



Policy-driven ecosystems for new vaccine development



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ABSTRACT

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.

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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

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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 communalities 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 (Lönnroth et al., 2010). TB primarily affects lower socioeconomic groups and

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