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STS perspectives on the components of innovation in human embryonic stem cell research: A US case-study

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Abstract:

The focus of this paper is on the commercialisation of human embryonic stem cell science in the United States. Breaking this down into the individual components of innovation enables the identification of the ways that human embryonic stem cell science moves from the laboratory into the market-place. This paper aims to develop a specific theoretical view as to how current STS scholarship on stem cell science might inform a critical analysis of the stem cell bioeconomy.

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Introduction:

Human embryonic stem cell research is time-consuming, expensive and technically demanding. At minimum, transforming basic scientific research into viable therapeutic applications relies on significant amounts of funding and the resources and infrastructure to conduct quality research. Translating basic research into saleable products also depends on rigorous clinical testing and, ultimately, consumer demand. Long lead-times in product development and as yet unresolved scientific uncertainty further complicate the path to therapeutic applications.

The United States is one of the dominant players in the global stem cell economy. A large private science sector, a skilled scientific workforce, deep financial markets and a strong intellectual property regime gives the US stem cell industries significant leverage over those in other nations. This paper will present an analysis of the components of innovation in the commercialisation of human embryonic stem cell science in the US. The overall aim is to understand how the translation of scientific knowledge about embryonic stem cells into commercial products occurs and how the social studies of stem cell science can illuminate this process.

Innovation policy components and human embryonic stem cell science

The development of scientific and technological products for the market is not a linear process. Commercialisation relies on a complex network of elements that provide the right conditions for the translation of scientific and technological knowledge into marketable products. Writing about the commercialisation of university-based research, Brian Rappert and Andrew Webster explain that:

> It is necessary to see commercialisation in terms of socio-technical, organisational and political dynamics which enable social actors to stabilise and secure knowledge in ways that will render it appropriable and exchangeable. We must look, in other words, at the ways in which a structure of appropriation is built by social actors. (2002:2)

Which is to say; scientific and technological knowledge become commodities in the most basic sense through the operation of the social and political structures which create them. Human embryonic stem cells, for example, are simultaneously technical, social, political and economic entities created by the institutions through which they circulate. As such, the creation, distribution and use of stem cells in

the global economy are subject to a wide-range of regulatory and organisational factors governing their transition from invention to product.

Moreover, these factors will differ across regions, industries and countries (Webster 2000: 3). There is increasing pressure on states to maintain national competitiveness and capitalise on the market potential of science and technology (Cerny 1997). Given this, developing policies to enhance national innovation systems and thus, national competitiveness '…has been a defining feature of the modern state' (Webster 2004: 9). Understanding the innovation system and what the significant factors are for a specific region and industry highlights the socially, politically and economically contingent nature of how scientific and technological knowledge can be translated into products for the market. In the case of human embryonic stem cell research, this has significant implications for the future development of the industry and how nation-states compete in the global bioeconomy.

Following Salter (2007a), the components of stem cell innovation broadly fit into five categories: science, market, consumer confidence, regulation and global governance. The first category, science, covers the extent of R and D investment, how science is organised, the supply of materials for conducting research and the labour pool. The second category, market, refers to issues of ownership, intellectual property, public-private partnerships, availability of venture capital, the success of small biotechnology companies, and the involvement of large pharmaceutical companies. Consumer confidence is the third category and envelops the strength of industry practices around the supply and storage of materials (including good cell practice), the conduct of basic science (good laboratory practice), trust in the procedures and results of pre-clinical and clinical trails (good clinical practice), and reliability in the manufacture of cell products (good tissue practice and good manufacturing practice). The fourth category, regulation, examines how cultural values affect the development of ethical positions and legal frameworks in relation to stem cell science. The fifth and final category concerns the impacts that global governance regimes like TRIPs (Trade Related Intellectual Property), TRIMs (Trade Related Investment Measures) and GATTs (General Agreement on Tariffs and Trade) have on the conduct of stem cell science.

The commercialisation of human embryonic stem cell science is particularly affected by several major factors. These include: the supply of oocytes and embryos for research; the availability of skilled researchers to conduct research; intellectual property regulations;

public and private investment strategies; the standardisation of procedures for retrieval, storage, supply and use of human embryonic stem cells; and regulatory frameworks about what kinds of research can be conducted (Salter 2007a). These factors are also affected by state reaction to the global knowledge economy, the situation of states within this international framework, and how states intervene in the commercialisation process in order to enhance their position within the global knowledge economy (Salter 2007b).

The US position within the knowledge economy is based on the model of 'the competition state' (Waldby 2005; Dickins 2006; Salter 2007b). How different states respond to the demands of the global knowledge economy can be classified in a number of ways; the competition state is one of many possible positions adopted by states in the knowledge economy (Salter 2007b). Competition states aim to facilitate conditions of innovation in such a way that innovation becomes self-sustaining (Salter 2007b: 5-8). Consequently, what we see with human embryonic stem cell research in the US is that regulation is aimed at the market and primarily focuses on the supply of products. State intervention in the commercialisation process in the US is thus limited to regulating intellectual property, standardising production mechanisms, encouraging financial investment and the ethical conduct of clinical research. The overall agenda of human embryonic stem cell research in the US is to maximise the market potential of therapeutic applications of human embryonic stem cells and facilitate the market dominance of US-led research and development.

The next part of this paper will outline the structure of human embryonic stem cell research in the US. Breaking down the US human embryonic stem cell economy into the components of innovation outlined above demonstrates the pathways to commercialisation. This innovation framework allows a finer grained understanding of how human embryonic stem cell research is developing in the US and how it has become a multi-billion dollar industry within the global knowledge economy.

Stem cell research in the United States:

Most stem cell research in the US focuses on the use of adult or non-human stem cells, with only eight companies (two public and six private) engaged directly in human embryonic stem cell science (Biophoenix 2006). Human embryonic stem cell research in the United States is primarily conducted in small to medium sized, and one or two

bigger biotechnology companies. Some universities also conduct HESC (NIH Stem Cell Information 2006) and the US-based pharmaceutical companies are becoming increasingly interested in the field too (Regalado 2005). Five of the eight US based companies working on human embryonic stem cells are aiming towards therapeutic applications, with the first clinical trials approved in 2005 (Biophoenix 2006: 83). Current products derived from human embryos on the market are mainly for use in diagnostics. As yet, there are no therapeutic products derived from human embryos available in the US.

Regulation is the most contentious of the innovation components in the US stem cell economy. There are no federal laws that specifically govern the field of human embryonic stem cell science in the US other than the 2001 decision to limit public funding. On the 9th of August, 2001, President Bush declared that federal funding would only be given to human embryonic stem cell projects which use cell lines that met certain criteria. Specifically, this meant that publicly funded research could only be conducted using the stem cell lines already in existence at the time the announcement was made, that were derived from excess IVF embryos, and were produced with properly informed consent (NIH Stem Cell Information 2006). Since 2001 though, some states have made their own laws regarding both the regulation of research and the use of public funds. There are seven states that are in favour of embryonic stem cell research and have earmarked substantial state funding for research (California, Illinois, Virginia, New York, New Jersey, Connecticut, Massachusetts), and five states are specifically against any research on embryos or foetuses (South Dakota, Minnesota, Oklahoma, Pennsylvania, Louisiana) (Washingtonpost.com 2005). Other states with legislation in place fall somewhere in between, with different regulations about what kinds of research can be conducted and the use of public funds. The vast differences within the state legislation that does exist makes it exceptionally difficult to compare regulatory regimes. A list of the most recent legislative developments in the US can be found on the National Conference of State Legislatures web-site (http://www.ncsl.org/programs/health/genetics/embfet.htm).

The development of a regulatory framework for human embryonic stem cell science in the US has been undoubtedly shaped by the moral, political and social climate as much as the scientific or commercial situation. The human embryonic stem cell debate in the US has been fundamentally affected by right to life organisations, church groups, political parties and patient advocacy groups. In a country with a long and bloody history of abortion politics, the debate

over human embryonic research is not surprising: 'Stem-cell research is irretrievably linked with the abortion debate and probably always will be' (Wertz 2002: 676). President Bush has exercised considerable discretionary power in decision-making about human embryonic stem cell research during the terms of his office, as have some Governors in the individual states of the Union. This makes the US quite unique in the global stem cell bioeconomy, with individuals wielding more power than elsewhere in the world.

The fact that individual states in the US are making their own laws with regards to human embryonic stem cell research is significant. The National Institute of Health is the main source of funding for biomedical research in the US and the limitations on federal public funding for human embryonic stem cell research have had a major impact on the kinds of research that can be conducted. Given that human embryonic stem cell research is a multi-billion dollar industry, individual states are keen to enhance their overall economic competitiveness by supporting this field of research in particular. Consequently, some of the US states have adopted the 'competition' model response to the global knowledge economy (Waldby 2005; Dickins 2006; Salter 2007b) outlined earlier. California's Proposition 71 is the most progressive of the state positions, directing a staggering three billion dollars of public monies over ten years to human embryonic stem cell research and establishing the California Institute for Regenerative Medicine (CIRM) (Holden 2004; Lysaght 2005). This is '…the biggest-ever state-supported scientific research program in the country' (MSNBC.com 2004). The Californian commitment to human embryonic stem cell research, along with other state-based initiatives, reflects the economic expectations that surround the stem cell industries.

Human embryonic stem cell science in the US is organised through academic, business and personal networks, with no centralised structure. There is no central licensing regime or regulatory body with central oversight over the use of human embryos in research in the US like there is in Australia (Harvey 2005) or the UK (Salter and Salter 2005). The National Academy of Sciences has produced guidelines for the conduct of human embryonic stem cell research in the absence of other federal oversight (Marwick 2005; National Research Council and Institute of Medicine of the National Academies 2005 and 2007), yet these guidelines have no enforceability in any way beyond what individual institutional review boards might decide. Given this, human embryonic stem cell science in the US could be said to have an ad hoc organisation, with individuals, groups, and companies purely reliant on

business, academic and personal relationships coupled with entrepreneurial skill. Adult and foetal stem cell research in the US is similarly organised, although discussion of these is outside the scope of this paper.

There are various different formal networks in the US that facilitate interactions between researchers, venture capitalists and others. Such networks might consist of stem-cell researchers, biotechnology companies, venture capitalists, patient-activist groups and trade organisations. A few examples include: BayBio; Coalition for the Advancement of Medical Research (CAMR); Bay Area Start-up Network (BASN); Alliance for Stem Cell Research (AFSCR); and the Stem Cell Action Network (SCAN). There are also different government initiatives in place that aim to provide business development support in the states where biotechnology is heavily concentrated (Herrera 2005; Wilan 2005; BIO 2006). Such support might include facilities, managerial expertise, legal advice, and/or networking opportunities.

The extent of how funding is directed within the US stem cell economy is almost impossible to determine. US science has been historically notable for its considerable focus on state supported basic research (Bush 1945). Yet the limitations on public funding for human embryonic stem cell research in the US have ensured that it is almost entirely driven by private investment. In general terms, this also means that basic research has to be seen to have some clinical promise and be geared towards translation into commercial products. Overall, US human embryonic stem cell research must be commercially viable and become a locally sustainable industry. The US biotechnology sector has operated a business model along these lines since Genentech emerged in the 1970s (Robbins-Roth 2000). Biotech business is based on developing cutting-edge research for the market, either in the form of clinical products or patentable techniques and processes (Robbins-Roth 2000). Like the early days of US biotechnology, the speculative nature of human embryonic stem cell research, the difficulty and the expense of the research and the uncertainty of any commercial success makes it a high-risk venture for private investment. Increasingly, government funded research is also being expected to produce marketable products; a shift that has developed in response to changes in science policy during the Reagan administration, the transformation from Fordist to post-Fordist modes of production, and an explicit emphasis on technology transfer within the university system since 1980 (Cooper 2007a; Zeller 2005). This emphasis on commercial viability means that both basic and translational research must have marketable promise. There is no

extant data on the division between basic and translational research in the US, yet high commercial expectations and the lack of public funding threaten to undermine the long-term successfulness of human embryonic stem cell research because of a perception that basic research will be ignored in favour of producing marketable products (Herrera 2005; Levine 2005; Spar 2004; Martin et. al. 20060.

Identifying where research materials come from is also complicated. Publicly funded researchers can only use a limited range of cell lines. The NIH Stem Cell Information web-site hosts the 'NIH Human Embryonic Stem Cell Registry', which is a list of the providers of federal sanctioned stem cells, including the National Stem Cell Bank at the University of Wisconsin-Madison (http://www.nationalstemcellbank.org). The National Stem Cell Bank offers reduced fees for university-based research and would seem to be the most viable option for publicly funded researchers. In private research however, materials can come from anywhere. Private companies or non-federally funded researchers have few restrictions on them regarding the use of materials. Regulation in this area is limited to the ethical use of human subjects in research (i.e. the suppliers) and best practice regarding the cells themselves. Private researchers may be using overseas sources or networks within the US to obtain the necessary materials, but this is almost impossible to determine without further empirical research. Some evidence points to poor populations in Boston and Silicon Valley and students from nearby Ivy-league schools being used as resource pools for the stem cell industries via paid oocyte donation (Waldby 2006a; Waldby and Cooper 2007). Paid oocyte donation has been acceptable practice in the US IVF industries for some time and redeploying this supply for the research market appears to pose few problems (Waldby 2006b).

The availability of labour has become a significant issue within the US stem cell industries. Scientists who would ordinarily have stayed in the US have left the country to conduct their research elsewhere. The reasons for this are varied. Lack of support and opportunities in the US have been cited by some. Another reason is that sophisticated stem cell research industries in countries outside the US have attracted people with US qualifications back to their countries of origin (eg. India and China) (Salter, Cooper, Dickins, Cardo, 2007; Salter, Cooper, Dickens, 2006). The suggestion has also been made that changes to immigration policy post-9/11 meant that overseas born nationals who might have stayed in the US after their training and taken up scientific careers, are now forced to go back to their countries of origin (Florida 2004). One commentator has even gone as far as to suggest that the

controversy around stem cell research means that young scientists have chosen other research fields (Herrera 2005: 776). US policy towards fixing the labour supply problem typically focuses on encouraging more people into careers in science and engineering, starting with giving all school age students better and more diverse science education (*American Competitiveness Initiative* 2006).

One of the more notable changes in the science innovation system over the last 30 years has occurred in the emphasis on transforming basic research into commercial products. The US science innovation system is currently heavily structured around recouping costs through commercialization (Sorrett, Rabinow and Billings 2003). In general terms, increased international competition in the late 1970s and changes in intellectual property law in the early 1980s (Chopyak and Levesque 2002) substantially altered the science-industry relationship and turned US science into a profit oriented project like any other. Indeed, the US stem cell industries have been driven by a perception that there are potentially highly lucrative markets in the area. The exact nature of how lucrative these markets are expected to be however, is a matter of some considerable discussion (Salter 2007b).

The market components of the US innovation system are in some respects well-known. Large reserves of financial capital, significant state funding and a robust intellectual property regime have substantially contributed to the dominance of the US in the global biotechnology economy over the last 30 years. This economic strength has filtered through to the more recent stem cell industries (Wilan, Scott and Herrera 2005). Yet at the same time, the speculative nature of stem cell research makes it difficult to pinpoint the exact degree to which the US is dominant in the global stem cell economy. Conflicting assessments of the future markets for stem cell based products and the political sensitivity of the issue renders the real future potential of human embryonic stem cell research indeterminable (Salter 2007b). In other words, the promise of stem cell research is staked on the *anticipation* of substantial future markets (Salter 2007b). Some commentators warn however, that the US is set to lose market dominance in the stem cell bioeconomy. This appears to be based on a range of factors, at least one of which involves concerns about intellectual property (Giebel 2005; Kintisch 2006; Taylor, Scott and Greely 2006; Anonymous 2007; Holden 2007; Opar 2007).

A robust intellectual property regime around biotechnology emerged in the US in the early 1980s. The Bayh-Dole Act of 1980 coupled with the Stevenson-Wydler Act the same year radically changed the terrain

around what could be patented. The main intention with these Acts was to '…promote widespread utilization of federally-sponsored inventions' (Rai and Eisenberg 2003: 290) by giving university based researchers and federally funded research institutions ownership rights over patentable products. Thus a new era of commercial incentive in state-funded research began. Philip Cooke argues (2001) that the success of biotechnology in the United States is based on an aggressive approach to sourcing and exploiting university-based research by venture capitalists – such as happened with Genentech - and that this model of VC-university collaboration was accelerated by the Bayh-Dole Act (271-274).

Furthermore, the 1980 Supreme Court decision in *Diamond v. Chakrabarty* that 'anything under the sun that is made by man' is eligible for patent protection also changed the US intellectual property regime (Rai and Eisenberg 2003). The *Diamond v. Chakrabarty* case determined that patent rights could be extended to genetically modified micro-organisms. This decision set a precedent that allowed human embryonic stem cells to be considered patentable, a situation which has greatly enhanced the commercial prospects within the US stem cell economy. In effect, patenting makes cell based entities into more clearly defined products that can be bought and sold. Stem cell patenting is not consistent around the world, with US patents not necessarily enforced elsewhere (eg. Herder 2006; Gill 2007; Baldock 2006; Salter 2007c). Even within the US, some key patents have been called into question over their validity (Taylor, Scott and Greely 2006; Anonymous 2007; Kitisch 2006; Opar 2007; Holden 2007). Three of the Wisconsin Alumni Research Foundation (WARF) patents are the most well-known examples of the ongoing debate over intellectual property (Rabin 2005). The WARF patents are extremely broad, and cover a significant amount of current research practice (Waldby 2006a; Rabin 2005). High licensing fees for their use and broad reach-through rights on products developed from them are argued to be unnecessarily hindering the progress of US stem cell research (Taymor, Scott and Greely 20006; Anonymous 2007; Kitisch 2006; Waldby 2006a; Opar 2007; Holden 2007). Two consumer groups in the US (the Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights) legally challenged the WARF patents in 2006 with a preliminary ruling from the US Patent and Trademark Office in 2007 supporting their claim (Simpson and Davicher 2007; Holden 2007). A final decision is pending (Holden 2007).

Information on the other market components of innovation in the US is harder to come by. Only two of the eight companies cited in the report

referred to earlier (Biophoenix 2006) are publicly listed, whilst the other six are privately owned. The two public companies are Advanced Cell Technology Inc. and Geron Corp. Of the private companies conducting human embryonic stem cell research in the US, there is less information. Stem Cell Therapy International was founded with capital from the Australian Global Capital Corporation. Stem Cells Inc has shares in UK based ReNeuron and signed over some of its intellectual property to the Canadian company Stem Cell Therapeutics Corp. Apart from these few examples, data on ownership, partnerships and funding arrangements is indeterminable.

There is also some indication that large pharmaceutical companies in the United States have been conducting in-house human embryonic stem cell research (Regalado 2005). The big pharmaceutical companies have generally stayed away from stem cell research because of long delays in getting products to market and the high level of uncertainty around the successfulness of stem cell derived therapies (Martin et. al. 2006). But it would seem that this situation is slowly changing. In the US, Becton, Dickinson and Company, GE Healthcare and Johnson and Johnson are all working with human embryonic stem cells (Regalado 2005). Swiss-based Novartis also have plans to conduct human embryonic stem cell research in the US (Regaldo 2005). Becton, Dickinson and Company has licensed ES Cell patents from WARF; GE Healthcare is working on drug screening; and Johnson and Johnson has an equity stake in Novocell. Significantly, Martin et. al. argue that without the collaboration and investment of big pharmaceutical companies, such as occurs elsewhere in biotechnology, innovation in the stem cell industries is likely to be held back (2006: 806).

In sum, the market components of the stem cell innovation system are hard to pinpoint. The most obvious aspect of the market in the US is an intellectual property regime that has facilitated broad patenting of stem cell products. Intellectual property ownership is the driving force behind investment in human embryonic stem cell research and consequently, commercialisation (Salter 2006c). With limited public funding of research in the US, patent rights become particularly significant in developing the human embryonic stem cell economy. Overseas patent regulations - which are very different to the US - also impact on the commercial success of US stem cell research.

The next component of the innovation system is that of consumer confidence. Produced by the standardisation of industry practices, consumer confidence builds trust in the stem cell economy (Salter

2007a). Standards that apply to human embryonic stem cell research include: Good Clinical Practice, Good Manufacturing Practice, Good Tissue Practice, and Good Laboratory Practice. Developing these guidelines is a process that does require a centralised structure, or at least some agreement about industry bench-marks. In the United States, the Food and Drug Administration (FDA) is responsible for setting standards and regulations in relation to '…the production and marketing of any stem-cell based therapy involving the transplantation of human cells into patients' (Halme 2006: 1730). The FDA has Good Tissue Practice rules which cover all human cells, tissues, and cellular and tissue-based products (www.fda.gov/cber). The FDA also has Good Manufacturing Practices guidelines for medical devices (www.fda.gov/cdrh). The Department of Health and Human Services has produced the 'Guidance for Investigators and Institutional Review Boards Regarding Research Involving human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles' that contains a list of the relevant guidelines affecting stem cell research in the US (Office for Human Research Protections 2002). In addition, any research using human subjects comes under the jurisdiction of the Department of Health and Human Services regulations for human subjects (OHRP 2002). Given all this then, it would be fair to say that in the US consumer confidence is produced through a complex array of regulations designed to ensure that human embryonic stem cells in use and in circulation adhere to rigorous clinical, ethical and scientific standards.

And finally, the last of the innovation components addressed here is how the US situation is located from the perspective of global governance. The US is a signatory to the major international agreements TRIMs, TRIPs and GATTs that all have ramifications for different components of the innovation system. There is no extant literature on how any of these agreements relate to human embryonic stem cell research, but it could be argued that as they favour the US in any case, the effect would in fact, be negligible. In other words, given that such agreements were written with US interests in mind (eg. protection of US industries, property rights and investments) (Salter 2007c), the current approach towards human embryonic stem cell research will remain as is.

It is worth noting however, that whilst the United States undoubtedly has some significant global strength within the biotechnology sector, this dominance is not clear within human embryonic stem cell research. A climate of fear and uncertainty (Resnik 1999) combined with excessively restrictive funding regulations around human

embryonic stem cell research – plus the undoubted success of other countries in the same arena - has meant that the US is at risk of losing its market dominance within this field. In terms of international agreements then, the emphasis on protecting US industries from outside influence may be more detrimental rather than beneficial in the case of human embryonic stem cell research.

There is a legitimate need for more specific forms of international agreement around stem cell science. It has been widely documented, for example, that an internationally robust ethical regime needs to be established (eg. European Union; the Hinxton Group; the International Society for Stem Cell Research; Resnik 2004). It is further argued that an international stem cell agreement would also facilitate greater international collaboration between researchers currently affected by conflicting legislative frameworks (Resnik 2004). In addition, an international agreement specifically about stem cells would provide a clearer intellectual property framework than is currently provided by TRIPs (Resnik 2004). Although the issues of stem cell research and human cloning have been debated at the UN for a number of years, the UN's recent declaration lacks any real legal force. The EU is in the process of developing a coherent and legally binding framework.

Overall, the US human embryonic stem cell economy is weaker than it could be due to a lack of public funding, competition from overseas markets, and patenting problems strangling local competition. On the plus side, US economic dominance means that companies are always going to be interested in developing a US base in order to access stronger financial markets, more private investment, and the possibility of conducting relatively unrestricted human embryonic stem cell research. Access to research materials (eg. oocytes) and a large pool from which to find suitably qualified research labour are also significant draw-cards for conducting human embryonic stem cell research in the US.

The social studies of stem cell science

This section of the paper will turn to addressing some of the theoretical interventions that have been made into understanding the stem cell bioeconomy from a Science and Technology Studies perspective. The social studies of stem cell science has become a fast growing sub-discipline within Science and Technology Studies and can be broken down into four main categories. These categories are as follows:

feminists and others, public engagements, social anthropology and commercialisation.

The first of these categories, feminists and others, refers to a specific body of work that focuses on the materials used for human embryonic stem cells: where they come from and the political implications of how they are derived. The kinds of questions feminists and others ask about embryonic stem cell research include: what are the psychological, physical and emotional implications of being the suppliers of material to stem cell research? The exploitation of female junior research associates in the Hwang affair, for example, clearly demonstrates the need for an analysis along these lines. Beyond explicitly woman centred approaches, other theoretical intervention from the social studies of science explores the questions about identity and difference that are raised by the promise of human embryonic stem cells.

The second category engages with media studies scholarship, social movement theory and policy studies to examine how human embryonic stem cell science is thought about and regulated within different communities. Public engagements follow a strong tradition of public understanding of science (PUS) within science and technology studies, whilst also displacing many of the assumptions that underpin such an approach. This branch of the social studies of stem cell science demonstrates that there are diverse stakeholders within a fluid and dynamic public arena interested in this debate.

Social anthropological accounts of human embryonic stem cell science comprises the third category of the schema presented here and focus on the specific ways that it has come into being and how it works. Social anthropological accounts of human embryonic stem cell science also adopt an approach developed in Science and Technology Studies, but with some innovative variations. Social anthropologists study human embryonic stem cells and the meanings that are created around them from institutional perspectives: for example, in the laboratory, the clinic or the legislature.

The fourth and last category comprises the commercialisation experts, who examine the different outcomes of the progression of stem cell science into the market place. For example, the commercialisation of human embryonic stem cell science has implications for public trust in science (Chalmers and Nicol, 2003). Also, the market success or failure of stem-cell technologies says much about the market-science relationship (Martin, Coveney, Kraft, Brown, Bath, 2006).

With its focus on commercialisation, this paper is initially oriented towards the last of these categories. Yet it also aims to find some way of drawing the disparate bodies of social studies of stem cell science together, with a particular interest in human embryonic stem cell research. Taking as a reference point the components of innovation discussed previously, the rest of this paper aims to examine how the social studies of stem cell science can be used to inform the development of a theoretical approach to understanding the human embryonic stem cell bioeconomy.

Feminists and Others:
Of the feminist scholarship within the social studies of human embryonic stem cell science, Donna Dickenson's (2006) argument about the supply of oocytes for research is significant. Dickenson has famously argued that donating oocytes to research is akin to live kidney donation: that is, being an egg donor is technically difficult, medically risky and has potentially long-term implications for the donor. Dickenson argues that women are erased from the stem cell question and that women's labour in supplying ova should be considered a necessary, valuable and productive part of stem cell research, either commercial or humane. Furthermore, Dickenson suggests, women should be protected by contracts which view consent as contingent and relational in terms of ova supply, not straightforward contracts typical of capitalist patriarchy.

Building on Dickenson's argument about the exploitation of women mandated by altruistic donation regimes such as apply in the case of IVF and stem cell research, Catherine Waldby and Melinda Cooper (2007) turn their attention to a detailed study of women's labour in the stem cell economy via the practice of *paid* oocyte donation. For Waldby and Cooper, women's labour in the stem cell economy is structurally and politically parallel to women's labour in the sex industry. Given these parallel's, and building on Marxist-socialist feminist arguments that sex-work is work in the most ordinary of senses, Waldby and Cooper suggest that better safe-guards and more political power be given to women who choose to sell their eggs. The current situation of poor women from the global south being exploited for the reproductive and medical services of the global north is an untenable one, and Waldby and Cooper, following Dickenson, argue that it could be remedied by treating the supply of oocytes along with other reproductive materials and services as work.

Alongside these explicit arguments about mitigating the effects of the stem cell industry on women, other significant work in the social studies of stem cell science also fits this feminist remit by exploring the impacts that stem cell science has on human identity in general. Important research within the social studies of stem cell science focuses on the transformations that have occurred with concepts and practices associated with materiality as a result of this new development in biomedicine.

For example, Catherine Waldby (2002) argues that stem cells have moved from being ordinary parts of the body to precious commodities containing 'biovalue', where '[b]iovalue refers to the yield of vitality produced by the biotechnical reformulation of living processes' (310). Moreover,

> [human embryonic s]tem cell technologies are…particularly productive sources of biovalue precisely because they can rehabilitate what would otherwise be needless waste and transform it into a spectacularly active, flexible and manageable tissue resource. (Waldby, 2002: 313)

The re-organisation of life and its redirection into a *resource* for the industries of biotechnology, biomedicine and bioscience is a function of biovalue. In *Tissue Economies* (2006), Waldby, with Robert Mitchell, demonstrates how the production of biovalue results in the formation of entire economic systems of production and exchange around any number of human tissues. For Waldby and Mitchell, this fundamental transformation in how tissues are valued has resulted in significant social, political and economic impacts on traditional models of medical diagnosis, research and treatment.

In engaging with this question of how market forces have impacted on contemporary biomedicine, Melinda Cooper (2006a) argues that stem cell science has substantially altered the boundaries between life, death and the market. For Cooper, stem cell science facilitates a restructuring of the categories of normal, human life such that long-established criteria of living bodies are becoming undone. Cooper argues:

> …stem cell research homes in on points of non-coincidence between ageing in general and the body's multiple reserves of renewable tissue, uncovering a kind of latent 'surplus' life, even in the most worn-out bodies… (2006a: 3)

This idea of 'surplus' that Cooper identifies here challenges traditional notions of the human body as whole, complete, bounded and finite. Stem cell science reconfigures the notion of vitality as something not limited by the physical limitations of the natural, normal human body.

Furthermore, Cooper argues, reconfiguring the body this way fundamentally alters the basic market relationship. Cooper writes:

> …for the commercial life sciences, including the pharmaceutical sector, what counts is no longer the scale and volume of the market in tangible bio-commodities, but rather the speculative accumulation of a future 'innovation' value – a surplus of life, information and profit. (2006a: 11)

Stem cell science opens the discrete categories of the body to market forces that trade not on an exchange of body parts, but on the future potential that can be gained from harvesting and developing these components into something else (Cooper 2006a: 16).

Eugene Thacker extends these kinds of viewpoints about the transformation in biomedical science further to argue that biotechnology is a posthuman industry (2003). In Thacker's words:

> Biotech is not to be confused with bioengineering or prosthetics; that is, biotech is not about interfacing the human with the machine, the organic with the nonorganic. Rather, biotech is about a fundamental reconfiguration of the very processes that constitute the biological domain and their use toward a range of ends… (2003: 94)

Thacker argues here that contemporary biotechnology such as stem cell science creates a radically new and different view of what bioscience can do to the body. For Thacker, stem cell science fundamentally reinvents materiality such that the biological becomes completely reconstituted. It is important to note though that this is not an absolute transition: the posthuman does not displace or replace the human. As Thacker states:

> …the posthuman wants it both ways: on the one hand, the posthuman invites the transformative capacities of new technologies, but on the other hand, the posthuman reserves the right for something called "the human" to somehow remain the same throughout those transformations. (2003: 94)

In terms of stem cell science, Waldby's (2002; 2003), Cooper's (2006a; 2006b) and Thacker's (2003; 2002) ideas about the transformations taking place through biotechnology render the category of the human quite problematic. The biological uniqueness of stem cells has quite particular social, political and economic implications. Whereas more traditional feminist arguments focus on how the bodily labour of women is used to generate human embryonic stem cells, these other viewpoints focus on how stem cells understood as products made via the labour of the body have consequences for traditional notions of bodies and identities.

Public engagements:
This category of social studies of stem cell science focuses most explicitly on the ways that human embryonic stem cell science is experienced within the broader community. Chris Ganchoff (2004) argues that human embryonic stem cell science should be understood as a 'field of biotechnology' (758). Ganchoff's analysis demonstrates the varied ways that different stakeholders are engaged in stem cell science. In Ganchoff's terms:

> Actors take part in social movements as patients, supporters/opponents and citizens, among other categories, and this … analysis has demonstrated how each of those categories is important in struggles over potential identities and futures. (2004: 769)

Ganchoff's concept of the 'field of biotechnology' is useful for understanding the range of social and political action around human embryonic stem cell science as part of a coherent sphere of public interaction.

For example, Tamra Lysaght, Rachel Ankeny and Ian Kerridge (2006) conducted a news analysis of the development of California's Proposition 71 and found that:

> …arguments that might have been expected to dominate the discourse surrounding stem cell research, specifically those relating to the moral status of the embryo, in fact did not. Indeed, no single issue dominated the discourse. (116)

This is an intriguing finding given that much media and academic analysis about the pros and cons of stem cell research has used the destruction of embryos in the process of conducting research as the main argument mobilised against stem cell research. Lysaght et. al.'s findings suggest instead that the reactions against stem cell research focused on the lack of any benefit for embryonic stem cell research as opposed to other avenues, like adult stem cell research (2006: 116).

This is an intriguing result that highlights Ganchoff's idea of a 'field of biotechnology' and how the terrain can change. Another study by Clare Williams, Jenny Kitzinger and Lesley Hendersen (2003) on how the embryo was situated in the debate about stem cell research in the UK in 2000 found quite different results. They write:

> The stem cell debate was framed as, above all, a controversy about the status and the potential of the embryo (rather than other potential controversies such as the validity of the science per se or the context in which it was being realised). (Williams et. al. 2003: 796)

Williams et. al. further argue that the embryonic stem cell debate was constructed in oppositional terms: on one hand, embryonic stem cell research was regarded as '…an abuse of embryos which set dangerous precedents' (797), and on the other hand, the benefits were seen to outweigh the costs (2003: 797). Also, Williams et. al point out: the women who produced the oocytes that resulted in embryos were entirely erased from the debate (2003: 807). They argue that the embryos at the centre of the debate would appear to apparently emerge from thin air, with the women who produce them marginalised in any media coverage (Williams et. al. 2003: 807).

This discrepancy between the embryo focus of the stem cell debate in the UK in 2000 found by Williams et. al. (2003), and the findings by Lysaght et. al. (2006) that the embryo was no longer the significant concern when debating California's Proposition 71 four years later is interesting. It suggests on the one hand, that there are profound disagreements over human embryonic stem cell science in the UK and the US. On the other hand, it also suggests that public concerns about stem cell research are changing quite significantly. In either case, this difference shows that community responses to biotechnology are localised and specific responses to particular developments within the field. In other words, that the 'field of biotechnology' (Ganchoff 2004) around human embryonic stem cell science is not static.

Social Anthropology:
The next category of social studies of stem cell science is one of the largest in the field. Social anthropology in this field identifies emerging social relations within the stem cell economy. Sarah Franklin argues, for example, that with the advent of human embryonic stem cell research and the emphasis on using excess or spare IVF embryos only for this kind of research, embryos can now be considered to have a 'double value' as both reproductive and therapeutic material (2006). In this paper, Franklin studies the clinical settings and the decision-making processes that go into deciding how an IVF embryo – potentially a desperately wanted child – becomes excess or spare and subsequently transformed into valuable therapeutic material. Franklin's ethnography demonstrates that this transition is a complex one, and is far from simply determined by an agreement to donate embryos to research.

Peter Glasner (2005) has looked at how research materials are generated and stored, with a specific focus on stem cell banking. Glasner argues that:

> …embedded in the transnational movement of tissue, stem cells and scientific expertise between North and South, there is a technoscape in motion (Appadurai, 1996). This fluid global configuration of technology, high and low, mechanical and informational, that now moves at high speeds across various kinds of previously impervious boundaries, has facilitated the rapid growth of the 'supply chain' of stem cell technology from embryo to potential therapeutic application. (2005: 363)

For Glasner, stem cell banking is a complicated process of standard-setting within a globally diverse moral economy around stem cells. The UK Stem Cell Bank in particular must become '…an institution capable of successfully standardizing procedures for use by laboratories, clinics, patients, pharmaceutical companies and fiscal, scientific and regulatory interests' (Glasner 2005: 359). Put another way, for a stem cell bank to be the pre-eminent source of stem cells and obviate the sourcing of cells from anywhere else, it has to be able to successfully influence the production of standards.

Steve Wainwright, Clare Williams, Mike Michael, Bobbie Farsides and Alan Cribb (2006) examine in what contexts and how basic research in stem cell science is transformed into potential clinical applications. The researchers follow the progressive development of stem cell therapies from their initial development in the laboratory right through to the final applications as patient treatments and how clinical results inform further research: in other words, they follow the bench-to-bedside relationship (Wainwright et. al. 2006). Wainwright et. al. write: '…while there is a plethora of ethnographies that focus on either the bench or the clinic, few social research studies have examined *both* the bench and the bedside' (2006, my emphasis).

Nik Brown and Alison Kraft focus on the gaps between the expectations placed on stem cell science and the reality through a study of cord blood banking (2006). Given that there have been very few therapies developed from stem cells to date, Brown and Kraft are interested in how the hopes that are typically attached to stem cell science have been mobilised. The hope, or hype, as some might say, has been the driving force behind legislative development, public debate and substantial funding of stem cell science. Yet Brown and Kraft want to know: is this justified?

Alex Faulkner, Julie Kent, Ingrid Geesink and David Fitzpatrick (2004) use a classically anthropological analysis to unpack how Mary Douglas' concept of purity applies to the social study of stem cell science. Faulkner et. al. argue that purity is an important concept in stem cell

science, with serious implications for the success of experiments and clinical trials. Without pure populations of stem cells, for example, experiments can be rendered worthless, as impurities render scientific data meaningless. Purity in scientific research also applies to clinical trials – if data, sources, ethics procedures etc – are impure, then results are compromised and valuable time and resources wasted. Purity is therefore also an important concept to consider in terms of good manufacturing practice and standards of consent (Faulkner et. al. 2004).

From these few examples, it is clear that the social anthropological concerns of stem cell science are many. What is demonstrated by these analyses though is that stem cells, as relatively new objects of scientific and social experience, draw forth quite specific relationships between science and medicine. As a branch of contemporary medicine, stem cell science reconfigures the domain of possibility, practicality and safety that underpins traditional medical practice.

Commercialisation:
The final category of analysis within the social studies of stem cell science is focused on the relationship between science and the market. In a study of the impact of commercialisation in biotechnology on public trust in science, Australian law specialists Don Chalmers and Dianne Nicol (2004) write:

> …[the] elision between public and private biotechnology research has accelerated challenges to traditional core science values summed up by Robert Merton as "universalism, collegiality, disinterestedness and organised scepticism". The commodification of scientific knowledge is but one example of the entry of market rhetoric into previously non-commodified social and political institutions. (121)

Chalmers and Nicol mean here that contemporary biotechnology is a long way from the established model of what science should be, as documented by sociologist Robert K. Merton in the middle of the twentieth century. For Merton, science is supposed to operate as a not-for-profit institution, and scientists are meant to work co-operatively, openly and for the greater good (1942). Chalmers and Nicol argue however, that biotechnology and its marketisation has meant that science is no longer conducted in such a manner. For Chalmers and Nicol, one of the more serious impacts of this is a decline in how the public view scientific outputs and the practice of science as an authoritative institution.

Paul Martin, Catherine Coveney, Alison Kraft, Nik Brown and Philip Bath (2006) argue that now is second wave of stem cell innovation, with the first-wave actually occurring in the early 1990s in the United States. Pointedly, this first-wave of stem cell innovation was only notable because of its profound commercial failure (Martin et. al. 2006). Martin et. al. warn that the current commercial environment for the commercialisation of stem cell research is heading towards the same route. Martin et. al. write:

> …the commercial prospects for stem cell technologies remain highly uncertain and that innovative public policies should be adopted to prevent 'market failure'. (801)

The type of policies they suggest which might prevent such a catastrophe are based on already existing business models and place an emphasis on building public-private partnerships. Currently, there are only two main business models in the stem cell industry: one based on the production of novel therapeutics (autologous, allogeneic, cell growth factors) and the other focusing almost exclusively on tools and reagents (eg. cord blood banks). This limitation is potentially threatening to the long-term survival of the industry as:

> ...there is a real danger of 'market failure', whereby a number of potentially clinically important therapies are not developed owing to lack of commercial viability of investment. (Martin et. al. 806)

A 'new type of innovation model' would involve less reliance on government funding to develop innovative science and more opportunities for private companies to get involved with academic research.

Taking these two arguments together, a decline in the public trust in science, coupled with the all too possible market failure of viable therapeutics, opens up a space for the exploitation of the stem cell economy and the rise in commercially dubious products vying for market share. Chalmers and Nicol and Martin et. al. seem to be auguring for greater regulation of both the norms of science (understood here in the classical Mertonian sense) and the open encouragement of the shift towards commercialisation in new ways. In achieving both these outcomes, they argue, the potential for the stem cell economy to become the latest version of fool's gold could be prevented and a robust market for effective stem cell cures developed in its place.

Conclusion: the social studies of stem cell science and the components of innovation

Webster (2000) argues that there are four key factors that shape all innovative activities. The first is the social-technical practices and organisation of innovative activities. The second is that expectations associated with innovation have to be instituted across more than one organisation. The third factor is that management has to be aiming towards developing innovative activity well into the future. And the final factor is that there are specific organisational practices for governing innovation, which will be different depending on whether the organisation is publicly or privately funded. Michel Callon puts it another way:

> STS shows how successful technologies, in moving form 'invention' to 'innovation', depend on the mobilization and stabilization of social and material networks. (Callon, 1987, in Webster 2002: 447)

What then, do the social studies of stem cell science demonstrate about the innovation system of the US stem cell economy?

Human embryonic stem cell science makes a quite radical intervention into the science-market-medicine relationship (Salter and Salter 2005). Traditional commercial models that rely on drug discovery, development, testing and application are becoming increasingly complicated by the economic, social and political ties between people and biological products; legal, scientific and political instruments; and public engagements with medicine, regulation and community health. Changing norms of science, challenges to the expectations placed in medicine, and shifting understandings of what is possible for the natural, normal human body all affect how scientific knowledge about human embryonic stem cells is translated into commercial products.

First, and most obviously, concerns about the supply of material for research, coupled with the political sensitivity built up around the use of public funds for research on embryonic material in the US demonstrates that there are limits to how the body can be used as a resource for medical treatments. That is, what constitutes an appropriate resource for use in medical practice and how that resource might be deployed is clearly contested in the case of human embryonic stem cell research. This has always been the most contentious aspect of the embryonic stem cell research agenda. The global socio-ethical restrictions raised by the prospect of human embryonic stem cell research shows that the socio-political consequences of medical research have always been a significant focus of the debate.

This is nothing new. The discipline of medical ethics has always negotiated the boundary between fair and unfair practices in medicine (Salter 2007d). However the debate over embryonic stem cell research speaks to something else as well: that the premise of modern medicine might in fact be contested. Modern medicine operates on the assumption that more research will always equal better cures. Yet the disparity in beliefs about embryonic stem cell research across the US demonstrates that there are clear limits to where these cures should come from, raising the question that perhaps this model of medicine is open to debate. Played out within the stem cell economies then is a tension between the desire to use the healthy capacities of the body as a marketable resource for curing ill health, and the idea that the body is an inviolable unit of basic social coherence. As demonstrated by feminist and other perspectives from the social studies of stem cell science, the relationships between bodies, medicine and markets are being increasingly transformed by the possibilities opened up by human embryonic stem cell research.

Second, the market components of the innovation system in the US show how the speculative potential of stem cell science is the driving force behind the development of this field of biomedicine. This is true in the US in particular due to lack of widespread state backing. Elsewhere in the world state governments provide a high degree of support and administrative infrastructure that doesn't exist in the US. The US also has the strongest financial markets, such that any slack in government support can potentially be taken up by the private sector. The desire for market-share and profits out of this potentially lucrative business is the motivating element for the private sector.

Yet there are some flaws in a booming stem cell economy. The most obvious point is that therapeutic applications are a long way off and that their development relies on complex relationships between material supplies, financial flows, human capital and public expectations. Increasing emphasis on the commercial prospects of stem cells threatens to destabilise the whole endeavour through changing the practice of science altogether. In doing so, the relationship between science and medicine is potentially thrown into doubt and the future financial stakes in the stem cell economy increases in uncertainty. The most significant concern is the potential for 'market failure' (Martin et. al. 2006).

This uncertainty is highlighted through the social studies of science literature on public engagement and social anthropology. These two areas of inquiry show first, that the stakes are high in the stem cell

economy and second, that the terrain is open to contestation and disagreement. The social anthropological investigations into the nature of stem cells and the environments in which they are created show that stem cells are socially mediated entities that rely on the social relationships which bring them into being. Furthermore, the literature on public engagement demonstrates that these social relationships are always negotiable. Taken together these two perspectives make plain that stem cells are not produced in the laboratory and applied in the clinic. Stem cells are created through a diverse range of social fields that have significant effects on the kind of work that can be conducted in the laboratory or the clinic.

The ambiguity and doubt about what the future of stem cell research will be that is articulated through the disparate analyses of the social studies of stem cell science reinforce the concern that the stem cell economy might collapse under its own ambition. The science is still in its infancy, the industry is reliant on a sophisticated financial and regulatory infrastructure, the issue is politically sensitive, the evidence about the therapeutic value of embryonic stem cells is proving to take a long time to collect, and there is little indication of significant commercial success in the field. The social studies of stem cell science further demonstrate that the stem cell economy is based on an uncertain projection into the future and it opens up new modes of health, illness, embodiment and material exchange that are not easily reconcilable with the easy implementation of scientific knowledge into a marketable product. Nevertheless, the absence of state regulation in the US and the overall global strength of the US in the stem cell economy make certain that any prospective developments will be of significant interest to anyone interested in the future commercial success of the field.

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