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Constructing Regional Advantage for the Stem Cell Biotechnology Sector in Madison, Wisconsin, USA

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미국 위스콘신주 매디슨시 바이오산업의 지역우위 구축 과정: 줄기세포 분야를 중심으로

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Abstract : Built upon an evolutionary and institutional perspective on regional development, this article examines regionally 'constructed advantage' for the stem cell biotechnology sector in Madison, Wisconsin, USA. Constructed advantage can be defined as a regional development condition that is supported by local institutions and policy. For the understanding, the case study historicizes the development of University of Wisconsin-Madison as an 'entrepreneurial university' on the basis of 'The Wisconsin Idea' in the beginning, and then highlights the role of the university as the institutional foundation of knowledge generation and innovation in the city-region's stem cell sector. In addition, the study also outlines recent local and regional institutional development aiming at promoting the commercial use of stem cell technologies, with particular emphasis on state policy measures aimed to promote the commercial development of major progresses in stem cell research at the University. The article's findings suggest that the 'institution-technology' interplay be an important aspect of knowledge-based regional development, as well as the development of emerging technology.
Key Words : Biotechnology industry, Stem cell, Constructed advantage, Entrepreneurial university, Institution

요약 : 본 논문은 지역발전에 관한 진화 및 제도주의적 관점을 바탕으로 미국 위스콘신주 매디슨에서 줄기세포 바이오산업 분야에 '구성된 우위(constructed advantage)'를 검토하였다. 구성된 우위는 제도적으로, 정책적으로 마련된 지역발전의 조건으로 정의되고, 이를 살피기 위하여 우선 위스콘신주립대학이 '위스콘신 사상(The Wisconsin Idea)'을 바탕으로 '기업가 대학(entrepreneurial university)'으로 발전하는 과정을 역사적으로 탐구한다. 그리고 그러한 대학의 성격이 매디슨 지역에서 줄기세포와 재생의료 분야의 지식 생산과 혁신 창출에 중요한 제도적 근간이 되었음을 밝힌다. 한편, 줄기세포 기술 상용화를 촉진시키기 위하여 마련된 지역의 제도적 발전상도 기술하였는데, 특히 위스콘신대학에서 발생한 줄기세포 연구의 상용화를 촉진시키기 위하여 마련된 최근의 주정부의 정책을 강조하였다. 이를 바탕으로, 본 논문은 '제도-기술 상호작용'이 출현기술(emerging technology)과 지식 기반의 지역발전 분석에서 중요한 측면이 될 수 있다고 제시했다.
주요어 : 바이오산업, 줄기세포, 구성된 우위, 기업가 대학, 제도

Ⅰ. Introduction

Progress in human embryonic stem (hES) cell research since the mid-1990s holds the promise of regenerating damaged cells and tissues in the human body. Stem cell technology is hoped to play a role in curing chronic

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diseases such as diabetes, Parkinson's disease, heart disease, and spinal cord injury. Despite existing social concerns over the source and use of hES cells, many regions endeavor to utilize the nascent biotechnology for regional development. In the United States, for example, eleven states have implemented *regional* innovation policy supporting hES cell research by the end of 2009 (Stateline.org., 2008; McCormick *et al.*, 2009).[1] Korea also has a history of promoting the development of the hES sector as a *national* project until a series of Dr. Woo-Suk Hwang's human cloning success reports turned out to be fabricated experiments in 2007. As a result of such efforts, 190 stem cell companies have been established around the world until August 2016 according to biotechnology industry database company BioPharmGuy. However, given that still a number of preclinical research and clinical trials for cell therapy are underway (Trounson and McDonald, 2015), the stem cell biotechnology can be seen as an emerging technology at this time.

In this context, it is increasingly important for economic geographers to understand and explain how regions nurture such an emerging biotechnology sector. However, as Feldman and Lendel (2010) recently note, economic geographers pay little attention to the spatiality of *emerging* technological fields such as stem cell science. In addition, existing geographical studies have yet to delve into how biotechnology regions emerge and develop out of a specific segment of biotechnology. Instead, they tend to examine the role of broadly defined biotechnology sector in regional development. Some scholars have recently begun to examine the influences of knowledge specialization on the formation and evolution of biotechnology clusters (e.g., Cooke, 2005a; Coenen *et al.*, 2006; Gertler and Vinodrai, 2009), but they focus exclusively on similarities and differences between two sub-sectors of biotechnology (i.e., agro- food biotechnology versus health biotechnology) and stop short of specifying the sector further.[2]

In order to fill the research gap, this article examines the process of developing the stem cell sector in Madison, Wisconsin, USA. The significance of this case study lies in the fact that the University of Wisconsin-Madison

Fig. 1. Location of Madison, Wisconsin, USA

(UW-Madison) is "the birthplace of stem cell research" as former Wisconsin Gov. Jim Doyle (2006) proudly notes in a column contributed to *Wisconsin Technology Network News*. Indeed, Madison is the place where Dr. James Thomson, a development biologist at UW-Madison succeeded in isolating and culturing hES cells for the first time in 1998. While it remains to be seen whether and to what extent the hES cell technology helps economic development in Madison (*Wisconsin Technology Network News*, 2008), it is certainly true that many local and regional policymakers see the novel biotechnology as an important regional knowledge asset upon which their future economy is to be built.

Against this background, this article investigates regionally "constructed advantage" (De la Mothe and Mallory, 2004; Cooke and Leydesdorff, 2006) for stem cell biotechnology sector in Madison, a medium-sized city located in the American Midwest (Figure 1). The idea of constructed advantage underscores the importance of understanding the role of institutions and public policy in creating and maintaining regional advantage for the economy. In this

Table 1. Major Biotechnology Clusters in Midwest, USA (2016)

Rank	City	State	Biotechnology companies
1	Madison	Wisconsin	46
2	Indianapolis	Indiana	33
3	Ann Arbor	Michigan	32
4	St. Louis	Missouri	31
5	Chicago	Illinois	27
6	Cleveland	Ohio	23
7	Minneapolis	Minnesota	20
8	Cincinnati	Ohio	18
9	St. Paul	Minnesota	16
10	West Lafayette	Indiana	10

* Data : BiopharmGuy website, www.biopharmguy.com.

sense, it is distinct from Porter's (2008) "competitive advantage", a firm-centered conceptualization of regional advantage (Bristow, 2005; Asheim *et al.*, 2006). Given that the stem cell industry is still a goal rather than what is achieved (Backer and Deal, 2008; *Wisconsin Technology Network News*, 2008; OECD, 2009), the process of constructing regional advantage is a relevant analytical focus of the case study. Thus, built upon an institutional and evolutionary perceptive in the regional development studies (Amin, 1999; Martin, 2000; Cooke *et al.*, 2004; Asheim and Gertler, 2005), this article explicates the "path-dependent" development of stem cell sector in Madison.[3]

The stem cell sector is the primary focus in this article, but Madison's status in the U.S. biotechnology industry is noteworthy as an important context for this research article.[4] In the Midwest region (including Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska, Ohio, Wisconsin, Wyoming), the development of biotechnology industry is relatively weak in comparison to leading biotechnology "megacenters" (Niosi and Bas, 2003) in California and Massachusetts. In the database of BioPharmGuy that lists 4,228 biotechnology companies in the United States as of August 2016, and only 646 biotechnology companies are identified in the Midwest region. While no biotechnology "super"-cluster (such as San Diego and Boston) has emerged in the region, biotechnology firm formation is found to be most active in Madison that hosts 46 biotechnology firms including three stem cell companies (Cell Line Genetics, Cellular Dynamics International, and Stratatech).[5] As Table 1 shows, Madison has more biotechnology companies than much larger metropolitan areas such as Chicago, Minneapolis-St. Paul, and Cincinnati in the Midwest region.

Stem cell companies in the city have recently made important progresses not only in research and clinical trials, but also in investment gains. For example, induced pluripotent stem cells (iPSC) manufacturer Cellular Dynamics International (CDI), which was co-founded by Dr. Thomson in 2004 and named as one of 15 top U.S. biotechnology companies in 2008 by FierceBiotech, filed for initial public offering (IPO) in 2013 and has been acquired by Fujifilm Holdings in 2015.[6] Another Madison-based regenerative medicine company Stratatech specialized in human skin substitute was merged to the global organization of Millinckrodt, a Dublin-based specialty pharmaceutical company. These transnational merger and acquisitions suggest that Madison is becoming a globally connected biotechnology cluster, and that its strength in stem cell research and business makes an important contribution to this ongoing development. Given that both industry leaders in the global stem cell sector were emerged out of research at the University of Wisconsin-Madison, this city level case study may provide an important insight regarding the relationship between local university and

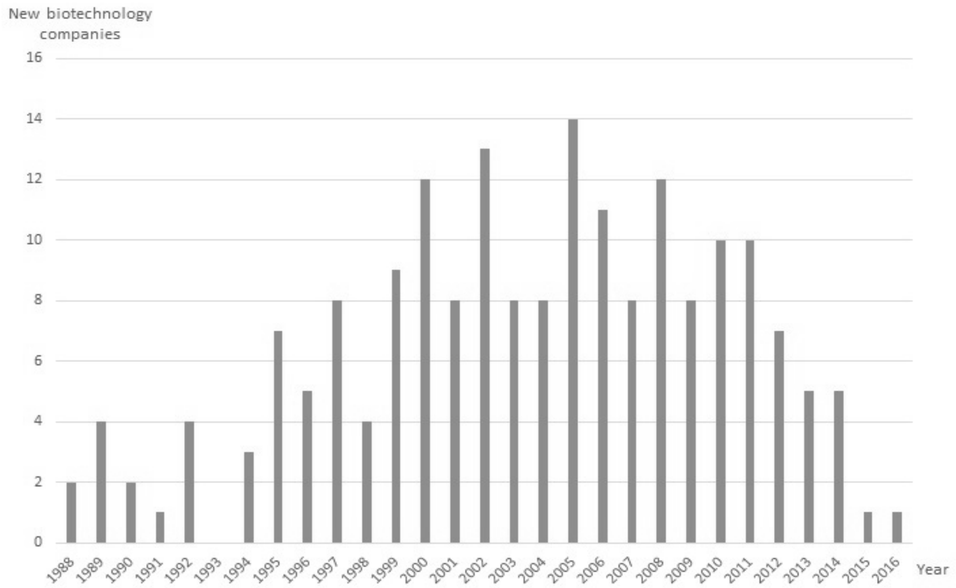

Fig. 2. New Biotechnology Companies in Madison by year (1998–2016)

global business. In this context, this article aims to report how Madison has emerged to an important node in the stem cell sector, and to do so it reviews local institutional assets and policy measures.

Due to space limit, this article does not provide a lengthy literature review in a separate section, and key theoretical and empirical insights which inform this case study are summarized in Endnotes at the end of this article (see Notes 2 and 3). The following sections are primarily focused on presenting empirical findings from the case study, which is based on an archival research carried out between 2005 and 2010. This period is very important to Madison's biotechnology industry because the current development is largely indebted to measures taken at the time and new firm formations in the biotechnology sector was most conspicuous as Figure 2 demonstrates. Evidence in this paper is mainly drawn from newspaper articles, magazines, institutional reports, and government documents, which the author collected at the time.

This article therefore is composed of five sections including these introductory comments. The next Section 2 outlines the U.S. federal regulatory framework that poses legal and financial constraints on hES cell research in Madison, and the subsequent Section 3 explains how local institutions in the city helped Dr. Thomson to overcome the regulatory hurdles, avoid associated uncertainties in his research, and ultimately make a major scientific breakthrough. This account is centered on the role of *academic entrepreneurship* promoted at UW-Madison in partnership with its technology transfer arm – the Wisconsin Alumni Research Foundation (WARF). The Section 4 shows the way in which the technological development has reshaped local and regional institutional environment. In so doing, the section highlights new state government initiatives and local institutions attuned to support stem cell research and bioscience in general. Finally, the final Section 5 synthesizes major findings in first three sections and outlines the implications of the case study on the institutional approach to the understanding of regional development. Most crucially, the concluding section places emphasis on the institution-technology interplay as an important aspect of examining knowledge-based regional development.

Table 2. Major Changes in hES Cell Research Policy in the United States, 1993–2009

Date	Events
June 1993	President Clinton and U.S. Congress enact the NIH Revitalization Act legalizing federal funds for human embryo research
July 1995	U.S. Congress passes Dickey-Wicker Amendment banning federal funds for research involving the creation and destruction of human embryos
January 1999	U.S. DHHS interprets Dickey-Wicker Amendment in favor of permitting hES cell research (hES cells "are not a human embryo")
August 2000	NIH publishes a new guidelines in accordance with DHHS's legal interpretation
August 2001	President Bush issues an executive order limiting the number of stem cell lines eligible for federal research funds (hereinafter "the 2001 ban")
July 2006	President Bush vetoes Stem Cell Research Enhancement Act lifting the 2001 ban
June 2007	President Bush vetoes Stem Cell Research Enhancement Act for the second time and issues an executive order encouraging adult stem cell research
March 2009	President Obama issues an executive order lifting the 2001 ban
July 2009	NIH releases new guidelines in accordance with Obama's executive order

* Compiled by the author from various sources.

II. A Turbulent Regulatory Environment for Stem Cell Research in the United States

In the U.S. federal system, local and state governments enjoy a relatively high level of political autonomy and policymaking authority. However, local actions and measures are limited by federal policy as well. Historically, as Shelley *et al.* (1996) note, federal regulations are enormously powerful at the local and regional levels if they are linked to the allocation of financial resources. For example, state governments could not help raising the drinking age to 21 after the U.S. Congress had passed a law limiting highway funds to states with younger drinking age in 1983.

Given that university-led biomedical R&D activities such as stem cell research are mainly funded by federal agencies (Moses III *et al.*, 2005), it is necessary to understand the nature of federal funding regulations in the beginning. The National Institutes of Health (NIH) is the key federal agency in charge of governing stem cell research in the United States.[7] Due to social controversy over the research such as ethical concerns over the destruction of early stage human embryos and the potential use of hES cells in human cloning (Monroe *et al.*, 2008), stem cell research policy at the NIH has been highly politicized and unsettled over the last two decades (Table 2).

In 1993, President Clinton and the U.S. Congress gave the NIH the authority to fund human embryo research for the first time. However, the legislation known as NIH Revitalization Act was soon overturned by 1996 Dickey-Wicker Amendment, which banned the use of federal funds for any research involving creating and destroying human embryos. Meanwhile, the Amendment could not illegalize hES cell research as a whole when Harriet Rabb, a senior lawyer at the U.S. Department of Health and Human Services (DHHS) released an official interpretation of the Amendment in 1999. The document states that hES cells "are not a human embryo within statutory definition" (PBS, 2005). This interpretation led the NIH to develop new guidelines outlining fundable stem cell research in 2000. Under the guidelines, federally funded researchers were allowed to utilize existing hES cells in research process but forbidden to derive stem cells from human embryos. Therefore, stem cell researchers had to seek private sponsors in order to extract hES cells.

The federal stem cell research policy became more restrictive during the George W. Bush Administration

(2001-2009). On August 9, 2001, former President Bush issued an executive order limiting the number of stem cells eligible for federal funds. In order to receive federal funds, researchers should use hES cells whose derivation process had already begun on or before the executive order's issue date. As a result, only 22 stem cell lines were eligible for federal research funds during Bush's presidency. Scientists and stem cell research advocacy groups criticized the restriction and lobbied the Congress to pass Stem Research Enhancement Act twice in 2006 and 2007, but Bush vetoed both bills intended to lift the 2001 ban. It was not until July 2009 that the restriction became ineffective in accordance with President Obama's executive order lifting the ban.

III. Putting the First hES Cell Discovery in its Place

"Scientists make science, but they do not do so entirely as they choose. Yet if scientific endeavor can yield true accounts about certain aspects of the world, it can do so only at particular times, in particular places, through particular procedures. This means that every aspect of science is open to geographical interrogation… There are always stories to be told of how scientific knowledge came to be made where and when it did." (Livingstone, 2003: 13-14, italic added)

On 6 November 1998, the journal *Science* reported Dr. Thomson's groundbreaking discovery of isolating hES cells from in vitro fertilized eggs and reproducing them (Thomson *et al.*, 1998).[8] It was hoped to enable regenerating malfunctioning cells and tissues in the human body and thus revolutionize transplantation therapies. Such an expectation led *Science* to name the hES cell discovery as the breakthrough of the year in 1999 (Vogel, 1999). More recently, *Time Magazine* (2008) citing Dr. Thomson's achievements in stem cell science named him as one of the world's most influential people in May 2008. His reputation still lasts in the field of stem cell research, such that he was named as the second most influential stem cell figure at the World Stem Cells & Regenerative Medicine Congress in 2013, only after Japanese physician and 2012 Novel Laureate Dr. Shinya Yamanaka who succeeded in identifying mature mice cells that can be reprogrammed to immature stem cells.

The rise of Dr. Thomson as a "star scientist" (Zucker *et al.*, 1998) is helped by a strong research base at UW-Madison. Indeed, the university, which hosts 2,175

Table 3. Top Five Research Universities in the United States, 1990-2008 (R&D experiments in millions of dollars)

Rank	1990	1992	1994	1996	1998	2000	2002	2004	2006	2008
1	JHU	JHU	JHU	JHU	JHU	JHU	JHU	JHU	JHU	JHU
	($669)	($736)	($784)	($798)	($854)	($901)	($1,140)	($1,375)	($1,500)	($1,680)
2	MIT	MI	MI	MI	MI	WI	UCLA	UCLA	WI	UCSF
	($312)	($393)	($431)	($469)	($497)	($554)	($788)	($773)	($832)	($885)
3	MI	Stanford	WI	WI	UCLA	MI	MI	MI	UCLA	WI
	($311)	($368)	(393)	($413)	($447)	($552)	($674)	($769)	($811)	($881)
4	WI	WI	MIT	WA	WI	UCLA	WI	WI	MI	MI
	($310)	($353)	(364)	($406)	($444)	($532)	($662)	($764)	($800)	($876)
5	Stanford	MIT	A&M	MIT	WA	WA	WA	UCSF	UCSF	UCLA
	($300)	($324)	(356)	($381)	($432)	($529)	($627)	($728)	($796)	($871)

* Source : Derived from Academic R&D Expenditures (1992-2010) available at National Science Foundation website

**Acronyms : A&M = Texas A&M; JHU = Johns Hopkins; MI = Univ. of Michigan; MIT = Massachusetts Institute of Technology; Stanford = Stanford Univ.; UCLA = Univ. of California, Los Angeles; UCSF = Univ. of California, San Francisco; WA = Univ. of Washington; WI = Univ. of Wisconsin-Madison

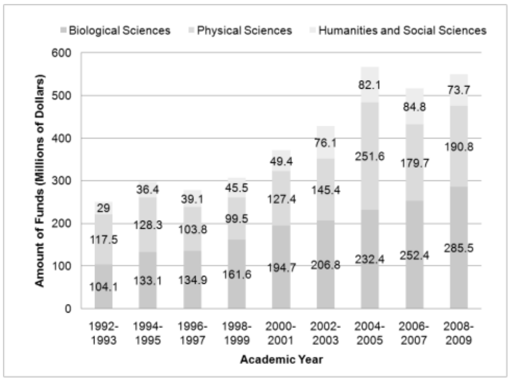

Fig. 3. Annual extramural research funds awarded to UW–Madison by discipline since the 1992–1993 academic year

faculty members and 11,756 graduate-level students (UW-Madison, 2010), has been a prominent academic R&D performer in the United States. As the Table 3 below demonstrates, the university has been a consistent top-five U.S. research university since the early 1990s. UW-Madison also exhibits strength at biological sciences (including agriculture, health and medicine, and veterinary science). As Figure 3 illustrates, the amount of extramural research funds in biological sciences has steadily increased at the university since the early 1990s while other disciplines experiencing the periods of ups and downs.

In addition to human and financial resources, UW-Madison also has a long tradition of academic entrepreneurship which promotes the commercial use of academic knowledge. Such a legacy was crucial to the 1998 discovery of hES cells. The remaining of this section examines UW-Madison as a what Etzkowitz (2002) calls "entrepreneurial university", and then highlight it as a key institutional foundation of knowledge generation and innovation in Madison's stem cell biotechnology sector. In a broad sense, an *entrepreneurial university* refers to a higher education institution involved in entrepreneurial activities such as patenting, licensing, creating new firms, establishing incubators and science parks, and facilitating regional economic development (Rothaermel *et al.*, 2007).

The tradition of academic entrepreneurship at UW-Madison dates back to 1925 when the Wisconsin Alumni Research Foundation (WARF) was established as the university's independent technology transfer arm. When Dr. Harry Steenbock, a biochemistry professor found a method to enrich vitamin D in foods and drugs in 1924, he decided to patent the discovery and wanted to assign the patent to UW-Madison. However, social norms at the time were against patenting university research, such that colleagues at UW- Madison criticized his intention and UW Board of Regent finally refused to handle the patent (Apple, 1989). At the time, in addition, there was no formal law legitimizing patenting public research such as Bayh-Dole Act.[9] Under the institutional environment unfavorable to university patenting, the WARF had to be a legally separate entity from the university.

Despite significant organizational independence, WARF pursues "The Wisconsin Idea" – the guiding principle of UW-Madison's regional engagement since the late 19th century. The most widely known description of The Idea is that "the boundaries of the University are the boundaries of the state" (Stark, 1995: 1–2), suggesting that that the university should serve the state. Traditionally, UW-Madison practiced The Idea in two ways (Stark, 1995): (1) offering public policy advice to the state government; and (2) disseminating scientific knowledge applicable to agricultural and dairy industries (e.g., the invention of Babcock tester to measure the butterfat content of milk in 1890). In order to fit The Idea into the knowledge-based economy of the twenty first century, UW-Madison has recently redefined it to include: building Wisconsin's economy; advancing health and medicine; educating young and old; and, enhancing quality of life (The Wisconsin Idea web site).

The first two areas (i.e., building Wisconsin's economy and advancing health and medicine) are what WARF is deeply engaged with. In order to help regional economic development, it serves as a key intermediary between UW-Madison and industry. To do so, WARF files patent applications on behalf of UW-Madison researchers and licenses patents to private companies. Between 1999

Fig. 4. Wisconsin Institutes for Discovery

* Photography by Jae-Youl Lee on December 11, 2010.

and 2008, WARF filed 1,798 patent applications and was granted 899 U.S. patents. WARF's annual patenting licensing income in 2008 was $54.1 million (UW-Madison, 2010). At the same time, it promotes the local and regional use of its patents. Approximately 30 percent of WARF's 500 commercial licensing agreements active in 2008 were made in Wisconsin. WARF has also spawned 40 UW-Madison spin-off companies in Madison area since the early 1990s (Wisconsin Alumni Research Foundation). In turn, WARF's revenues from patent licensing and managing spin-off companies are used to provide research funds at UW-Madison. In the academic year 2008–2009, WARF provided UW- Madison with $64 million funds, which accounted for 22% of $296 million non-federal research awards at the university (UW-Madison, 2010).

Concerning the field of health and medicine, WARF has provided financial supports for improving biomedical research infrastructure at UW-Madison. In 2000, for example, WARF donated $80 million to the university to share its construction cost for BioStar research cluster at the center of UW-Madison campus. More recently, it has made a $50 million donation to the university to help the construction of Wisconsin Institutes for Discovery, an interdisciplinary bioscience research and commercialization facility, which opened in December 2010 (Figure 4).

Owing to WARF, UW-Madison has become a leading biotechnology patenting institution at a global scale. In a global analysis of university biotechnology transfer and commercialization, Milken Institute ranks UW-Madison as a top-ten biotechnology patenting university in 2004 (DeVol *et al.*, 2006). WARF's active biotechnology patenting affects regional performance as well. A recent OECD report identifies Madison as the 40th biotechnology patenting region in the world (Van Beuzekom and Arundel, 2009). This is a great achievement for the medium-sized city with a population of about 250,000. Madison outperforms much larger metropolitan areas such as Beijing, China (42th), Stockholm, Sweden (47th), and Indianapolis in the United States (48th). Finally, the recent development of stem cell biotechnology sector in the city is also largely indebted to a longstanding entrepreneurial university partnership between UW-Madison and WARF.

WARF began to support stem cell research after Dr. Thomson had succeeded in deriving embryonic stem cells from non-human primates in 1995 (Jain and George, 2007). The organization provided research funds to Thomson in partnership with Geron, a California-based biotechnology company. The financial supports from two private entities allowed Thomson to set up a privately funded lab at UW Hospital (The Capital Times, 1998). Given that any federal fund could not be used towards hES cell research under Dickey-Wicker Amendment (see above), separating his lab from a public higher education institution (i.e., UW-Madison) was a necessary measure. Indeed, as a *Washington Post* (1998) article reports, Thomson "did the work [hES cell research] in a room in which not a single piece of equipment, not even an electrical extension cord, had been bought with federal funds, to ensure he did not violate the congressional ban."

While the WARF funded Thomson's research, officials at UW-Madison helped him to avoid ethical controversy. To do so, the university organized an ad hoc bioethics committee before his hES cell research. After reviewing ethical standards for fetal research in the US, Canada, and the UK, the committee confirmed that Thomson's research would not create human embryos for research purpose, allow embryos to develop to the stage of having neural structure, nor clone whole organisms (*Milwaukee Journal Sentinel*, 1998; Jain and George, 2007). Regarding the source of human embryos, the committee made it sure that only leftover embryos from infertility treatment could be donated to Thomson's lab under the consent from patients. Under the committee's supervision, Thomson's research team could study human embryos, which an international collaborator sent from Israeli in vitro fertilization (IVF) clinics in 1997 (Vogel, 2002).

Had it not been for the above-noted local supports the "first" discovery of hES cells could have made elsewhere. In the mid to late 1990s, many other research teams around the world also had knowledge and know-how to cultivate hES cells (Holden, 2007). However, they made slower progress than Thomson due mainly to the lack of financial resources and the difficulty of acquiring sufficient human embryos. Reflecting on the state of hES cell research at the time, Dr. Douglas Melton, a Harvard stem cell scientist told Science that "had any other stem cell scientist been given the same starting material [i.e., embryos] and financial support [as Thomson], they could have made the same accomplishment." (Holden, 2007: 187)

Put another way, financial and material resources as well as knowledge were crucial to Thomson's hES cell discovery. UW-Madison and WARF made the resources available to him. Thomson acknowledged the significance of their institutional supports in an interview with Jain and George (2007: 544) by saying that "we probably would not be here had it not been for their [UW-Madison and WARF] efforts". In short, a longstanding entrepreneurial university partnership in Madison was the key institutional foundation of the first discovery of hES cells in 1998.

IV. Constructing Regional Advantage

Following the 1998 discovery, the City of Madison has experienced rapid improvements in local and regional institutional infrastructure for the stem cell biotechnology sector (Table 4). Most notably, an immediate policy reaction came from the state government, which had implemented no sector-specific initiative aimed to promote stem cell research and bioscience in general before 2000. In the 1999 State of the State Address, former Wisconsin Gov. Tommy Thompson (in office from 1987 to 2001), a Republican, honored Dr. Thomson as a "bold pioneer who is leading Wisconsin into the next millennium" (*Wisconsin State Journal*, 1999) even though he had been a staunch anti-abortionist. One year later he announced a $317 million BioStar Initiative. The Initiative was aimed to build a bioscience research cluster at the center of UW-Madison campus. The BioStar research cluster was planned to build and renovate research facilities for genetics and biotechnology, microbial science, and biochemistry.

Democrat Gov. Jim Doyle (in office from 2003 to 2011) was also a strong supporter of stem cell biotechnology. Under his leadership, state biotechnology policy became more attuned into stem cell research and

Table 4. Chronology of Constructing Regional Advantage for Stem Cell Biotechnology Sector in Madison, 1995 – 2008

Date	Events
Nov. 1995	Thomson succeeds in deriving non-human primate embryonic stem cells
Nov. 1998	Science reports Thomson's discovery of isolating and culturing human embryonic stem cells
Dec. 1998	USPTO grants a patent for non-human primate embryonic stem cells to WARF (U.S. Patent 5,843,780)
Jan. 2000	Gov. Tommy Thompson announces a $317 million BioStar Initiative
Feb. 2000	WARF establishes WiCell Research Institute to distribute hES cells
Mar. 2001	USPTO grants a patent for hES cells to WARF (U.S. Patent 6,200,806)
Nov. 2004	Gov. Doyle announces a $750 million Biotechnology and Stem Cell Research Initiative
Oct. 2005	NIH designates the WiCell as the National Stem Cell Bank
Apr. 2006	USPTO grants a patent for a method to proliferate hES cells to WARF (U.S. Patent 7,029,913)
May 2007	UW-Madison establishes Stem Cell and Regenerative Medicine Center
Nov. 2007	Science reports Dr. Junying Yu's discovery of genetic reprogramming of human skin cells to create the world's first iPS cells
Sep. 2008	WiCell launches WISC Bank to distribute iPS cells

* Compiled by the author from various sources.

Table 5. Details of Biotechnology and Stem Cell Research Initiative in 2004

Category	Details
Research facilities	- $375 million Wisconsin Institutes for Discovery (WIDS) at UW-Madison - $134 million Wisconsin Institutes for Medical Research (WIMR) at UW-Madison - $132 million collaborative research center between the Medical College of Wisconsin and Children's Hospital of Wisconsin in Milwaukee (Medical College and Children's Research Institute)
Funding programs	- $105 million research funds to the University of Wisconsin Medical School and the Medical College of Wisconsin - Wisconsin Initiative for Alzheimer's Research ($1.5 million funds per annum)
State legislation	- A new state law easing entrepreneurial activities among academic researchers - Tax incentives for venture capital investment in early-stage biotechnology firms

Source : Adapted from Grove (2004)

* Research facilities: WIMR and Medical College and Children's Research Institute are in operation. The first facility of WIDS costing $150 million is under construction. The State Government of Wisconsin, WARF, and John Morgridge, a UW-Madison alumnus and former CEO at Cisco respectively contributed $50 million for the first phase of WIDS project.

its commercial and therapeutic explorations. In his economic development agenda entitled *Growing Wisconsin* (Doyle, 2008: 33), Doyle states "a goal to capture 10 percent of the [stem cell] industry by 2015". For the purpose, he launched a new $750 million Biotechnology and Stem Cell Research Initiative in November 2004 (Table 5). Doyle's Initiative is composed of three research facilities focused on interdisciplinary and translational research, two research funding programs, and two new state legislations aimed to promote academic entrepreneurship and venture capital investment. Moreover, Doyle issued an executive order which directs the Wisconsin Department of Commerce (DOC) to spend $5 million to attract stem cell companies in April 2006 (Milwaukee Journal Sentinel, 2006).

At the local level, UW-Madison and WARF also actively promote the development of stem cell sector. To do so, UW-Madison opened Stem Cell and Regenerative Medicine Center (UW-SCRMC) in May 2007. The Center facilitates information exchange and interactive learning among more than 70 UW-Madison faculty members engaged in stem cell research (Wisconsin State Journal, 2007). For the purpose, the Center coordinates lab equipment sharing, collaborative researcher training, and interdisciplinary research among basic scientists and clinical researchers. In addition to institutionalizing a culture of collaboration, UW-SCRMC has organized Stem Cell Research Oversight Committee in charge of developing hES cell research policies and guidelines applicable to UW-Madison researchers. The Committee is composed of not only stem cell scientists but also university officials, law school professors, bioethicists, and religious leaders. As such, UW-SCRMC is attempting to take various social concerns into consideration while promoting innovations in such a controversial technology field.

Alongside with UW-Madison, WARF plays an important role in improving local institutional condition for the stem cell sector. Both technological and financial resources of WARF allow it to make such a contribution in Madison. When Dr. Thomson disclosed hES cell inventions to WARF, it filed patent applications to the U.S. Patent and Trademarks Office (USPTO). In the early 2000s, in turn, the USPTO granted the patents for non-human primate and human stem cells, and the methods to proliferate these cells to WARF. While maintaining the intellectual property right of major hES cell technologies, WARF was able to make a significant institutional change in Madison. It is the establishment of WiCell Research Institute in February 2000.

The WiCell as a subsidiary of WARF distributes Thomson's stem cell lines worldwide. Alongside with Harvard Stem Cell Institute, the WiCell has become a major distributor of hES cell lines in the world (McCormick *et al.*, 2009; also see Own-Smith and McCormick, 2006). In addition to distributing stem cells, WiCell also offers training programs to scientists. In that way, as Jain and George (2007) note, both codified and tacit elements of stem cell knowledge are disseminated through WiCell. Citing these contributions, the NIH designated WiCell as The National Stem Cell Bank in October 2005. Thus, the WiCell as the host institution of the federal agency is now responsible for distributing federally approved hES cells and providing technical supports in the United States. Finally, WiCell has acted as a conduit to attract human capital in stem cell science to Madison. It has hired more than 40 stem cell scientists by the end of 2009.

WARF's financial, as well as technological, resources have been used for local institutional development. As noted above, it has contributed $50 million to a $150 million state project of building Wisconsin Institutes for Discovery (WIDS), which is the main component of Doyle's Biotechnology and Stem Cell Research Initiative (Figure 4; Table 5). The WIDS is a biomedical research and commercialization facility devoted to advance stem cell knowledge into a therapeutic stage. For the purpose, it is designed to facilitate collaborations between public and private sectors, and house two separately managed institutes – the public Wisconsin Institute for Discovery (WID) belonging to UW-Madison and the private Morgridge Institute for Research (MIR) owned by WARF. In February 2008, WARF hired Dr. Thomson as director of regenerative biology program at the MIR, in which pre-incubator stage stem cell companies will also be located.

Meanwhile, it is noteworthy that the role of WARF in Madison has been deepened while it participating in the WIDS project. Not only does the WARF have its own stem cell research institute (i.e., the MIR). It has also become a state policy implementer in the project. Indeed, WARF has taken the role of project manager responsible for constructing the WIDS and designing its research programs since UW Board of Regents named it in April 2006. As such, the WARF's role is not confined to a patenting and licensing organization. Rather, it is becoming a more proactive "regional innovation organizer" (Etzkowitz, 2008) in Madison.

V. Conclusion

To summarize, the case study makes two major empirical observations. First, the hES cell discovery in

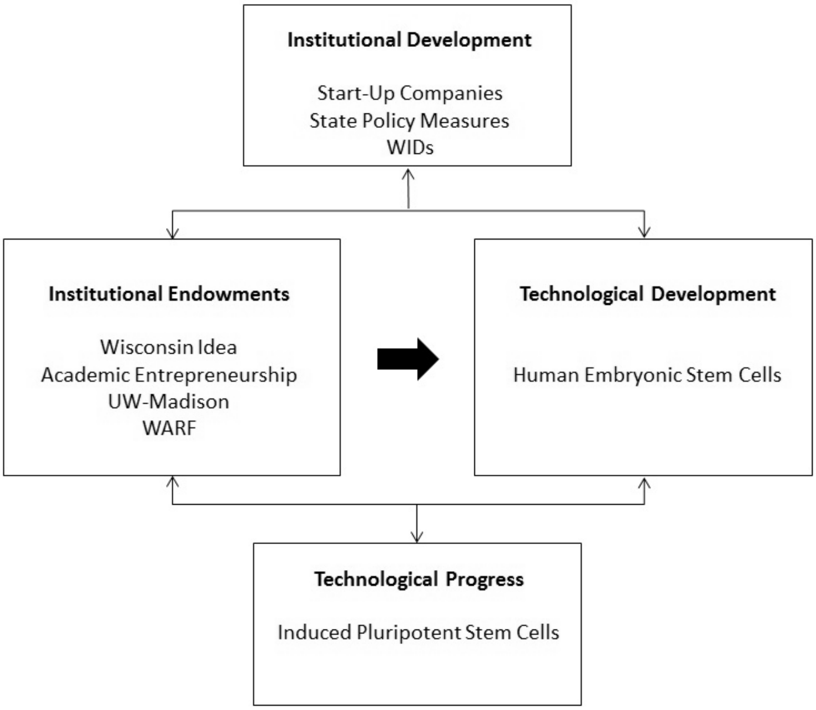

Fig. 5. Institution–Technology Interplay in the Stem Cell Biotechnology Sector of Madison, Wisconsin, USA

1998 was possible in Madison thanks largely to local institutional endowment. More specifically, a long tradition of academic entrepreneurship at UW-Madison and WARF acted as a buffer to reduce the pinch of unfavorable federal hES cell research policy in the late 1990s. The second key observation is that the technological development has helped to reshape local institutional infrastructure. It set an important context for implementing state biotechnology initiatives in Wisconsin since 2000. In addition, UW-Madison and WARF have established a series of new institutions aimed to construct regional advantage for the emerging biotechnology sector. In a synthesis of two findings, I conclude, institution and technology mutually shape each other in Madison (Figure 5).

The institution-technology interplay helped Madison to see another major breakthrough in November 2007. A joint research team of UW-Madison and WiCell led by Junying Yu, an associated scientist at the UW-Madison Primate Research Center announced the world's first discovery of induced pluripotent stem (iPS) cells (Yu *et al.*, 2007). These cells are indistinguishable from hES cells, but immune to ethical controversy because they were induced from human skin cells (Morgridge Institute for Research, 2008). Following the discovery, WARF applied for a patent at USPTO. It also established WiCell International Stem Cell Bank (WISC Bank) in September 2008 in order to distribute the newly discovered stem cells. As the story of iPS cell discovery demonstrates, the ongoing institutional development puts Madison in an advantageous position in the stem cell biotechnology sector. Thus, as local and regional policymakers hope, the city may have a globally competitive stem cell biotechnology cluster in the future. However, it must be noted that Madison's success in the sector will depend on how local and regional actors deal with challenges posed by the federal regulatory framework on the one hand and ethical controversy over the nascent biotechnology on the other.

A series of empirical observations in this article confirm the institutional and evolutionary perspective on regional development. As advocates of the approach would expect, the ongoing development of stem cell sector in Madison is largely indebted to local institutional endowment. On the other hand, the study informs the literature in two ways. First, the nature of the university's regional engagement needs to be reconsidered. The conventional institutional theory regards the university as a knowledge generation institution. Such an understanding of the university's role in regional development poses a serious limit to explaining the way in which UW-Madison and WARF have been involved in the development of stem cell sector in Madison. Their longstanding partnership not only enabled the 1998 discovery, but it also has encouraged the commercial exploration of the technology. In capturing both aspects, the notion of "entrepreneurial university" (Etzkowitz, 2002) is enormously helpful in this article. In this regard, I agree with Cooke and Leydesdorff (2006) who suggest that a close dialogue with the scholarship on university entrepreneurship would benefit the institutional analysis of knowledge-based regional development in economic geography (also see Feldman, 2000; Bramwell and Wolfe, 2008).

In addition, the article also highlights a largely overlooked aspect of local and regional institutional development. The conventional studies tend to focus exclusively on the effects of institutions on knowledge generation, technological development, and innovation in the region. Meanwhile, they come short of examining a possibility that scientific knowledge and technology may have the power to drive institutional changes in the region. In contrast, the article problematizes the possibility and finds that the 1998 discovery of hES cells has also acted as a catalyst for improving local and regional institutional conditions for stem cell biotechnology sector. The lack of federal support for the controversial technology has made it necessary for local and regional actors to devise their own institutional arrangements.

In short, the interplay between institutions and technological development is at the heart of the construction of regional advantage for stem cell biotechnology sector in Madison. It remains to be seen whether and to what extent the nascent technology field boosts economic activities and increases employment at the city and regional scales, but it is hardly disputable at this time that the institution-technology interplay has helped the city to become a global leader in the sector.

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1) The eleven states are California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, New Jersey, New York, Rhode Island, and Wisconsin.
2) Such studies focus on two interrelated factors conducive to the development of biotechnology regions. The conventional analysis highlights the importance of regional assets including universities and other research institutes (e.g., Preveser, 1997; Audretsch and Stephan, 1999; Feldman, 2000), "star scientists"(Zucker *et al.*, 1998), and entrepreneurial support service providers such as venture capital companies and law firms (e.g., Kenney and Patton, 2005). More recent studies examine how extra-local factors (e.g., national institutional framework, transnational big-pharma companies, and global knowledge networks) complement regional assets (e.g., Niosi and Bas, 2003; 2004; Bagchi-Sen *et al.*, 2004; Coenen *et al.*, 2004; Cooke 2005a; 2005b; 2006; Trippl and Todtling, 2007; Moodysson, 2008; Gertler and Vinodrai, 2009). For a recent comprehensive review of the geographical studies of biotechnology regions, see Birch (2007).
3) This perspective comprises a significant part of "new economic geographies" (Thrift and Olds, 1996; Lee and Wills, 1997). The notion of "institutional thickness" (Amin and Thrift, 1994) represents the early institutional approach, which sees a high level of interaction among local institutions as the key precondition for regional development. More recently, scholars emphasize the importance of integrating national regulatory

framework into the understanding of local institutions (e.g., Amin, 1999; Martin, 2000; Asheim and Gertler, 2005). The case study in this article is grounded on the latter institutionalist viewpoint.

4) Madison is a medium-sized city where about 250,000 people reside, but as the capital city it plays a role as the administrative and political center of the State of Wisconsin. While public employees at the state capitol and the City of Madison comprise a largest occupation group in the city, the University of Wisconsin-Madison acts as a catalyst for local economic development as it attracts talented people and generates start-up companies.

5) BioPharmGuy database is used for an inter-regional comparison, and there are much more biotechnology companies in Madison than those that the database identifies. According to BiotechProfiles: Madison Companies & Jobs (www.biotechprofiles.com), Madison has 209 biotechnology companies specialized in bioinformatics (9), contract research (5), drug manufacturing (10), food and agribusiness (24), human diagnostics (18), lab reagents (43), medical devices (50), pharmaceuticals (38), and others unclassified (12).

6) Fujifilm has recently expanded its business area to regenerative medicine in line with its longstanding involvement in X-ray technologies, and before the acquisition of CDI it became the parent company of Japan Tissue Engineering in 2014 (for more details, see Komori, 2016).

7) In 2002, federal funds accounted for 64% of $19.6 billion biomedical research expenditures at U.S. universities (Moses III *et al.*, 2005).

8) A few days later, another research team led by Dr. John Gearhart at Johns Hopkins University released a different method to extract hES cell from human fetal tissues (Shamblott *et al.*, 1998).

9) The passage of Bayh-Dole Act in 1980 resulted in the growth of university technology transfer offices (TTOs) and academic patents in the United States (Sampat and Nelson, 2002; Mowery and Sampat, 2005).

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