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Pursuing endogenous high-tech innovation in developing countries: A look at regenerative medicine innovation in Brazil, China and India

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ABSTRACT

Few studies in developing countries have examined innovation in an emerging field such as regenerative medicine (RM). Here, we compare case studies of the RM sectors in Brazil, China and India to help understand RM innovation from a systemic perspective. Innovation in developing countries is usually described as a process of reverse engineering carried out by firms, but we argue that this description is not well suited to innovation in an emerging field such as RM. We show here that innovation in new emerging fields can occur in developing countries by diverse processes not yet discussed in the literature. We introduce the main types of actors in RM innovation, look at the interactions between users and producers, and discuss the advantages and challenges of innovating in RM that are faced by the emerging economies. We find that RM innovation in these countries is demand-driven and occurs under conditions unique to countries with lower-resources. We also find that firms play a smaller role in RM innovation at this stage, showing the importance of considering wider innovation actors in the study of novel innovation dynamics.

1. Introduction

Most sectoral innovation research has until recently focused on developed countries (Malerba and Mani, 2009b). For several decades there has been, however, the belief that specific technologies may play an important role in the advancement of developing country economies. Pérez and Soete believe that certain technologies – or certain stages of a technology's development toward maturity – present developing countries with "windows of opportunity" to catch up (Pérez, 2001; Pérez and Soete, 1988). These windows of opportunity may be influenced via a number of factors, including through the creation of appropriate institutional frameworks, government policies and skilled human resources (Niosi and Reid, 2007). New wave technologies may differ from more traditional sectors with respect to the capabilities required for innovation – these new technologies may require greater R&D and patent intensity, strengthening of the knowledge base, and greater linkages to users (Mytelka, 2006). Pérez and Soete (1988) believe that the "crucial ingredient" for the advancement of developing countries is to enter early into new technology systems, or they risk remaining stuck in a cycle of investing in mature technologies, steps behind the richer nations.

New emerging technologies have been discussed generally in terms of how they contribute to the national innovation systems of developing countries, and what opportunities and challenges they present for those interested in participating in these waves. There has been little discussion in the literature, however, of what innovation in any of these emerging technologies looks like. This paper will begin to address this gap by discussing the process of innovation in one newly emerging field where some developing countries have been active – regenerative medicine.

Regenerative medicine (RM) is an interdisciplinary field that is still very new worldwide. Although the human body is able to recover from some illnesses and small injuries, it remains unable to heal more extensive damage caused by old age, trauma and disease. Increasingly over the last few decades, researchers believe that the regenerative properties of stem cell, tissue engineering and gene therapy based technologies may eventually be the key to more extensive re-growth of damaged tissues and organs. Regenerative medicine is highly interdisciplinary and lies at the intersection of genetics, cellular biology, biomaterial engineering, computer science, chemistry, and medicine, among many others, and is estimated to have a global market value of over $US 500 billion, according to the United States Department of Health and Human Services report (US Department of Health and Human Services, 2005).

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Most RM applications are targeted to treat chronic illness, and over 80% of chronic disease deaths occur in low and middle income countries, severely impairing the capacity of low GDP countries to address primary healthcare concerns (WHO, 2005). Capacity in regenerative medicine (RM) is limited in most developing and emerging economies, and there is concern that without their involvement in RM, the resulting products will not be affordable to developing countries and will not reflect their health needs (Greenwood et al., 2006a). Our studies of RM in China, India and Brazil have showed that these developing countries have already developed significant capacity in this field, from basic research to clinical trials (Lander et al., 2008; McMahon et al., 2010a,b).

This paper examines innovation in the emerging technology field of RM across China, India and Brazil. This is one of the first discussions of the process of endogenous science-based innovation occurring in developing countries, and has implications for how innovation in the emerging economies is perceived. We argue that innovation in emerging fields is possible in developing countries, and occurs through processes other than "reverse engineering" not yet captured by the literature. We describe the innovation processes that are occurring and the components of the RM innovation system. We then discuss the implications of our findings for how innovation in developing countries is conceived, including on the role of demand in shaping innovation, and on the unique aspects of RM innovation in those countries.

This paper is structured as follows. We begin in Section 2 with a brief introduction to the literature on models of innovation in developing countries, and describe our methodology for this study in Section 3. We introduce the reader to the process of RM innovation in our countries of interest in Section 4.1 and the key components of the RM innovation systems in Section 4.2, showing that the model of firm-centric reverse engineering is insufficient to capture RM innovation in the emerging economies. We then discuss RM innovation on a more systemic level by showing the user–producer relationships that shape demand for RM innovation, as well as the challenges and advantages to pursuing endogenous high-tech innovations in emerging economies (Sections 4.3 and 4.4 respectively). We end the paper in Section 5 with our main findings.

2. Background

Sectoral systems of innovation (SSI) can be defined as a network of actors and linkages between organizations and institutions involved in the creation, diffusion and use of knowledge within a particular technology or sector. The sectoral system based approach to studying innovation is intended to be a broad, flexible, and adaptable tool that allows qualitative and quantitative comparative analysis across countries and regions (Malerba and Mani, 2009b). Most sectoral innovation studies have been conducted in developed countries, but sectoral innovation focused on developing countries is now on the rise, as indicated by the number of papers presented on sectoral innovation in annual Globelics conferences, and as seen by the publication in 2009 of the first book on sectoral innovation in developing countries (Malerba and Mani, 2009a). Very few studies using sectoral innovation frameworks have examined new biomedical fields in developing countries. While there are no studies of RM innovation in developing countries other than our published case studies, biotechnology has been identified as sector of innovative opportunity by authors using innovation system frameworks (Niosi and Reid, 2007; Thorsteinsdóttir et al., 2004). These papers further point to Brazil, India and China as being among the leaders of biotechnology in the developing world.

The broader innovation systems literature on catch-up of latecomer countries has focused on transitional economies that have succeed in developing rapid economic growth and technological "catch-up", particularly those known as the Asian Tigers: Taiwan, South Korea and Singapore. The literature on technological change in developing countries seems to suggest that their technological trajectory is fundamentally different from that of developed countries. Several models indicate that technologies are acquired from developed countries and then assimilated and adapted by developing countries (see for example Hobday et al., 2004; Kim, 1998; Utterback and Abernathy, 1975; Wong, 1999).

One such model of technological change is Kim's model of technological development (Kim, 1998, 1999). Kim adapts the Utterback model to better reflect developing country advancements, and describes developing country innovation as a process of acquisition, assimilation and improvement. By acquiring mature "packaged" technologies including all manufacturing know-how, latecomer countries can "acquire" technology. Then follows a period of process innovation, in which competition between new entrants encourages improvements in the manufacturing process to improve and differentiate products. Some firms may acquire enough endogenous capacity through this process to make innovative improvements to the originally imported mature technologies and become internationally competitive. This process is opposite in many respects to the development process of affluent countries, and is sometimes referred to as reverse engineering.

Lee and Lim describe different models of catching up based on selected South Korean industries (Lee and Lim, 2001). The models they describe include: (1) path-creating catching up, (2) path-skipping catching-up and (3) path-following catching up. In the first two models, the industry is able to "leap-frog" ahead by skipping steps that previous entrants went through, whereas the third is more similar to the Utterback model, depending on "duplicative imitation" followed by "creative imitation".

Wong similarly describes the innovative process of emerging economies from the perspective of the late-comer, but highlights potential differences in the way these late-comer firms react and develop (Wong, 1999). Wong describes the rapid industrial and technological catch-up of South Korea, Taiwan and Singapore and introduces five models of development that differ in the extent and speed of innovation in the manufacturing process and final product. Wong includes models similar to Kim's, but also describes models in which process innovation is the key goal, or where product innovation occurs in tandem to process innovation. Wong stresses that firms in these emerging countries will evolve different strategies that play to their unique strengths and resources than would be developed by latecomer firms in advanced countries. He first describes several general first mover advantages: early capture of consumers, capture of key resources, and learning curve effect. In addition to the absence of these advantages, latecomer firms in emerging economies suffer from distance from users, distance from leading sources of technology, and shortage of specialized input resources/infrastructure. Latecomer advantages for late industrializing countries include lower resource costs, sheltered markets, and information asymmetry. Knowledge flows from developed to developing countries are larger than knowledge vice versa, owing to the knowledge on developing country firms being less accessible or locked in local languages (Wong, 1999).

Many others have also explored the difficulty of developing technological capacity in emerging economies. For example, the transition dilemma between the 'catch-up' phase and true leadership is explored by Hobday et al. (2004), who describes how firms and sectors move between these stages. Ernst (2002) has explored the innovation systems of developing countries by studying the international networks that allow the import of mature technologies for reverse engineering.

The key similarity between all of the frameworks described above is that the focus is on how *latecomer firms* to a field become involved in the eventual creation of new knowledge. This is the

sticking point of all these models in terms of their applicability to new emerging high-tech fields, such as RM innovation in emerging economies. In RM, there are no available mature technologies or products to import, and firms are not yet latecomers to the market. Instead, these countries aim to be at the forefront of RM from the beginning. This agrees in concept with Lander's et al. analysis of RM in India, where they indicate that RM innovation in India may differ from the reverse engineering model that makes up the pharmaceutical and biotechnology industries of these countries, marking a shift in India's life science innovation paradigm (Lander and Thorsteinsdóttir, 2011). Some of the current literature acknowledges that developing countries may pursue innovation in emerging technologies once these countries have accumulated sufficient endogenous technology capacity, however this is described usually only after the firms or industries have moved through the other stages of imitation and assimilation within a given field (Hobday et al., 2004; Lee, 1988). The characteristics, challenges and advantages of innovation in fields emerging globally have not been described.

All of the above models are designed to describe the characteristics of innovation strategies that helped the Asian Tigers and a few other countries to catch up with more industrialized nations during a specific period of time – largely in the electronics and manufacturing sectors. There may be less room for countries to engage in the old models of technological catch up now (Lundvall et al., 2009). Reverse engineering and imitation based strategies that were the stepping stone of the Asian Tigers are now impaired by stronger patent rules, greater fiscal prudence, and the removal of international trade barriers (Lundvall et al., 2009). Fortunately for emerging economies and other developing countries, there are "multiple generic evolutionary paths for rapid tech catch-up" (Wong, 1999). We propose here that one of these paths could be the pursuit of new emerging technologies, such as RM. According to Wong, there is a tendency within the innovation literature on the Asian Tigers to focus too much on their common characteristic and undervalue their differences (Wong, 1999). We risk doing exactly this if we do not fully take the opportunity to explore how innovation occurs in emerging technologies in developing countries, and how today's regulatory, financial and political environments impact the process of RM innovation.

3. Methods

The findings presented here are based on our research of the RM sectors of China, India and Brazil conducted over the past five years. The individual case studies of each country have been previously published (Lander et al., 2008; McMahon et al., 2010a,b). These countries were selected for these case studies following a study conducted in 2006 that identified China, India and Brazil as being the only developing countries that had RM capacity across five types of activities: government funding, goods and services, companies, publications and academic institutions (Greenwood et al., 2006b). We define "developing countries" throughout this paper as countries of low and middle income, as classified by the World Bank. We use the colloquial term "emerging economies" to refer to a subset of developing countries with high growth rates, which includes China, India and Brazil.

We began our study with a broad interpretation of innovation, which included both ideas and processes that were new to the world, as well as those that are new to the country. Some argue this wider definition is more appropriate for developing countries (Ernst et al., 1998) where firms are learning to design and implement products and services that are new to them irrespective of their prior use in developed countries. We employ this wider definition for inclusivity – however as we show later, this does not imply there is no new to the world innovation occurring in these countries. RM is a new field with very few products and services yet on the market, thus much of the R&D activity in this field involves new-to-the world innovation. We use publications in international peer reviewed journals as one indicator of new to the world knowledge production, using "stem cell" and "stem cells" as search terms in the Web of Science database; methodology is further described previously (McMahon et al., 2010a).

Our studies on RM innovation in China, India and Brazil are largely based on interviews with in-country RM experts. A total of 150 key informants were interviewed: 47 in China, 53 in India and 50 in Brazil. Key informants were selected based on their expertise in RM through a process of purposeful and snowballing sampling, and were selected to represent actors from different parts of the innovation systems framework. For example, we interviewed key informants representing research institutions, hospitals, firms, educational institutes, government agencies, policy institutions, regulatory agencies, patent offices and bioethics organizations, among others. Interviews were semi-structured (guided by predetermined interview questions but interviewers were allowed to depart from these questions to pose follow-up questions and to follow the direction of the interviews). Interviews ran one to two hours in duration, were conducted in the language of choice of the interviewee and were digitally recorded. The bulk of the interviews were conducted in English, but simultaneous translation to English from the participant's first language was provided as requested. Interviews were conducted and attended by DM or DM and HT in Brazil, DM and HT in China, and HT and/or Bryn Lander in India. Interviews were transcribed verbatim and thematically analyzed by DM to identify salient themes and organize them into conceptual categories.

Our interviews represent a snapshot of the RM scenes in the countries we studied according to some of the RM experts influencing their development; they are specific to the time they were conducted, and interviewees' views do not necessarily represent those of everyone in the field, nor do interviewees necessarily agree with all ideas presented in this paper. Results of the interviews were triangulated with the analyses of key documents, government reports and policy information to insure a high degree of validity and analytical rigor. Evidence for opinions and facts presented in the interviews were discussed between authors and corroborated or triangulated with evidence from other sources when possible – only results with a high degree of confidence are included here.

The Ethics Review Office of the University of Toronto Research Services approved our research protocols and informed consent was obtained from all participants. Quotes from the interviews used in this paper are referenced with an interview number to maintain the anonymity of our participants.

4. Results and discussion

Regenerative medicine is a priority area of development in each of China, India and Brazil and all three countries have made important advancements in the field. Following aggressive recruitment of Chinese-born scientists back to China and substantial funding, China was the world's second most prolific publisher of peer-reviewed articles on stem cells in the world in 2011. Brazil and India's RM sectors are more modest in size, but still contribute several hundred publications on stem cells annually. Brazil has funded a number of clinical trials, including one of the largest stem cell trials for heart disease in the world, funded directly by the Brazilian Ministry of Health. India's Department of Biotechnology has supported around 55 programs for stem cell research. All three countries have built national stem cell centers, with the intention of producing high quality stem cell lines for research. Our case study

publications of regenerative medicine in China, India and Brazil provide further detail on the sectors of each country, and further support that these countries are already engaging in innovative activities, despite RM being a new emerging field. What remains to be seen is the process by which this innovation occurs.

4.1. The process of RM innovation

As discussed above, innovation is typically described as a process of reverse engineering in developing countries, but our research here clearly indicates that there is no single answer to how innovation occurs. It seems RM innovation does not adhere to one predominate strategy, such as reverse engineering, but involves instead a mix of approaches. The emerging economies are using all the techniques at their disposal, including new-to-the-world innovation, process innovation, business innovation, and at times, importation of ideas from other countries.

When asked if the RM sector of their country was primarily producing new-to-the-world innovation or if these innovations were only new to the country and had been previously made abroad, many respondents answered "both". One Brazilian interviewee explained:

> "I think it is happening both ways. Because, firstly, most such research has economic interests. If you see some new good product, good procedure that can be adapted in Brazil, obviously this is easy way to start. But in parallel, as I mentioned, we have some very good basic research. [Brazilian researchers] like to innovate new things. And in this area we are doing okay, and so I can say we are doing both equally." [Interview BR16]

Not all RM research and development in Brazil, China and India is innovative on a global scale and some RM ideas and strategies have been imported or imitated. Protocols published in academic journals around the world can and have been replicated in the emerging economies, and are a good mechanism for catching up with the latest protocols or RM breakthroughs. However, it is important to note that this knowledge is not merely a developed country hand-me-down, but is, in fact, the way science moves forwards everywhere around the world.

Emerging economies have made certain milestones that, while not new to the world, are new to the country and which open up opportunities for further innovation. For example, while induced pluripotent stem cell (iPS cell) lines were not first created in Brazil, Brazil was able to create its own unique iPS cell lines, enabling Brazilian scientist to research and innovate with these embryonic-like genetically induced adult cells. In China, the government-approved gene therapy produced by Sunway Biotech Co. in Shanghai was inspired by an American drug called Onyx-015 made by Onyx Pharmaceuticals Inc., but Sunway developed its drug independently and patented their version in China (Guo and Xin, 2006). By relying on clinical trial data from the United States that showed clinical efficacy of the drug, Sunway was able to focus its efforts on a lower risk gene therapy that could reach the market relatively quickly. Sunway became the first to fully develop, test and commercialize this product, and have subsequently obtained exclusive worldwide rights from Onyx (Guo and Xin, 2006).

At times the RM sector has relied on incremental and process innovation. One interviewee in India stated: "Innovating is all about not only doing different things but doing them differently" [Interview IN10]. An Indian government representative indicated that he believed India had particular strengths in process innovation, in particular to make innovations affordable, accessible, acceptable and available. For example, the LV Prasad Institute in India has treated over 700 patients for ocular burns using corneas grown from limbal stem cells, which they believe to be the largest successful application of stem cell therapy in the world (C-TRACER, 2010; Champalimaud Foundation, 2011). While the researchers that developed this protocol did not invent this procedure, they claim the improvements they have made to the protocol allow for a much smaller sample of limbal cell tissue to be initially removed, increasing the success and availability of the treatment. The institute is now testing the efficacy of a new protocol to use cells from the oral mucosa when limbal cells are not available, and has begun preclinical testing of induced pluripotent stem cells for treatment of some forms of retinitis pigmentosa (C-TRACER, 2010).

Business innovation has been important to the sustainability of new RM companies, particularly those still investing heavily in research or interested in starting clinical trials of their RM treatments. Funding for clinical trials and R&D can be hard to obtain, and firms may rely on the production of secondary less innovative products or services in order to stay afloat through the pre-market product development phase of their more innovative RM products and services. For example, Shanghai Qisheng Biological Preparations in China has several marketed products that help fund research on novel bio-scaffolding products. According to a company representative, Excellion in Brazil was founded to facilitate stem cell R&D, but generates income from other services, such as culturing skin cells, manipulating bone marrow cells, and conducting toxicity assays. Vector Gene Technology Company Ltd. in China is also marketing several gene vectors and plasmid DNA to produce revenue while it develops a number of gene therapy treatments.

New-to-the-world innovation is also an important part of RM innovation in the emerging economies. Research published in international peer-reviewed journals needs to be novel and not published before, and all three countries have drastically increased their publications over the past decade. China is one of the most prolific publishers of stem cell research in international peer-reviewed journals in the world, and India and Brazil have increased their publications from almost nothing in 2000 to 189 and 283 respectively in 2011. A few interviewees we spoke with held patents or had submitted patent applications on their RM research in their countries and abroad, further indicating their work is innovative. RM researchers we spoke with felt they are driven to make internationally significant innovations, and are proud of their accomplishments in the field:

> "We don't want to just copy other research; we want to do something innovative. The leaders are first class researchers, they impact the field. . .we want to be first class, to have an impact" [Interview CH17]

For example, Brazil has developed the world's first treatment that allows Type 1 diabetic patients to achieve long-term insulin independence without constant immunosuppression, and is the only treatment that impedes the progression of Type 1 diabetes in humans. China produced the world's first mouse cloned from iPS cells, which two labs published separately on the same day, showing that Chinese stem cell researchers are both internationally and domestically competitive. This innovative cloning technique was listed as one of the "Top 10 Medical Breakthroughs for 2009" in Time magazine.

More Indian interviewees discussed the importance of process innovation to RM, perhaps believing the success of process innovation in the generic pharmaceutical sector can be reproduced in India. Incremental and process innovation also came up frequently in Brazilian interviews, whereas Chinese interviewees focused their discussion on more new-to-the-world innovation. The exclusion of incremental innovation discussions in China does not, however, imply that they are not using these tactics, as shown in the above example from Sunway Biotech Co., but may reflect instead their clear desire to become innovation leaders with a global impact.

4.2. Components of the RM innovation system

The previous section addresses the process of innovation, but does not address specifically who is innovating. Here, we explore the main actors and institutions of the RM innovation systems in these countries to highlight similarities and differences with traditional innovation systems. Literature on innovation systems in developing countries places significant emphasis on the role of the firm, however here we show other players take on a central role in the process of innovation. The differences in innovation system composition can be attributed both to the location of these systems in developing countries, as well as to RM being a health-based technology.

4.2.1. Firms

Innovation system literature typically places the role of firms as central to the innovative process, as they integrate knowledge of different actors to formulate products and services. Most of the empirical studies of innovation on developing and transitional economies have focused on industries with a strong commercial sector, and have focused on latecomer firms and firm behaviors and strategies. Our results show there is very little commercial activity in RM thus far in these countries – seemingly less than the RM fields of developed countries. We find the central role of firms somewhat muted for three main reasons. Firstly, commercial RM development are only beginning globally, and the long-term high-risk investments needed for RM have made investors hesitant – particularly in the emerging economies, where angel and venture capital investors are sparse. Secondly, innovation in RM is reliant on research in academic institutions, research centers and hospitals, in part due to its science intensive nature and the immaturity of the field, but also because of the heavy investment from government in these countries. Regenerative medicine is a priority area and without private investment, most of the development is occurring in the public sector. Thirdly, the role of hospitals is particularly pronounced given that the commercial path of stem cells is thus far unclear. Hospitals play an important role in clinical testing and distribution of health products and services. While the firms may still play an important role in developing products for the health sector, it seems pharmaceutical companies in China, India and Brazil remain undecided as to the commercial value of stem cells. Depending on the degree of manipulation and culturing, stem cells and tissue engineering could be considered as a drug or as a service performed in hospitals, further decentralizing the innovation process from firms. One Chinese researcher we interviewed said, for example:

> "I think the country is still debating on stem cells as a new drug or a new treatment. So that's, that's still open debate" [Interview CH6]

He believed that firms saw RM as more of a treatment, making them hesitant to invest:

> "They [pharmaceutical companies] still think stem cells are unsellable – so in other words it can never become a small cure that you can take everyday, right? So they are basically not interested". [Interview CH6]

This is not to say there are no roles for firms in RM in China, India and Brazil, only that other actors have a larger role to play in this immature health-based industry. China has several companies focused on bringing tissue engineering, gene therapy and stem cell technologies to market. China has also approved the world's first two gene therapies, produced by the firms Sibiono GeneTech and Sunway Biotech. In Brazil, several companies are collaborating on clinical trials in hospitals to produce cell therapies. India's private sector was the most active of the three countries – India has a number of RM firms sponsoring clinical trials, and commercial cord blood banks are investing in stem cell R&D. Some companies/hospitals in China and in India have also begun selling stem cell therapies for a large number of indications to patients directly, in a contentious practice often referred to as "stem cell tourism". We also expect firm activity will increase as more evidence of safety and efficacy is accumulated, as more products near commercialization, or as initial commercial success is demonstrated.

4.2.2. Government

The extent to which government can shape innovation in developing countries has been much debated, and while not unexpected, it seems significant to note that government support has been instrumental to the development of the RM sector in our countries of interest. According to our research, governments have been instrumental to the development and support of RM in China, India and Brazil through three main types of support: financial, policy and regulatory support. Researchers in all three countries indicated that levels of funding were adequate, and that government policies were supportive. All three countries have developed and are refining the regulations needed for the eventual commercialization of RM products and services. Government interest in clinical applications of research has also seemed to help all three countries advance in the field quickly.

4.2.3. Universities and research centers

This research shows universities and other public research centers are essential to RM innovation in two ways: firstly, they are the main educational and training establishments that produce the human resources needed for science intensive fields. Secondly, most of R&D for RM is currently carried out in public universities and research centers. The R&D we observed conducted in universities dwarfed that conducted by firms. While universities often play a central role in R&D intensive innovation, they seem to have almost completely displaced the firm as knowledge producers in the RM sector of these countries. Universities may transfer their knowledge to firms or hospitals; some firms base their research on initial work done by publicly funded research and university spin-off firms was a common start-up strategy. The importance of academic research was particularly strong in Brazil, where firms traditionally do little high-level research in science-intense fields.

4.2.4. Hospitals

In all three countries, hospitals are an important part of RM innovation. Hospitals are both essential for the recruitment of patients and administration of therapy in clinical trials, and will be the likely distributor of future RM therapies to end users, the patients. Top researchers will require tight linkages with hospitals and clinicians for safe and efficacious translation of RM. A few interviewees across all three countries indicated that while some large hospitals may be conducting stem cell research, many doctors of smaller hospitals were not well informed of RM advances and would likely be uncomfortable recommending it to patients unless greater attention was made to supplement their education and training.

Some hospitals in China and India are already administering therapies to patients. One interviewee estimated about 200 hospitals across China are distributing stem cell therapies to patients without proof of safety and efficacy, although new Chinese regulations requiring clinical trials for stem cell therapies may change this landscape in the future. At least some of these hospitals in both China and India target their advertising to international patients, showing the global relevance of hospitals to the emerging economies' RM sectors.

4.2.5. Other types of organizations

This research identifies several other important actors in the development of RM, including cord blood banks, in vitro fertilization (IVF) clinics, animal testing facilities and specialized supply companies. Other groups, such as ethicists and media centers, have also had an important influence on regulation development and knowledge flow.

Cord blood banks and IVF clinics are uniquely positioned to collect and distribute human biological materials and tissues needed for stem cell research. In all three countries, IVF clinics are a source of human embryonic stem cells (hESCs) for researchers. In China, some stem cell researchers have close linkages with IVF clinics, or run labs in hospitals with IVF clinics in order to ensure access to these cells. Cord blood banks may act as a major repository of stem cells if RM therapies become mainstream. In anticipation of the medical benefits RM may generate, many parents across Brazil, China and India have begun saving or donating cord blood in private and public cord blood banks. In India, cord blood banks are also engaging in research. Across all three countries, at least a few cord blood and stem cell banks were positioning themselves to be the middleman between the patient and the hospital, acting as a source of both cells and technical expertise on their extraction, purification, and storage.

In addition to cells, RM researchers need access to a variety of specialized supplies in order to conduct their work. Small RM supply companies have started up to provide the reagents and products needed by RM scientists, such as vectors for gene-therapy researchers or media for the cultivation of clinical grade stem cells. This is important, as delays and costs associated with importation of reagents, equipment and specialized research materials were a major challenge for many of the researchers we interviewed.

Other groups, while not involved in RM research and development, have had important influences on the flow of RM knowledge. Ethicists in China, for example, took a lead in developing regulations and guidelines that shape RM research in China. In Brazil, the domestic media has been essential to the distribution information about the risks and potential benefits of RM to the general population, particularly while Brazil's Supreme Court was debating the legality of embryonic stem cell research.

4.2.6. The role of institutions

Institutions comprise both the formal regulations and policies and the informal social norms and behaviors that influence how innovation actors interact. Each country's RM innovation system has developed within unique cultural, political and economic climates, and these influences have created considerable differences in how formal institutions have developed. All three countries have debated at least some of these regulations during their development or implementation, and the struggle to develop adequate regulations has been particularly pronounced in Brazil and China.

In Brazil, the legality of hESC research was challenged by the Catholic Church in the Supreme Court, which contested that hESC research violated the constitutional right to life and human dignity. The courts launched Brazil's first public consultation to seek the views of different stakeholders prior to upholding the law in 2008. Human embryonic stem cell research and iPS cell research is more limited in Brazil, owing perhaps to this late start. In India and China, there have been no public debates over embryonic stem cell research and researchers have been very active in these areas. Regulatory challenges and debate has instead primarily been on the unapproved and scientifically unsupported use of stem cells in patients. While new regulations have been developed to address these issues in both countries, a lack of enforcement and transparency around these regulations means they have resulted in little change in practice.

By comparison, until now, intellectual property regimes do not seem to have had an important impact on RM innovation in these countries. Most RM researchers in the countries we focused on seem not to emphasize patenting, and patenting was particularly low in Brazil where patenting of biological related innovations is very restrictive. It is, however, uncertain if this will continue as the field matures and it is unknown what effects patents will have the field in the long term within the emerging economies.

Informal institutions have been important to the development of RM in each country. Several interviewees told us that traditionally China did not have a strong scientific research culture, but that RM was helping develop skilled students and researchers that are making internationally significant contributions to scientific research. One interviewee stated:

> "In our tradition we did not encourage innovation enough. The Chinese have never asked why the sky is not falling down. . .Now they are just at the stage of learning or being trained. And that's not to train one generation, that's to train culture. That will take time." [Interview CH5]

Interviewees in Brazil also found that research culture is important; one researcher in Brazil stated:

> "I say that most of our greatest difficulty is the culture. It's not exactly money or technology or – it's the culture" [Interview BR9].

Overseas training programs may be important for the development of "research culture" in addition to any particular technical skills. Training and recruitment of scientific diaspora may then be an important input of scientific culture in addition to the human resources it brings, as these researchers become responsible for training a new generation of researchers.

Informal institutions outside of the emerging economies can also influence RM developments. When interviewees were asked how they felt their RM sectors were perceived internationally or outside of the country, some interviewees claimed that while a few top researchers may be recognized in their fields, in general the RM sectors of their country were under-estimated internationally, and that their research credibility was low. In Brazil, interviewees believed this was largely because the outside world had little knowledge of Brazilian activities in RM, leading to a mistrust of Brazilian products. In India and China, some interviewees felt that there was damage to their reputation caused by international discontent with the activities of the stem cell tourism industry, and caused by recent scandals in Asia about research integrity (Cyranoski, 2010; ISSCR, 2009; Padma, 2010; Xin and Marshall, 2006).

4.3. RM innovation is demand driven

Demand is a driving force in firm-centric innovation, but the effects of demand have been largely ignored in terms of their influence on innovation within health systems and in the medical sector (Thorsteinsdóttir, 2007). Here we explore why China, India and Brazil have invested in RM despite commercial uncertainty, instead of waiting to import technology from developed countries. The impetus is two-fold: developing RM is seen as a step toward becoming a more knowledge-based economy that is also fueled by demand for low-cost appropriate health technologies. Governments, researchers and some entrepreneurs have responded to a desperate need for new treatments for chronic diseases with investments of time and money in RM. Many of these innovators in China, India and Brazil feel domestic innovation in RM is essential to ensuring that products and services that are developed are appropriate and affordable to their populations.

Demand-driven innovation in healthcare influences the way products are manufactured to fit consumer needs and tight user–producer relationships are required for innovative products to successfully reflect consumer needs. In RM, this reflects a need for understanding between scientists and clinicians with the end-users, patients. Failures to form successful user–producer relationships may mean that developed products are not suitable or that patients are not receptive to using them. User–producer feedback typically occurs in hospitals both during clinical testing and during delivery of pharmaceutical products and therapeutic services. In RM, donations of cells and tissues from the public form another feedback link, where potential final users supply producers with the materials needed to conduct the initial R&D. Without the support of the general public, discarded embryos, adult stem cell samples and cord blood samples would not be available.

The pressure for affordable products and services seems to be stronger in Brazil, China and India than in more affluent countries. Some interviewees indicated that China and India had an advantage over international RM research because they were able to generate more cost effective research and products, as many research inputs such as labor costs are lower. While some Brazilian researchers believe importation costs have actually made research there more costly than in developed countries, they indicated that Brazilian researchers were more creative in the laboratory than their American counterparts due to having to adjust experiments to cut costs or accommodate for importation delays of reagents and equipment. This is akin to the creativity needed in "scarcity conditions" described by Sutz (Srinivas and Sutz, 2008). By developing RM products and services in the country, we find RM therapies will likely be more affordable locally than abroad. This is consistent with earlier evidence that endogenous innovation can help foster development of cost effective health technologies (Thorsteinsdóttir et al., 2004).

RM therapies are being developed in the emerging economies in response to patient needs. For example, doctor visitations can be quite cumbersome in China where quality clinics may be difficult to access outside city centers. One gene therapy company China, Vector Technology Company Ltd., is developing a new treatment for rheumatoid arthritis that would decrease the number of hospital visits required by the patient, as well as decreasing the cost of treatment by at least half. Researchers in China and Brazil are interested in developing a treatment for diabetes that could decrease or eliminate dependence on insulin injections.

Products developed endogenously may be designed in accordance with local social and cultural norms. In all three countries, the general populations seem accepting of new technologies where a clear medical or social benefit exist, and key informants believe the public eagerly awaits RM treatments. In China and India, traditional medicines are important to the general population, and may make these cultures more receptive to alternative types of treatment such as RM. Some interviewees in China and India believe that because the idea of encouraging the body to healing itself is central to many of the traditional medicine practices, these populations may be more receptive to RM. Additionally, China and India do not share the same ethical contentions stem cell research present in some Western countries. These cultural attitudes have allowed China and India to pursue embryonic stem cell research not permitted in many other countries. Brazil's culture is also surprisingly supportive, despite the Catholic Church's opposition to embryonic stem cell research. While Brazil's population is primarily Catholic, two thirds of the population fully support and another 20% partially support hESC research, with only 2% of the population completely opposed (IBOPE Inteligência, 2008).

Although it is important to have the support of users during the development of novel products, uninformed or indiscriminate support of a high-tech field such as RM can create misunderstandings and unfair expectations from the users. In all three countries, the education level of the general public is variable, and many individuals lack the education needed to understand succinctly the research and products being developed in RM.[2] Media coverage, including newspapers, television, and radio are largely responsible for general public education on RM, however, many journalists are ill equipped to effectively present these topics to the public. Key informants in China and India indicated that the media was often too positive in their interpretation of RM and was responsible for creating unfair or misleading expectations of RM in the short term.

> "Oh I think [the media is] positive, yeah. Too positive. So we, we avoid to contact the media. Because sometimes they will make small things big." [Interview CH12]

Key researchers across all three countries indicated that there was still a lot of work to be done before therapies would be ready for general use, but felt that the general public believed the therapies would be soon available. As one researcher stated:

> "I always hold the belief that providing a dream is a nice thing. But sciences are not based on the dream. Science actually relies on the actual practice, so we believe that we should give people more practical ideas." [Interview CH1]

This dichotomy between expectations of researchers and the general public could be harmful in the long-term if researchers avoid reporting results to the domestic media, if users become mistrustful when expectations are not reached, or should harm come to users through premature application of RM.

In contrast to the public's overly optimistic view of RM, doctor's hesitations to use RM may act as a barrier to the adoption of new RM therapies and services. The older generation of doctors, especially outside major cities, may not have sufficient training or education to understand the relatively new concepts behind RM, which could lead to mistrust of new RM therapies. In particular, the adoption of Chinese approved gene therapy products has been difficult because doctors hesitated to provide it to patients. One gene therapy expert said: "Because of the early stage, education is hard work. Yeah, you need to change the doctor's conception" [CH0]. Firms producing gene therapies are responding to this difficulty by providing training sessions and educational materials to explain to doctors how gene therapy products work and under which conditions they are of most value to patients. Similarly, stem cell and tissue engineering products and services will need the support of doctors, who mediate the relationship between users and producers. Greater scientific evidence of safety and efficacy may also help instill consumer confidence in innovative RM products and services.

4.4. Advantages and disadvantages to engaging in RM

As discussed above, innovation in developing countries is usually described as a process in which developing countries acquire, assimilate, and then adapt technologies acquired from developed countries (Hobday et al., 2004; Kim, 1998; Utterback and Abernathy, 1975; Wong, 1999). These models of innovation in developing countries describe characteristics that are unique to developing countries. The models developed thus far, however, also rely on the assumption that the emerging economies are latecomers. While these arguments are well suited for the context for which

[2] While the general public of Brazil may have heard of stem cells due to widespread media discussion of stem cells, particularly in urban areas, our interviewees often felt that the public did not have any significant understanding of these technologies, which field observations confirmed. Members of the public we spoke with informally did not understand basic information about how stem cell technology works, or how close RM is to being clinically available.

they were developed, we have shown that innovation based on a model of reverse engineering does not adequately describe innovation in an emerging field such as RM, where there are few products to imitate. It follows then that at least some of the characteristics of innovation in low and middle countries described in the literature will not accurately describe RM innovation. Using a sectoral approach, we explore here to what extent the latecomer advantages and disadvantages described for transitional economies apply to the RM context, where these countries are not necessarily "latecomers" to the field, but could instead be considered early movers. Some of these may be still relevant for this new context, where as others will no longer apply.

We find that some of the latecomer advantages previously described by Wong are largely true for the emerging economies' RM sector as well, such as low resource costs, sheltered markets, and information asymmetry (1999). Although economic progress has resulted in price increases, China and India still benefit from low resource costs, real-estate overheads, and wages compared to most developed countries. Language differences and lack of knowledge or mistrust by affluent-country firms of developing countries' private sectors are expected to act as barriers to the arrival of new foreign health care products to the domestic markets, which helps to shelter domestic RM firms. Firms are largely not in need of sheltering however, as the immaturity of this field has not yet created intense international competition. Information access asymmetry is also an advantage for emerging economy researchers, who are able to access leading information on RM published in international peer reviewed scientific journals with ease. It is more difficult for the international community to access papers published in domestic journals, government reports and other R&D related information, particularly when languages other than English are used. Several researchers from Brazil and China claim too that international journals are sometimes hesitant to publish research from developing countries, resulting in further information asymmetry.

Because they are not latecomers to the field, these countries do not miss out on the early capture of consumer markets. Emerging economies instead benefit from the enormous markets their large populations provide. Several key informants in India and China viewed their enormous population as an advantage in RM research and development as it increases access to patients with unique diseases and patient availability for clinical trials of new RM products and therapies.

The disadvantages of developing country innovation described by Wong (including user–producer distance, distance from technology sources, and shortage of specialized inputs of resources/infrastructure) are largely not relevant to RM innovation in the emerging economies. For example, user–producer relationships in latecomer fields are typically distant because firms in developing countries would fabricate products for sale in the more affluent countries. The target market for RM products in the emerging economies, are however their domestic populations, and so RM users and producers enjoy physically close relationships. Similarly, in new high-tech endogenous creation of knowledge, sources of technology and resulting capacity and infrastructure are domestically maintained.

The emerging economies do, however, suffer certain disadvantages owing to their emerging country status, including comparatively limited funding compared to more affluent countries and difficulties related to building infrastructure and specialized knowledge in the short-term. Emerging economies have dedicated funding to RM, but simply do hot have the financial resources comparable to that which more affluent countries are able to provide. Government grants are the principal source of funding, and little resources are available from private or venture capital groups. Private domestic investors are few – in the words of an interviewee from a new RM firm struggling with the costs of clinical trials, "It is hard. It's long. The experience is long time and the cost is very very high" [Interview CH0]. Many firms have little access to venture capital or to investors willing to endure the high risk and long timelines needed for RM product returns, making the sustainability of RM firms during this pre-market phase very difficult.

Knowledge is arguably harder to create in the short term in multidisciplinary and science intensive fields such as RM than it is for more industry based fields. The availability of skilled individuals in high-tech fields can be a limitation for developing countries interested in perusing innovative activities. Skilled personnel need to be educated, trained and provided with sufficient opportunities to make staying in their home country personally rewarding. The reform of academic institutions to train the next generation is difficult, costly, and far from immediate, although an essential part of a long-term solution. Despite some "brain-gain" strategies that China has employed, brain drain of skilled human resources is still a major problem in developing countries who loose many of their highly trained students to the developed world for further training or employment.

Emerging economies also do not have the same infrastructure to support science intensive or biomedical fields that is already available in more affluent countries. Research equipment, high-tech laboratories, clinical and preclinical facilities are all essential to biomedical innovation. Bureaucracy and red-tape are often endemic problems and regulatory clarity and enforcement are at times lacking. Governments can provide supportive policies and make important reforms, but all investments need to be prioritized alongside the development of other social, medical and scientific programs.

RM development has been largely successful despite the above challenges and all three countries have managed the infrastructure, investments, personnel and creativity to make a go of RM in their countries. Both scientific and healthcare capacity, however, are not necessarily equally distributed throughout the countries and may remain locked in city centers. Finally, even when emerging economies make progress in a field like RM, they still have to overcome a perceived bias of part of the international community that good science does not come from developing countries.

5. Conclusions

We have shown here that the simplistic model of innovation in developing countries, as a process of firm-lead technological transfer and amelioration, fails to fully capture what is actually happening in practice. We conclude instead that that innovation is happening in developing countries in parallel to developments in developed countries in emerging fields that have not yet reached technological maturity, and that this innovation happens in developing countries through process that are more complex than originally conceptualized.

We show that newly emerging technologies in high-tech sectors are not necessarily out of reach of emerging economies – Brazil, China and India have jump-started a new high-tech sector through direct financial, political, and human resource inputs. Because RM is a globally emerging field, they cannot rely on international transfers of RM technology into the domestic health system. Nor are there final products available for reverse engineering. Instead, these countries have invested heavily in the development of endogenous RM capacity and innovators use a variety of innovation strategies to build RM innovation. This conclusion has several important repercussions for how innovation in developing countries is perceived. It is unknown to the extent to which the innovation processes discussed here apply to other high-tech fields and more research on the process of innovation in other emerging sectors and further

exploration of innovation in developing countries is needed to develop alternative models to those currently in the literature.

Our exploration of RM innovation in China, India and Brazil support three secondary findings: First, the decentralized role of firms in these RM innovation systems shows the importance of looking at innovation from a systemic perspective. Second, high-tech innovation may be appropriate and beneficial for emerging economies' domestic populations. Lastly, this high-tech innovation occurs under conditions inherent to developing countries, and to RM.

The importance of universities and hospitals to biomedical innovation is perhaps not so surprising, particularly given that the commercial path of stem cells as a product or service has not yet been clearly determined. Nonetheless, there has still been significant RM private investment in developed countries, including by large pharmaceutical companies, whereas RM-related firms in China, India and Brazil are relatively small and largely separate from the pharmaceutical industry. It is instead the public sector there that has shouldered much of the investment in research and clinical trials, reacting to a growing demand for treatments to chronic diseases. The decentralized role of firms in these RM innovation systems shows the importance of looking at innovation from a systemic perspective and not assuming strong firm involvement. Universities and research centers are important sites for science-intensive innovation globally, yet the firm has remained central to empirical studies of innovation in developing countries, perhaps owing to a lack of published studies focusing on emerging technologies in developing countries. Lundvall (2007) has suggested that even in developing countries, firms should be seen as central to innovation and should be the focus of study of innovation in developing countries. Here, we conclude that study of a broader set of innovation actors is appropriate until the role of firms for different sectors of developing countries is better understood.

Our next finding is that demand driven high-tech sectors of emerging economies, such as RM, may be beneficial in nature to the country in question. While some may suggest that developing countries should build stronger science and technology systems by emphasizing exports and by focusing on acquiring turnkey plants and capital goods the way some Asian Tigers have (Kim, 1998), high-tech products developed for export may not be relevant or affordable to domestic populations (such as televisions or software). On the other hand, a clear objective of RM is to serve an increasingly important domestic health need and to provide cost effective solutions to incurable diseases. The development of high-tech sectors that reflect domestic demands, particularly in basic-need sectors such as health or potentially agriculture, benefit from greater proximity between users and producers. Endogenous development of these technologies increases domestic capacity, and allows the development of economically and culturally relevant products designed for local problems. This conclusion indicates that there is an important role for innovation to play in the high-tech fields of emerging economies, particularly where there is a clear market need or benefit to the domestic population. Policies thus should not necessarily focus exclusively on high-tech export-based fields, but should consider the development of high-tech fields that can concurrently have potential positive social, economic, and market effects.

The last finding – that RM innovation occurs under conditions unique to RM in emerging and developing countries – builds on the others and begins to explore the distinctive characteristics of high-tech innovation systems in emerging and developing countries. Some of the characteristics we discuss may be context specific, whereas others may be attributable to socio-economic status and thus relevant to a wide range of countries or sectors; more studies are needed to determine the broader applicability of these characteristics. For example, most developing countries would likely benefit from low resource prices, sheltered markets, and knowledge asymmetry. Some sectors will benefit from close user–producer relationships more than others, depending on the local market for the technology. For RM, user–producer interactions are important for all countries, even if the demands each places on the technology differ. Users have had a huge impact on RM innovation globally: innovation in some countries has been stalled or stunted due to user's discomfort with human embryonic stem cell research, and gene therapy trials were also temporarily stopped following the death of one participant in the United States, which decreased consumer and regulatory confidence in clinical use of gene therapy. Developing countries will likely also face greater limitations in the infrastructure and financial resources available compared to more affluent countries across a number of high-tech fields. While it is impossible to simply transpose successful elements of one system to another, we hope that our findings discussed here can have important implications for how innovation is understood in developing countries, and that it identifies some important elements to consider for policy makers interested in building capacity in emerging sectors such as RM. Developing country innovation in RM has thus far been poorly recognized; these studies should be of importance to policy makers and researchers interested in keeping appraised of RM developments globally.

Emerging economies have invested in RM as part of a quest to become more knowledge based economies; engaging in high-tech fields will need to be part of pursuing this goal. Because RM is still in its infancy, the emerging economies are joining the international community on more equal footing in this field and have a chance to make a global impact. In addition, investing in health can have important returns for the local population. In order to have an impact on markets, governments and researchers in RM will need to maintain their investments and pursuit of innovative therapies. Discoveries made in this field can influence the direction and priorities of the field; without the contributions from emerging economies, their strengths, resources and needs will likely not play part in determining the development path of sectors such as RM.

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