 2009, which still contained the long-standing Dickey-Wicker provision of 17 years. Existing stem cell lines may be used for this type of research. This reasoning played a role in the court's decision in the *Sherley* case as well as the order by President Obama in 2009, which read that researchers may 'support and conduct responsible, scientifically worthy human stem cell research, including human ESC research, to the extent permitted by law'.

Further statistics by Kathleen Stassen Berger in *The Developing Person Through the Life Span* 7 ed (New York: Worth Publishers, 2007) show that about a third of zygotes do not implant after conception. This effectively means that there are many zygotes that are lost, which could then be used for embryonic stem cell research and treatments. A 'cell line' is created when a non-fertilised human ovum is transplanted with a cell nucleus from a mature human cell and thus involves the process of changing the genetic composition of the cell. Before all the debates regarding this research, approximately 21 stem cell lines had been created with this method. These existing stem cell lines are used for any further research. Many articles were written explaining the research and funding issues, for example, James A Baker 'Stem Cell Research in the Courts: *Sherley v Sebelius*' (*Baker Institute Policy Report* – Published III Institute for Public Policy of Rice University (2012) January 50 at pp 1–2). In this article the comprehensive utilisation of existing stem cell lines are described.

The other crucial international case that recently decided whether this type of research can continue is *International Stem Cell Corporation v Comptroller General of Patent* (CH/2012/0488, 2013 EWHC 807 (Ch), 2013 WL 1563061), which was decided on 17 April 2013 in the Court of Justice of the European Union (CJEU). There was a similar question regarding two patent applications for stem cells used in research, and whether it contravenes the 'Biotech Directive' (para 3(d) of sched A2 implementing art 6(2)(c) of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions). The point was made that no part of the human body at any stage may be patented as prescribed in para 6 of this directive. The court found in its conclusion of this matter that the stem cells used was not able to develop into human beings and that these cells

should not be excluded from being patented (this refers only to the ESCs that is derived from existing stem cell lines). It was emphasised by the court that this decision will be limited to pluripotent stem cells only.

This battle of more than ten years has led the way to potentially saving millions of lives around the world. These ESCs can be used to grow different organs for transplantation. Although still an expensive procedure, patients will not have to wait for a suitable donor of an organ anymore. In South Africa, the legislature will have to amend the National Health Act and other legislation according to these international developments in order to enable South Africans to also benefit from these scientific breakthroughs and to obtain organs for transplantation.

Legislation in South Africa

Although breakthroughs have been achieved in the US, South Africa is still a long way from using these methods to save the lives of thousands of South Africans who desperately need organs for transplantation. Not only do we not have the facilities or funding for this human stem cell research and organ-growing methods, South African legislation has a *lacunae* that does not provide for these types of methods to be used.

The Human Tissue Act 65 of 1983 was repealed by the new National Health Act 61 of 2003, which became operational in 2005. Chapters 8 and 9 became functional in 2012, which provides for regulations on blood, blood products and gametes from living and dead persons. The new provisions have widespread implications for doctors assisting patients or their relatives with tissue donations, organ transplants and donations of human bodies or tissues, revocations of donations, and the confidentiality of donations.

According to s 60 of the National Health Act, it is illegal for any money to be paid for organs to be grown, other than for the physician doing the transplant and transplant costs. Already in November 2003, this dilemma was described in the *South African Medical Journal* in an article by KS Satyapal and AA Heffeejee titled 'Commerce in organs – an ethical dilemma' (2003) 93 (11) *SAMJ* 844. Although this article focused on organ trading on the black market, the same argument can be used with regard to buying organs grown by the new technology. Advanced research methods in the health care system and development of technology have left the National Health Act and also some other South African statutes outdated and out of touch with current medical research.

The most important observation to be made about the National Health Act is the fact that it is outdated when considering the latest research, techniques and developments in the areas of organ growth and stem cell therapy. This effectively means that South Africans will not be able to gain advantage or access to these new developments, techniques, research and methods. For example, s 56 of the National Health Act prohibits the removal of placental stem cells. Manipulation of any genetic material or reproductive cloning of a human being is also prohibited in s 57.

At a conference on 21 August 2012 themed 'Legal aspects relating to the application of Biotechnology', presented by Prof Pepper, director of the Institute for Cellular and Molecular Medicine at the University of Pretoria's Department of Immunology: Faculty of Health Sciences, the *lacunae* in the National Health Act, and the fact that the Act does not make provision for the complex changes and advancements of science and technology were discussed ('Does SA human tissue legislation in South Africa need to be self-regulated') (<http://www.unisa.ac.za/news/index.php/2012/08/does-sa-human-tissue-legislation-need-to-be-self-regulated/>, accessed 31-1-2014). Two totally unregulated areas in the National Health Act are cell therapy and transplantation in South Africa. The legislation in South Africa does not cater for the advances in research and organ-growing technologies, which now provide complete replacement organs being grown for humans.

Prof Pepper emphasised the legal and ethical grey area in the National Health Act and other legislation. Legislation is a very important component of the regulation of the use of the human body or body parts, new medical developments, and research on human subjects. Despite the implications of revolutionary scientific developments, the South African parliament struggled to create a principled framework for biomedicine and research. There are no binding norms, regulations, standards and guidelines from the Department of Health for operational requirements on a daily basis. These were left to professional bodies to cultivate their own norms and standards (Emeka P Amechi 'Regulating developments in embryonic stem cell research in Africa: A third person's perspective' (2007) 15 *African Journal of International Comparative Law* 85).

The future

The waiting time, costs and risks for donated organs can be reduced significantly or even eliminated if patients can grow new organs from their own genetic material. For this, stem cells are necessary. The road is still very long for South Africans to be able to obtain the benefit of this as legislation and regulations need to be adjusted to accommodate new developments in the medical field and keep stride with international trends.

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