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Policy-driven ecosystems for new vaccine development

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A B S T R A C T

This paper examines the relationship between biomedical policies and entrepreneurial R&D strategies. Public health programs have been unable to provide effective and affordable treatment of infectious diseases for the poor. While governments have become more open to private sector contributions to policy objectives, it is rare to find new ventures commercializing healthcare innovations for neglected diseases. Two case studies of entrepreneurial ventures, in the UK and China, provide evidence on how resource-constrained firms mobilize participants in policy-specific ecosystems to achieve their goals of new vaccine development for tuberculosis. Ecosystem analysis reveals how the innovators’ business models can align their strategies with national policy objectives.

1. Introduction

There is widespread recognition of the importance of biomedical innovation, but it is only recently that the translation of R&D into treatments for diseases affecting the poor has been recognized as a public policy objective. This calls for the integration of biomedical innovation into public health programs and new business models on the part of enterprises. Innovations in drugs and vaccines face challenges that include risks attached to technical research and development (R&D), market uncertainty and a long investment horizon for R&D funding. Life science ventures engage in demanding R&D efforts for which funding is scarce (Burki, 2009; Pisano, 2010). Technology push is insufficient: it is also necessary to pull innovations into the market to provide affordable products that meet the needs of patient populations.

Infectious disease burdens weigh heavily on lower socioeconomic groups. Tuberculosis is an age-old disease affecting over one-third of the world’s population. TB burdens are highest in developing countries, but a rise in drug-resistant tuberculosis in poor areas of developed countries is also a cause for concern. Current TB vaccines used in public health campaigns have advanced little since the first vaccine discoveries in the early 20th century. Multinational pharmaceutical companies have limited interest in innovations and improvements that are not expected to yield sufficient returns to satisfy shareholders (Trouiller et al., 2002). But in view of the economic and moral imperative to meet the needs of patients worldwide, private sector R&D initiatives are being pushed forward to combat tuberculosis (Harper, 2007). This requires new sources of funding and new relationships between public sector organizations, philanthropic trusts, medical foundations and entrepreneurial innovators. This paper explores firms attempting to commercialize improved TB vaccines in the light of national biomedical policies.

The research question centers on how business models can promote effective partnerships in both private and public spheres for entrepreneurial firms commercializing new vaccines. An associated question is the influence exerted by policy priorities on the strategies and business models on such firms. We submit that these questions can be usefully addressed by examining evidence on the relationships formed around ecosystem efforts to combat disease. Relevant national programs differ substantially; we explore whether any common themes arise in the commercialization of TB vaccines by new ventures in highly diverse national settings. We inform our analysis using evidence on two case studies of TB vaccine innovators, one based in the United Kingdom and one based in China. The benefits of a comparison of this kind is that if factors can be found that have an impact on outcomes in both contexts, this provides a rationale for further comparison and a search for context-dependent factors that may explain differences between the cases. Finally we examine whether the conceptual approach we propose is likely to illuminate similarities and differences for studies of technology policy and biomedical programs beyond the two cases studied.

Both case study firms were resource-constrained and faced the challenge of obtaining investment funds for R&D for a neglected disease that predominantly affects the poor. We conducted a cross-case comparison of business models used to implement these innovators’ strategies to see how these relate to their distinctive policy contexts. We conceptualize these issues in terms of an...
innovation ecosystem (Adner, 2006), but one in which participants form relationships to meet goals together that could not be achieved by them individually. This study demonstrates the application of ecosystem theory and a business model approach to firm strategy that may illuminate issues for innovators elsewhere who aim to leverage policy resources for biomedical and other technology innovations.

2. The role of entrepreneurial firms in innovation ecosystems

Innovations emerge from new inventions through a combination of inventiveness and market capabilities that create value for users (Afuah, 2003; Freeman, 1997). Innovation derived from technological advances can stem from multiple sources including traditional centers of knowledge production such as corporate pharmaceutical R&D laboratories, research institutes or universities (Lundvall et al., 2002). However, to encourage new sources of innovation, an ecosystem of multiple participants (Adner and Kapoor, 2010; Moore, 1996) may be required to coordinate knowledge flows and make available necessary resources.

Entrepreneurial firms have been key sources of innovation since the industrial revolution (Nairn, 2002). Despite the myth of the solo entrepreneur achieving prodigious feats, in practice entrepreneurs are more likely to succeed when they mobilize support by offering reciprocal returns to those who help them realize opportunities. Business ecosystems can enable new entrepreneurial firms to work with established business organizations to gain legitimacy and reduce risks (Eisenhardt and Schoonhoven, 1996). We investigate whether ecosystems may also link public and private participation in productive relationships to achieve common goals.

In some cases, firms form new ecosystems in order to create opportunities for innovation that had not previously been recognized (Garnsey and Leong, 2008). This requires business models that make it viable to innovate in this manner. In other cases an innovative new firm attempts to gain access to an existing ecosystem by showing that it has a contribution to make to other participants, including government organizations.

A government has many policy levers to encourage innovation but the deliberate fostering of ecosystems to support innovators is a relatively new notion. However this is a natural extension of policies that encourage national coordination between industrial, research and educational initiatives. For example, governments can prioritize areas for innovation through public funding schemes, strategic infrastructural investments and inclusive strategies set at ministerial levels. Economic investments in human and knowledge capital need to be sustained by the policy environment to create long term and predictable incentives for the private sector.

3. Entrepreneurial innovation and ecosystem resource flows

Entrepreneurs have a propensity to challenge conventional thinking, as Schumpeter (1934). Entrepreneurs who draw upon prior knowledge and understanding to recognize new opportunities, both social and economic, can fill market and knowledge gaps (Seelos and Mair, 2007; Shane, 2000). This often includes providing a new value proposition (Drucker, 1985). They obtain, build and organize resources in new ways to realize opportunities (Garnsey, 1998; Penrose, 1995). Entrepreneurial thinking provides strategic means to access external resources and benefit from new resource combinations (Burgelman, 1983; Hitt et al., 2001). This type of innovation to achieve strategic goals requires new business models embodying partnerships and alliances (Sanchez and Heene, 1996).

4. The ecosystem concept and innovators’ business models that create shared value

The innovative ecosystem approach enriches the concept of open innovation and extends beyond the ecosystem of business participants to include government institutions and policy input. The approach builds on research on partnership and alliances and on open innovation studies exploring how partnerships can compensate for the absence of vertical integration (Chesbrough, 2003). The ecosystem concept goes beyond the conventional industry value chain to include the funders, resource providers, standard setters and complementary innovators who make it possible for participants to generate value together. The ecosystem approach allows for elements of joint value creation to be included in strategic analysis (Adner and Kapoor, 2010). Ecosystems have a social dimension and can enable the creation of shared economic and social value (Porter and Kramer, 2011). Supportive ecosystems can reduce the innovation risks of execution, co-innovation and adoption for firms combating diseases of poverty (Li and Garnsey, 2013).

Entrepreneurs excel at coupling activities: they have the incentive to orchestrate interactions with others who can provide the resources they lack, but to do this they must provide some form of reciprocity. One way to do this may be to join an on-going ecosystem where they can make a contribution to others who reciprocate by supporting their innovations. Our evidence shows how an ecosystem for organizations combating TB was formed anew in the UK by a joint-venture, and how a new Chinese life science firm gained entry to and benefitted from an existing health ecosystem. We use the concept of ecosystem to identify commonalities and explore differences between the two case studies.

A business model approach to strategy (with the firm as the unit of analysis) complements the ecosystem approach. A business model renders operational the firm’s strategic objectives, which may or may not be made explicit. Teece (2010) has viewed the business model as the way in which a firm is organized to create and secure value in accordance with strategic goals. Participants in an ecosystem create value collectively but this also enables the value generation by individual units that is required for their survival. The joint value thereby created may be social as well as economic. Thus we propose that the innovative firm’s business model represents an attempt to respond to and to secure impact on a potentially supportive ecosystem, where strategic goals are difficult or impossible for the venture to achieve on its own.

For the poor who lack purchasing power, price and access limits effective demand, despite undeniable need. New technologies are slow to reach the poor and this is especially the case in healthcare (Hotez et al., 2007; Prahalad and Hammond, 2002). However, governments are increasingly providing policy levers to encourage biomedical research and development, and recognizing that private sector contributions may be needed for innovation. Public–private partnerships have expanded in coverage and new incentives and public support structures to engage the private sector in medical innovation are underway (Buse and Waxman, 2001; Hargreaves et al., 2011). Supportive R&D policy can enable a virtuous cycle of demand for innovative products and services (Commission on Intellectual Property Rights, 2006; Watanabe et al., 2000). Biomedical policy can provide private sector investors with a more predictable context for strategic investment and financial support of innovation efforts.

5. Tuberculosis

Tuberculosis is a curable infectious disease and yet it still claims 1.8 million lives a year with 9 million new cases per year (Lömmöth et al., 2010). TB primarily affects lower socioeconomic groups and
often populations with inadequate access to quality healthcare. It is easily spread in dense urban areas with poor ventilation and sanitation. If active TB is left untreated, a single person can infect 10–15 other people a year (Kumaresan et al., 2004). TB is now concentrated primarily in 22 populous and developing countries with one-third of those infected living in India and China, but drug-resistant variants are rising both in developing and developed countries (Fig. 1).

Tuberculosis is caused by a bacterium called *Mycobacterium tuberculosis*, which enters through the respiratory tract and primarily affects the lungs, but can also affect almost any tissue or organ of the body. If the bacteria are not contained, the disease will progress to active TB. Without adequate treatment, the infection can fatally damage the patient’s lungs. It is the leading cause of death in the most economically productive age groups of adults aged 15–59. With decreased productivity, decline in incomes and increased health expenditures, the poor are further pushed into the poverty trap.

6. TB vaccines

The first BCG tuberculosis vaccine dates back to 1908 (Bloom and Murray, 1992). It is striking that there has not been a new TB vaccine since 1921 and no new classes of antibiotics against the disease since 1963. The standard TB BCG vaccine now costs between US$0.10–0.20 per dose and has been administered to more than 4 billion people. It offers protection against severe forms of childhood TB in most populations, but is unreliable in protecting against adult forms of pulmonary TB (Kaufmann et al., 2010). The vaccine is not recommended for use in infants infected with HIV and is not protective in HIV infected adults.

New vaccination strategies are being developed to achieve higher levels of immunity than that can be accomplished with BCG alone. The Stop TB Partnership Working Group on New Vaccines is an international consortium that works towards developing a second-generation vaccine effective for all population subgroups and age-groups. This consortium maps the global TB vaccine pipeline and provides evidence of firms active in this domain.

In 2009, 12 new TB vaccine candidates were in clinical trials. Table 1 below lists sponsors of the new vaccine research and development from the Working Group TB Vaccine pipeline. The involvement of these high profile institutions show the priority accorded to this issue throughout the world.

7. Combating tuberculosis as a public policy priority

The aim of eliminating tuberculosis as a global public health concern is emphasized in the United Nations Millennium Development Goals (MDGs) to combat infectious diseases. In the United Kingdom, the UK Department of Health follows a framework for global health which includes a national strategy for achieving the MDGs and supporting health systems to systematically treat tuberculosis (Department of Health, 2011). The framework is also supported by the UK Department for International Development (DFID). In the very different context of the People’s Republic of China, tuberculosis rates have declined alongside increased economic development, but China has the world’s second highest absolute numbers of tuberculosis patients with 1.3 million new cases per year (Wang et al., 2007). In China, health policies are being reoriented from reactive to proactive prevention and treatment (Liu et al., 2013). Biomedical innovation features strongly in China’s national five-year central plans. In China’s 12th Five-Year Plan, biotechnology ranks number three as top priority industries (KPMG, 2011; Li and Woetzel, 2011). This opens opportunities in China for innovative life science ventures that seek support in commercializing research findings.

Both the UK and China highlight tuberculosis as a strategic policy area in public health, but these goals are set in the context of international development assistance by the UK whereas the context in China is domestic public heath. The following is an analysis and exploration of case studies of TB innovator firms in the UK and China that have responded to strategic goals set by government. A study of entrepreneurial healthcare innovators provides a promising context in which to study ecosystems for translating research into medical practice (Hodgkinson, 2001; Pettigrew, 2001). Since the national contexts are so different, if common factors and sets of relationships can be identified as
having impact, these would be shown to be of more widespread interest, as would be any similar features of the innovators’ business models. Marked differences between the cases will provide insight into the impact of national systems of innovation and public health.

8. Research method and data collection

The research design uses the two case studies of TB vaccine innovators as exemplars. Our purpose is not to test existing theory but to extend ecosystem theory together with a business model approach to strategy in order to address under-studied issues in technology policy and public health. The cases may elucidate approaches to strategy in order to address under-studied issues in technology policy and public health. The cases may elucidate relationships with other private and public sector organizations. The search process yielded a dataset of 12 private sector firms, 1 joint venture firm, 1 public enterprise and 1 not-for-profit biotech enterprise. Oxford Emergent Tuberculosis Consortium (OETC) and Hai-Gui (H&G) Biotechnology were selected as exemplars for several reasons. They provide examples of innovator firms from a high-income country UK, and a developing country, China, respectively. H&G Biotech was the only private sector innovator from a high-income country UK, and a developing country, China, respectively. H&G Biotech was the only private sector organization precisely because it is very special in the sense of being a joint-venture example. The companies are approximately the same size with two full-time equivalent staff coordinating a network of collaborators and partners in R&D.

The Oxford-Emergent Tuberculosis Consortium Ltd (“OETC”) had been developing the world’s most clinically advanced new TB vaccine candidate MVA85A/AERAS-485 (“MVA85A”). The unusual business model was of interest as a joint-venture structure set up by a publicly funded University and a biopharmaceutical firm listed on the New York Stock Exchange. The second case study, Shanghai H&G Biotechnology (“H&G”) is headquartered in a science and technology park in Wuxi, China. It is seeking to advance one of the newest TB vaccines in development (Ag85A/Ag85B) to enter into Phase I clinical development based on a novel scientific discovery of DNA vaccination.

We used both primary and secondary data sources for this study. Primary sources included interviews, surveys, and a focus group of experts (a Delphi method). A semi-structured interview schedule was devised to understand how the firm’s business models operationalize their strategies and how they created relationships with other private and public sector organizations. All interviews and data gathering took place between October 2009 and April 2012. Interviews varied from thirty minutes to two hours. Interviews were conducted with the respective company founders, general management team of OETC and R&D staff of H&G. Archival sources, company reports, review materials from external funders and government policy white papers were analyzed to complement and check personal and telephone interviews.

An international meeting was organized to bring together and facilitate networking between the subjects of the wider research program of which this formed part (Li et al., 2012). Participants included innovator firms and other global health ecosystem participants—funders involved in public and private partnerships, technical experts from the World Health Organization and member state/government representatives. These participants provided further evidence, making possible Delphi-style research that drew on global expertise in the field of TB vaccines (Bryman, 2008). Key executives from both OETC and H&G made detailed presentations at the conference. Partners were present and able to assess the presentations of the case study principals. This provided a further check on retrospective bias and facilitated triangulation.

9. Data analysis

The data analysis phase took place in three stages. First, the collected testimonies from semi-structured interviews were recorded and transcribed for textual analysis. The second step was to code the primary themes that emerged from the transcripts and case study. The emerging themes were cross-compared and

### Table 1

| Public institutions                                      | Private enterprises                      | Joint venture                              |
|---------------------------------------------------------|------------------------------------------|--------------------------------------------|
| Max Planck Institute                                    | Vanderbilt University                    | Emergent BioSolutions                      |
| UCLA                                                    | Finlay Institute, Cuba                   | Oxford-Emergent Tuberculosis Consortium    |
| NIH                                                     | Universiti Sains Malaysia                | (OETC)                                     |
| University of Oxford                                    | Institut de Pharmacologie et Biologie    | Not-for-profit organizations               |
| McManister University                                   | Structurale du CNRS                      | AERAS TB Foundation                        |
| Wuhan Institute of Biological Products                 | Cardiff University                       | Tuberculosis Vaccine Initiative (TBVI)      |
| Albert Einstein College of Medicine                     | Institut Pasteur                         | Public enterprise                           |
| University of Zaragoa                                  | Institute Pasteur of Lille               | Statens Serum Institute                     |
|                                                        | Shanghai Public Health Clinical Center   | Not-for-profit biotech                      |
|                                                        |                                          | Infectious Disease Research Institute (IDRI) |
analyzed in relation to relevant literature on innovation systems, innovation ecosystems, policy and entrepreneurship. This allowed us to identify a set of primary themes around business strategy and the way public health authorities and institutions influenced firms’ strategy.

The final step involved subjecting the case study evidence to independent analysis and checking of accuracy. At the conference, senior OETC and H&G representatives made presentations and provided updates. Their business models were examined and compared with comparable innovators (Miles and Huberman, 1994). The presentations were recorded (for publicly available podcasts) and input from key opinion leaders ensured that interpretation of the evidence took account of experts’ perspectives.

10. Oxford emergent tuberculosis consortium—A joint venture initiative

OETC was officially formed as a joint venture in 2008 between a public university commercialization transfer office (Oxford University/Isis Innovation Ltd) and an American publicly-traded biopharmaceutical company (Emergent BioSolutions Inc. NYSE: EBS).

10.1. Recognizing an opportunity

Early clinical work by Professor Helen McShane and colleagues at the University of Oxford indicated that MVA85A was well-tolerated vaccine and offered good protection to BCG naïve subjects and BCG vaccinated subjects. Strong results for Phase I clinical trials were reported in 2007, but Prof. McShane recognized that the University laboratory at Oxford had taken the project as far as it could go in an academic setting. Undertaking the next phase of clinical trials, a Phase IIb study to demonstrate vaccine efficacy, required significant financial resources that were not available at Oxford. However, The UK Wellcome Trust was willing to provide one-half of the trial costs if another donor could be found to commit matching funds. Thus from the start OETC was conceived as a joint project in an emergent ecosystem of donors, researchers and vaccine producers.

Isis Innovation, the university technology transfer office wholly-owned by Oxford started discussions with potential development partners on behalf of Prof. McShane’s research lab. American-based Emergent BioSolutions appeared as a potential candidate. Emergent is a biopharmaceutical company with expertise in the development, manufacture and commercialization of vaccines and antibody therapies. Emergent also has a UK office close to Oxford. The combination of a vaccine commercialization focus at Emergent and its having a UK presence was appealing for Oxford.

The chosen partnership vehicle between Oxford University/Isis Innovation and Emergent BioSolutions was a joint venture in which the university owned 49% of the shares and Emergent the remaining 51%. The Oxford-Emergent TB Consortium (OETC) joint venture was announced on July 23, 2008. OETC represented a single entity focused exclusively on TB vaccine development, which combined the relevant expertise and assets of both the university of Oxford and Emergent BioSolutions. Demonstrating that a commercial partner supported the MVA85A program was also an important factor in securing funding from the Wellcome Trust to support the infant Phase IIb trial.

The OETC deal was the most clinically-advanced out-licensing deal that Isis Innovation had completed up to 2008. Prof. McShane commented, “we were actively searching for a development partner to bring onboard commercialization expertise and to accelerate clinical work.”

A matching funder for the Wellcome Trust was found in the form of the Aeras Global TB Vaccine Foundation (“AERAS”). The public funding resources mobilized for the OETC joint venture from Wellcome Trust and AERAS were significant, with each contributing £4 million to support Phase IIb clinical trials (£8 million total). AERAS itself is a not-for-profit TB vaccine product development partnership (PDP) funded by the Bill & Melinda Gates Foundation and country-donors including the UK through its Department for International Development (DFID).

10.2. Mobilizing resources in an integrated ecosystem

Following the mobilization of funding resources, the first Phase IIb clinical trial commenced in South Africa in 2009 in collaboration with AERAS, the Wellcome Trust and the South African Tuberculosis Vaccine Initiative (SATVI) at the University of Cape Town. OETC did not have the resources to undertake and organize its own clinical trials and thus the partnership with the South African Tuberculosis Vaccine Initiative (SATVI) provided necessary infrastructure.

A second Phase IIb study evaluating the vaccine in 1400 HIV-infected adults commenced in 2010. This study was funded by the European Developing Countries Clinical Trial Partnership (EDCTP) via the UK Medical Research Council (MRC) unit in the Gambia, with additional financial support from AERAS and OETC.

OETC’s operating business model was like that of many small start-up biotechnology firms. It ran as a virtual R&D company with many supporting stakeholders. The consortium itself only has two full time staff. The joint venture continued to benefit from the TB vaccine clinical and scientific expertise in Prof McShane’s Oxford lab. Knowledge and findings were shared with OETC and also with the broader scientific community through publication of clinical results. Emergent provided manufacturing expertise and knowledge of scale-up suitable for a global vaccine supply at affordable cost. OETC’s management team was responsible for general oversight of the program with an agreed development plan, and coordinated all aspects of OETC’s corporate governance.

“The OETC joint venture business model structure had three primary roles to play in bringing MVA85A to market, and eventually to patients,” remarked Dr. Jacqui Shea, General Manager of OETC. First, the core intellectual property was housed within OETC and legal counsel and patent protection is handled by Emergent’s corporate capabilities. Second, OETC helped coordinate activity by all partners to align development objectives. Weekly and monthly teleconference calls were held by OETC and all partners as well as quarterly face to face update meetings. OETC acted as the primary funding centre where funds flowed in and R&D expenditure monies flowed out.

One additional advantage of the joint venture structure over a conventional partnership agreement was its commercial flexibility. For example, either one of the joint venture partners could negotiate to buy-out the other. The partner could continue to take on more development risk, but also have a higher upside of additional benefits. In addition, if neither development partner wished to continue, the shares could be divested. The joint venture structure was designed to be flexible and to capitalize on potential opportunities as they emerged.

10.3. Enabling knowledge and resources flows

As a hybrid organization, OETC was able to harness knowledge embedded in the technical and market capabilities of ecosystem participants. OETC ensured that knowledge flowed between the core partners in the joint venture (Fig. 2).

Fig. 2 represents the role played by OETC in linking the partners and coordinating their contributions to a shared goal of new
vaccine development. Through the University of Oxford, UK public science funding was directed into research and innovation. Public funding also came from the UK’s Department of International Development via its objective to fund research into neglected diseases. Although OETC is not a direct grant recipient of DFID tuberculosis funding, DFID supported OETC’s many collaborators. DFID funded the clinical trials through SATVI and it also is a funder to AERAS to encourage global R&D efforts in TB vaccines. Fig. 2 shows how ecosystem resources were mobilized to support OETC directly or indirectly through its collaboration partners to support shared strategic objectives.

11. Shanghai H&G biotechnology limited—A Chinese innovator in comparison

A second case study, Hai-Gui Biotechnology Limited ("H&G") is presented as Chinese evidence on the relationship between entrepreneurial innovation, business strategy and biomedical policy in TB vaccine commercialization. H&G Biotech was founded by scientist/entrepreneur Dr. Li Zhongming in 2003. H&G is a discovery-driven biotechnology company and is headquartered in Wuxi.

Dr. Li received his medical education in China. In 1986 he went to complete his post-doctoral research at the US Food & Drug Administration (FDA) in Maryland. Dr. Li spent the duration of his 17-year FDA-career with the infectious diseases department.

The founding of H&G was based on the scientific principle illustrated in two Nature papers (Lowrie et al., 1999; Tascon et al., 1996) on vaccination using DNA plasmid technology. Dr. Li analyzed the scientific proof-of-concept models contained in the paper and raised the question as to whether the same technology could be effective in humans.

11.1. Recognizing an opportunity

China carries 14% of the world’s TB disease burden, and after the 2003 Severe Acute Respiratory Syndrome SARS epidemic exposed the fragility of the public health system, political will was strengthened to fight infectious diseases. Central government increased funding for public health form $835 million in 2002 to $1.44 billion in 2004 (Wang et al., 2007). The federal, provincial and municipal Chinese governments recognize the importance of R&D and follow a policy of attracting the best overseas returning talent to their regions to start new enterprises. Regional incentives include start-up business tax breaks, R&D laboratory facilities, relocation benefits and access to a skilled labour pool. Federal incentives follow the national government’s five-year planning cycle, which emphasized the government’s focus to fight HIV/AIDS, TB and Hepatitis B to reduce mortality and morbidity by 50%. The 11th five-year plan allocated RMB 60 Yi ($1 billion USD) as a grant scheme to support research and development in these three medical areas. The 12th five-year plan ranks biotechnology as a key priority area for country development.

Dr. Li first had the idea of starting a TB vaccine biotechnology company in the late 1990s. He knew the US market was small, and the US government could afford to use second-generation antibiotic drugs to treat multi-drug-resistant TB (MDR-TB). However, with developing countries like China suffering from at least 200,000 MDR-TB cases per year, the government does not have the resources to offer second-line treatments as a free public good for all. “It is more meaningful to me to develop solutions for high-disease burden countries than for countries with very limited cases and limited emphasis,” said Dr. Li. The objective is also to make the vaccine affordable to the average patient in China, with a final purchasing price around 200 RMB (equivalent approx $30 USD) and a much cheaper alternative than $10,000 for second-line TB drugs in developed countries (Gupta et al., 2001).

While still living in the United States, Dr. Li started to build a resource base for his new venture. First, Dr. Li authored a Chinese book entitled “A New Generation of Vaccine” with Chinese co-authors and collaborators. The book gave credibility to H&G as a start-up enterprise and facilitated its access to the existing TB R&D ecosystem within China. Second, Dr. Li actively sought development partners through frequent visits to China, many of whom are chapter co-authors in the book. Dr. Li learned the importance of domestic national health policy with an emphasis on reducing the tuberculosis disease burden within China. China’s political leader, Premier Wen Jiabao spoke frequently about the need to work quickly and in his Fourth session of the 10th National People’s Congress and Chinese People’s Political Consultative Conference (2006) declared China needs to ‘build an innovation-oriented country ... continuing to strengthen basic research as well as research in technologies for public welfare applications’.

Dr. Li made the decision to move back to China in 2003. He took his idea to China where his private seed funding was matched by the local government on a 50/50 basis. “... We rely heavily on government support through macroeconomic policies in recruiting human capital, providing financing and infrastructure investment” according to Dr. Li. Regulatory laws specified that for biologics therapeutics to be tested in clinical trials on Chinese patients, the products must be produced in China, creating opportunities for Chinese firms. Dr. Li began collaborative efforts with Chinese state-owned biologics research institutes and
manufacturers. “Government support is based on five-year review and evaluations. If our product reaches clinical testing phase, the government will support it for another five years, it give us stability in long-term planning,” stated Dr. Li. The business model developed at H&G involves interaction with multiple government entities that constitute an ecosystem. If value is created through partnership, then all participants in the ecosystem will gain predictable funding from a central source.

11.2. Mobilizing resources in an integrated ecosystem

H&G had a mix of private investors and government grant funding to launch its R&D biotech business. Its resource base is centered on Dr Li as the founder/entrepreneur and coordinator between H&G and development partners. H&G conducts its operations on a virtual network with collaborators. At any one time, no more than six people are operating as part of H&G’s direct payroll. All other infrastructure or personnel is accessed through collaboration agreements.

H&G’s primary collaborators are state-owned hospitals and vaccine manufacturing sites. The WuHan facility is one of six good manufacturing practices (GMP) certified vaccine-manufacturing locations in China and produces the vaccine product for H&G’s clinical work. The WuHan facility is state-owned. H&G also collaborates with Beijing 309 Hospital as the future clinical trial site for its Phase I work. Closer to H&G’s Wuxi headquarters, Dr Li works with Fudan University TB Research Network Centre and uses its publicly funded laboratories.

Like other start-up biotechnology firms, H&G operates on a tight cash-burn budget. It is able to achieve its research milestones based on a combination of government financial grant support and collaborations with publicly funded infrastructure laboratories. It is able to keep capital expenditures low by operating on shared facilities and seconded personnel (graduate students from local universities). The public institutions are willing partners and benefit from the applied experience gained by their staff with industry. If the government recognizes good results, then all collaborators in the project receive increases in government grant funding. It is a business model of shared risk and shared rewards and is scalable within the Chinese context. Focused public policy has resulted in a business ecosystem where participants are given incentives to share resources and inputs into operations. Overall, the country benefits from increase in national innovation capabilities where new entrepreneurial firms and public sector institutions are gaining commercialization capabilities.

Vaccine development is a risky business. As a small start-up, H&G has tried to mitigate some of its individual firm risk by diversifying into diagnostics. Alongside its primary vaccine project, H&G houses a TB rapid diagnostic project, aiming to reduce TB diagnosis time from 30 to 5 days. “It is important to have diagnostic development arm for H&G”, says Dr. Li. “diagnostics have faster commercialization timelines and we are aiming for early cash flow to from diagnostic sales to sustain our vaccine project.” This is consistent with trends within other emerging economies that show the need for biotech start-ups to generate stable revenue from other sources to survive (Palmitkar, 2005).

11.3. Enabling knowledge and resources flows

Fig. 3 below shows the policy directed ecosystem for H&G. H&G relies on external resource providers and collaborative partners to create shared value from its business model.

The competitive advantage for H&G over other small start-up vaccine firms is the strong government support, which Dr Li gained through his expertise and effective relationship building. Public resources including both central government and municipal government funding dominate for H&G. The central government provides the majority of R&D infrastructure and the municipal government adds a second layer of public support as incentives for bringing overseas expatriate innovators to their region. This centralized funding is unique to China and differs from the context facing entrepreneurs working elsewhere on TB vaccines.

12. Discussion

We have used evidence from two case studies to explore connections between innovative firms attempting to commercialize improved tuberculosis vaccines and national biomedical policies. Our research question centers on the way ecosystems can facilitate (and benefit from) new business models that promote effective partnerships in both private and public spheres for new technology commercialization. We explored this question by seeking out evidence on the relationships of two new firms, both combating TB, with other participants in their respective ecosystems. We proposed that key relationships would be found linking firms and public bodies even in public health contexts so diverse as China and the UK. In this section, we interpret the evidence from the case studies with the aim of analyzing this interface and showing the wider relevance of their experience.

12.1. Common strategies despite different public policies

We do indeed find factors in common between OETC, Oxford, and H&G, Shanghai, despite their contrasting national contexts. Both firms are working in a market ignored by the mainstream pharmaceutical industry, which has consigned tuberculosis to the family of neglected diseases. Like other life science businesses, both firms face the challenges of managing long term risk, building knowledge and creating a learning environment (Pisano, 2006). However the policy-based ecosystems of China and the UK differ in the levers used to combat tuberculosis and the two firms have constructed distinctive partnerships that enhance mutual benefits in each context. In both cases there were collective efforts to create value among a group of organizations linked by common goals in a shared value chain. The business models of the case study firms were designed to create value by integrating their efforts with those of research organizations, philanthropic organizations, clinical trial partnerships and consortia, as shown in Fig. 2 for OETC and Fig. 3 for H&G. Participants in these ecosystems had a stake in the achievement of commercialization milestones and had aligned their incentives accordingly.

Both firms operate in networked partnerships to achieve their strategic R&D goals. OETC joined two participants in an emerging ecosystem to create a new joint venture to formalize partnerships. H&G emerged to fill a gap in the value chain for TB innovation, joining academic institutions that had the necessary incubator infrastructure and making use of production capabilities in state-owned enterprises. Neither OETC nor H&G has many full-time employees, but their core employees play a critical role—setting up and maintaining relationships that provide needed resources and offer the prospect of moving their innovations into use.

We found that it was critical for the firms to identify key ecosystem partners and align their own objectives with theirs. Both entrepreneurial ventures capture value for their network of collaborators by meeting clinical and development targets. When each clinical milestone is achieved, the affiliated partners benefit from the signals these milestones offer that their investments are having a positive impact, with associated publicity. This feeds back into the national policy loop.

Both TB vaccine developers are members of a key industry consortium that lobbies policy makers. This includes the Stop TB
partnership; both ventures influence and are influenced by this international coordination body. The Stop TB partnership can exert influence on macro health policy and funding for the global TB vaccine portfolio. The two firms’ efforts feed into their funders’ and partners’ strategies to eliminate TB as a global public health burden. Scientific studies and reports on clinical trial progress are shared annually through meetings with the Stop TB partnership. The firms both take part in annual reporting of clinical pipeline updates to the Stop TB partnership that receives reports from ecosystem participants. These include the South African TB Vaccine Initiative [SATVI], European & Developing Countries Clinical Trials Partnership [EDCTP], the Bill & Melinda Gates Foundation, Ministries of Health and TB Vaccine AERAS product development partnership. There is a reporting circuit with the individual ventures and their partners feeding information to policy makers who are able to draw on extensive evidence executing decisions.

12.2. Mobilizing relevant resources in the ecosystem—Differing strategies

OETC and H&G shared a need to be very responsive to resource availabilities. OETC built international partnerships in the USA, Senegal and South Africa, coordinated from Oxford, drawing on philanthropic funding and relationships with foundations. In contrast, H&G Biotech set up multiple domestic partnerships with Chinese collaborators that allowed for sharing of government funding.

The OETC joint venture structure allowed matching resource inputs from the philanthropic Wellcome Trust (UK) and a public–private development partnership body AERAS. The partnership structure is global as are the funding, research and operations of clinical trials. Resource providers such as AERAS are themselves structure allowed scope for entrepreneurial opportunity detection. The founder entrepreneur responded to government consultation on priority diseases for the country and found ways to match his knowledge with external resources. H&G entered an existing ecosystem of mainly Chinese organizations combating TB, but facilitated collaboration and rapid resource and knowledge flows between participants. The Chinese government initially supported centers of excellence and stimulated a new wave of entrepreneur-ship in local life-sciences companies. Subsequently, tuberculosis was prioritized in the 5-year plan for public health. Because H&G had gained the confidence of the authorities, it gained further resources from government, as did its collaborative partners. H&G’s partnerships are domestic and include Chinese R&D partners, Chinese private investors, and local and central government funders. H&G did have international connections, however, facilitated by the years spent in the US by its founder. As of 2012, H&G signed a memorandum of understanding to allow it to leverage AERAS’ international technical capabilities for planning Phase I clinical trials. In addition, as of August 2013, AERAS further strengthened its international policy ties with China with a formal R&D collaboration on TB vaccines between itself and the Chinese Center for Disease Control and Prevention (China CDC).

13. Incentives for collaboration shaped by public policy

Thus there are a number of common features in the activities of the case study firms despite their very different environments. These communalities are found because both companies had to be proactive in joining up participants in a supportive ecosystem, a task more difficult for OETC since it had to create an appropriate ecosystem where one already existed in China. In both cases it was necessary for the founders to identify an opportunity and take action to realize it, though the nature of the opportunity was shaped by public policy. In both cases they had to gain the confidence of other participants in the ecosystem by demonstrating expertise, achieving R&D targets and through effective management.

The major differences between the cases can be attributed in large part to different goals and priorities of national policy directives. There are obviously major differences between innovating in a market economy where private finance is the major source of investment, as in the UK, and in a planned market economy like that of China. The Chinese government provided a supportive structure for H&G, though H&G had to earn this support in competition with other private sector innovators in China. Tuberculosis and drug-resistant tuberculosis are priority public health concerns for the Chinese government. However public bodies were not the only players; a role for individual innovators was recognized in China. Starting in the late 1990s, the Chinese government had implemented incentives to induce expatriate Chinese scientists and entrepreneurs to return to China. H&G’s founder, Dr Li, responded to those incentives.
OETC operates in a market economy where funding for biotech ventures typically comes from the private sector in the form of venture capital. However this was not available for vaccines targeted at users in developing countries where economic returns are uncertain. OETC was faced with a challenging situation: “TB drugs, diagnostics and vaccines all are in need of more public funding support,” according to Dr Adam Stoten, deputy general manager for OETC.

OETC was constructed as a lean joint-venture to leverage resources from its two key contributors. In contrast with the longer horizon of the Chinese government, private sector players in the UK need to see results of their investment within the time span of managed funds and manager incentives. At the end of 2012, the phase IIb trial results did not show improved efficacy of the OETC vaccine as compared to the traditional BCG alternative for the target patient group (South African infants) (Tameris et al., 2013). As a result the joint venture was brought to a close. The University of Oxford and Emergent BioSolutions will continue their work separately. OETC joint venture efforts were not wasted however. “Progress in difficult fields like TB vaccines is always going to be slow, it’s always going to be iterative. But the only we learn is by doing trials like this,” stated Dr. Helen McShane upon release of trial results. “This was the first TB vaccine efficacy trial in infants in over 40 years,” Dr. McShane pointed out, “and the information gained from these trials can feed into the global TB vaccine R&D pipeline, allowing the remaining clinical vaccine candidates to iterate faster.” Her laboratory in Oxford will continue to analyze the results collected; however, the development and manufacturing processes arm of the joint venture will cease further development.

One of the drawbacks of a lean, virtual organization business model is that it has limited resources to secure its work when results fall short of expectations. An ecosystem can only create a safety net and build resiliency in the innovation system if it is sufficiently robust. The global ecosystem created by OETC had considerable potential but was also vulnerable to weak links, in particular the absence of long term funding arrangements. OETC funding was project specific and when clinical milestones were not met, the business model could no longer be supported under market pressures. If the vaccine trial had been successful, new resources would have flowed into the joint venture from public and private sources for the next clinical phase of work. If combating TB had been viewed as a domestic policy goal instead of being viewed in the context of UK aid for international development, the context for TB innovation by OETC might have been different. There were also additional challenges of proving efficacy in HIV-positive populations—adding additional scientific standards of vaccine efficacy.

The phenomenon of reverse innovation, where innovations developed for emerging markets turn out to have important applications in advanced economies is gaining recognition (Immelt et al., 2009). After decades when TB appeared to be under control, TB cases have doubled in London, raising an alarm for public health (Rodger et al., 2005). The prospect of reverse innovation to the benefit of donor countries may in the future be presented in order to attract funding and lobby government of advanced economies for support in combating TB. For example, infectious disease control strategies were usually set by government public health agencies, but now overlap with defense strategies and controlling threats to national security.

14. Limitations of this approach

The use of ecosystem concepts is fast gaining ground, but is sometimes criticized as using inappropriate biological metaphors. Penrose (1995), for example, rejected biological analogies because she believed they had determinist implications. But if a new venture can deliberately alter its ecosystem environment and the selection forces to which it is subject, this actually demonstrates the proactive entrepreneurial decision-making and motivation that Penrose viewed as a central object of inquiry. Moreover we are using the ecosystem analogy as a way of organizing related ideas, not as a literal analogy to an energy transfer chain in the natural world.

Another objection may be that the boundary of the ecosystem is ill defined. This is a criticism that can be leveled against any systems approach, since the boundary of a system is selected for purposes of analysis. Evidence on the firm’s transactions and business model identifies the ecosystem boundary. The parties with which the firm is in interaction are viewed as participants in the ecosystem, while the business model identifies players who affect a firm’s market position such as competitors and regulators who are also part of the firm’s ecosystem.

Some may object that enterprises requiring public–private partnerships rely too heavily on philanthropy and public resources. However, new science based firms are seldom initially self sufficient, and research based enterprise is usually supported by external funding of some kind (Pisano date). Even for innovator firms that are not focused on diseases of the poor, philanthropy and public grant funding are key contributors to early stage research.

15. Contributions to theory and practice

Our research question focused on how innovators’ business models can be devised to make the most of public policy. A related question is what influence policy can exert on firms’ strategies in the context of policy priorities. The two studies explored factors affecting the commercialization of TB vaccines by new ventures in different national innovation ecosystems. We identified a number of factors in common between these enterprises starting with the way both addressed TB as a neglected disease of the poor for which few commercial incentives to innovate are in evidence. In both cases there was opportunity recognition, typical of entrepreneurship, and attempts were made to use prior knowledge to build further capabilities. In neither case was it realistic for the entrepreneurs to ‘go it alone’ and both sought to align their business models with public policy priorities in order to access resources. Both enterprises are members of a global consortium, the Stop TB Partnership, which afforded them legitimacy and helped them lobby government and governments beyond their own borders. However the differences between the two cases were considerable and these were closely linked to their respective government priorities.

The Chinese entrepreneur had to gain the confidence of the authorities in order to be admitted to the on-going ecosystem for vaccine innovation in China. Once admitted the firm was guaranteed funding support so long as results were achieved because of the priority accorded to containing TB in China. For the UK venture it was necessary to build an innovative ecosystem of organizations seeking to create value collectively. This was done on a global basis since TB was not viewed as a domestic policy priority by the UK authorities. We do not know what would have occurred had the UK policy environment been more favourable to OETC; this counterfactual points to the need to conduct further comparisons of this kind.

Systems of technology innovation have traditionally been studied in high-income countries with a focus on innovation for commercial markets (Abernathy and Clark, 1985; OECD, 1991; Teece, 1986). An ecosystem approach enables us to identify
challenges facing innovative ventures in different settings as they relate to national systems of innovation and encompassing value creation in both commercial and social terms (Lundvall et al., 2002). Our case study evidence shows how research and development networks are needed to further R&D objectives. A supportive ecosystem promoted by government policy can help private sector innovation by filling resource gaps where commercial returns are lower than required by market expectations. Entrepreneurial companies can introduce a dynamic element into such networks and ensure that they do not simply rely on government handouts but seek new ways to create value for private as well as public investors.

16. Generalizability of findings

The ecosystem approach to promoting innovation in contexts of market failure can be applied to many other sectors beyond healthcare. For example, environmental ventures launching a new technology may also require the creation of a supportive ecosystem. Green ventures often require government or trust funding to accelerate the adoption needed to make the initial ecosystem creation viable; electric cars provide such an example (Kley et al., 2011). Social and environmental issues arise when sustainable development is the objective and here too there may be a need to align with policy priorities (Hall et al., 2010). The ecosystem perspective has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010). The ecosystem approach to supporting emerging supply and value chains and helping to pull the market has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010). The ecosystem approach to supporting emerging supply and value chains and helping to pull the market has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010). The ecosystem approach to supporting emerging supply and value chains and helping to pull the market has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010). The ecosystem approach to supporting emerging supply and value chains and helping to pull the market has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010). The ecosystem approach to supporting emerging supply and value chains and helping to pull the market has been applied to poverty alleviation through cooperation efforts to deliver improved education (Patrinos et al., 2009). At the intersection of education and international development, multilateral funding organizations such as the World Bank work to align with policy priorities (Hall et al., 2010).

In this paper, the strategic priorities guiding policy shaped the environment within which innovative ventures were operating in both settings. In China federal leaders explained their aims as follows: "We need to follow a policy of making independent innovations and ‘leapfrog’ advances in key areas of science and technology and supporting and guiding future development."—a statement of priorities from Chinese federal leaders. This was the basis for the creation of an ecosystem for TB innovations in China. The relevant guiding principle from the UK Health is Global Framework (Department of Health, 2011) is to "promote health equity within and between countries through our foreign and domestic policies, particularly through action on the social determinants of health." Governments can guide innovation through policy directives. But they are more likely to achieve their goals if they can embed strategic objectives in innovation ecosystems by supporting emerging supply and value chains and helping to pull innovations into use. In the particular cases studied this occurred to a greater extent in China where the priorities of policy and those of the case study firm, H&G, were better aligned than for OETC.

Breakthrough innovations for users with limited purchasing power require new relationships between technology innovators and government policy makers, and philanthropic foundations can also play a catalytic role. The Chinese case shows that government policy can mitigate risk and provide infrastructure, funding stability and a safety net for continued efforts in difficult technical areas. The UK case shows the potential of international collaboration and the creation of global ecosystems to promote innovation for demographic groups with unmet needs. New business models are required that build partnerships with other private and public sector organizations in a supportive ecosystem. Further work on business ecosystems bridging public and private sector activities is needed to provide conceptual frameworks and tools to advance work in biomedical commercialization for neglected diseases. Public health programs have been unable to provide sufficient accessible and affordable treatment of infectious diseases that mainly affect the poor. Governments acknowledge the need for partnerships and are working to enlist help from the private sector to pull through promising innovations. When public policy is embedded in an innovation ecosystem, this can encourage firms to devise business models that meet strategic goals aligned with those of policy where market incentives are weak but needs are pressing.

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