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Entrepreneurship and Global Health: Catalyzing the Ecosystem

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Entrepreneurship & Global Health: Catalyzing the Ecosystem

ABSTRACT

Innovative financing for global health may stimulate new waves of entrepreneurial activity. Global policies have created new sources of financing to accelerate knowledge generation for healthcare in resource-poor settings. This article outlines the emerging research concerned with the entrepreneurial response to opportunities and incentives at the bottom of the pyramid for healthcare. Questions arise to what kind of business models can be used to provide affordable healthcare on a viable basis. We examine public-private partnerships as one mechanism to catalyze the ecosystem and draw in stakeholders to contribute to the innovation value chain. We integrate entrepreneurship, innovation and ecosystem theories to discuss how the entrepreneurial firm builds resources and creates value in the healthcare ecosystem.

Keywords: entrepreneurship, global health, innovation value chain, resource-based theory, policy & practice

1. Executive Summary

This article addresses responses from the private sector to inequities in global health. New global policies have been designed to create incentives for healthcare innovation by mitigating risks for science-based business. These policies have been mainly directed at large pharma companies. Whether and how viable entrepreneurial innovation can be stimulated depends on business models adopted by entrepreneurs, the topic of inquiry in this paper.

The global healthcare ecosystem is complex with many interdependent business, social and political stakeholders influenced by developments in supply, demand and institutional arrangements. National policy makers not only provide oversight of the operations of healthcare firms, but also shape conditions affecting inputs through their regulations. To focus on business management and entrepreneurship, we examine the healthcare ecosystem of the entrepreneurial firm, our unit of analysis, to see how such firms can drive innovation in the value chain, guiding new concepts through discovery, development and diffusion.

A framework is proposed, combining the resource-based view of entrepreneurship, with concepts from innovation and business ecosystem literature. The case exemplar selected centers on the public-private partnership of the Meningitis Vaccine Project (MVP), a program established in 2000 solely for the purpose of eliminating meningitis epidemics in sub-Saharan Africa. MVP was founded by a $70M USD, 10-year grant by the Bill and Melinda Gates Foundation and has 21 primary stakeholders. MVP provides an illustration of a public-private partnership mobilizing resources in both public and private sectors, involving donor countries and foundations aiming at a common goal. Empirical evidence focuses on the innovator private sector firm, SERUM Institute of India Ltd ("SERUM") as an entrepreneurial innovator within the MVP partnership. SERUM matched its internal capabilities to opportunities in the innovation ecosystem to achieve commercialization for MenAfriVac™, the world's first vaccine approved for meningitis A. The MVP public-private partnership has brought together primary and secondary stakeholders in an innovation ecosystem that supports entrepreneurial activity in global health. Using a resource-based framework, we extend entrepreneurship theory beyond conventional applications and point to new business models for global health entrepreneurs.

2. Introduction

The global disease burden is not distributed equally[1]. Communicable, maternal, perinatal and nutrition-related diseases (classified as diseases of poverty) add up to over 50% of the disease burden of developing countries – nearly ten times higher than their burden in developed countries (Commission on Intellectual Property Rights, 2006). There is global demand for access to more biomedical knowledge, products and services. The costs of innovations have limited access for many patients in resource-poor settings (Henry & Lexchin, 2002; Pecoul, Chirac, Trouiller, & Pinel, 1999; Trouiller, et al., 2002). For neglected diseases[2], global supply is not able to fully meet demand. Studies show that rises in biomedical research funding have been aligned with disease burden in high-income countries, but not linked to new drug approvals (Dorsey, et al., 2009). Furthermore, of all chemical entities marketed between 1975 and 1999, only 1% were for neglected diseases (Trouiller, et al., 2002).

Health inequalities have been correlated with conflict, international security and economic development (MacQueen & Santa-Barbara, 2000; Sachs, 2005). The response by global governing bodies has been to provide funding for global health (Group, 2010; Hecht, Wilson, & Palriwala, 2009; Moses, Dorsey, Matheson, & Thier, 2005; Ravishankar, et al., 2009). Funding grants have also been made conditional on collaborating between stakeholders in the global healthcare ecosystem. This consists of primary stakeholders including patients, knowledge generation centres (public academic institutions and private life sciences firms), their suppliers, employees, partners and funders. Secondary stakeholders of the ecosystem include the systems of national healthcare within which these players operate, local communities, regulators, patient advocacy groups, civil society, non-governmental organizations and the broader scientific community. Almost all of the stakeholders in the healthcare ecosystem hold inter-locking relationships with each other and often cross boundaries between primary and secondary stakeholder status.

[1] World Health Report 2008. Primary health care: now more than ever. Geneva, World Health Organization 2009 (http://www.who.int/whr/2008/whr08_en.pdf) accessed October 18, 2010.

[2] World Health Organization defines Type I diseases: which are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases: are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Type III diseases: are defined being those that are overwhelmingly or exclusively incident in developing countries. Type II diseases are often termed *neglected diseases* and Type III diseases are often termed *very neglected diseases*. (Commission on Intellectual Property Rights, 2006)

Neglect of diseases has resulted from lack of effective demand and purchasing power by patients in poor countries. Entrepreneurs, as agents of change, have historically demonstrated ability to exploit neglected opportunities associated with human need (Nairn, 2002). Enterprise initially propelled adoption of industrial innovations such as the railroads and chemical companies in the 19th century and what became large scale science businesses such as DuPont AT&T (Bell Laboratories) and General Electric (Chandler, 1977; Pisano, 2010). However, in new science-based businesses such as biotechnology and healthcare, the convergence of science with business has presented difficulties in long-term risk management, knowledge integration and learning (Pisano, 2006). How science-based entrepreneurs discover and develop opportunities that lie beyond the pull of existing markets calls for further inquiry (Hall, Daneke, & Lenox, 2010). Here we examine how new financing sources can mitigate the risks of science and technology targeted at previously neglected diseases. Decreased risk can encourage new forms of entrepreneurial activity in the global health ecosystem.

To organize thinking on this complex topic we apply a resource-based entrepreneurial framework to the global health ecosystem to elucidate new sources of entrepreneurial and business model innovation. The paper is structured as follows: the first section addresses knowledge gaps in global healthcare and research on how public-private partnerships can provide opportunities for business to generate relevant knowledge. The second section proposes the conceptual framework that guides our research question and shows how this can be informed by evidence-based constructs. The third section utilizes a case study as an exemplar, applying the conceptual framework to empirical evidence from the Meningitis Vaccine Project.

The MVP partnership concentrated its development with the entrepreneurial firm SERUM Institute of India ("SERUM"). This paper builds on resource-based theory (Penrose, 1995; Wernerfelt, 1984) in relation to the innovation value chain (Afuah, 2003; Hansen & Birkinshaw, 2007), informing the framework with evidence on how SERUM utilizes a public-private partnership model to create and capture value in the global health ecosystem.

3. The recognition of existing knowledge gaps in global health

Developmental economists have shown that the burden of disease directly impacts country development (Collier, 2007; Sachs, 2005) and weak health systems help perpetuate the poverty cycle (Kremer & Glennerster, 2004). In developing countries, poverty decreases purchasing power and the inability of the poor to pay reduces effective demand, curbing the market pull incentive for private enterprise. The supply and demand mechanisms that reward private firms are largely absent in resource-poor settings.

In surveys conducted by the United Nations World Health Organization (WHO) developed countries account for 12% of the worldwide burden of disease from all causes of death and disability and account for 90% of all health expenditure worldwide (Murray & Lopez, 1997). The tension between the need for innovations to prevent and treat diseases in developing countries and the very constrained resources in these countries is widely recognized (Hotez, et al., 2007).

Recognition on this situation has led to greater priority being accorded to healthcare issues, leading to a quadrupling of donor assistance funding for health from $5.6 billion in 1990 to $21.8 billion in 2007 (Ravishankar, et al., 2009). The increase in funding has given rise to new coordination and mobilizing organizations such as The Global Fund to fight HIV/AIDS, Tuberculosis and Malaria and the GAVI Alliance for vaccines and immunizations. However even with increased funding, governments alone cannot resource and manage the healthcare innovation cycle of discovery, development and delivery. Private sector involvement is needed (Commission on Intellectual Property Rights, 2006). For example, two relevant initiatives have been made to engage private sector firms on the development agenda of resource-poor countries. New partnerships are arising from UK's Department for International Development (DFID) through its Private Sector unit[3] and US Agency for International Development's (USAID)'s Development Innovation Ventures (DIV) to support "game-changing innovations" through a combination of push and pull mechanisms[4]. A new global trend is emerging, involving partnerships between the private business sector and international development agencies.

[3] UK DFID Private Sector Unit Lauch October 12, 2010 http://www.dfid.gov.uk/Media-Room/News-Stories/2010/Mitchell-Private-sector-holds-the-key-to-tackling-global-poverty/ - accessed October 15, 2010

[4] USAID Announces Development Innovation Ventures October 8, 2010 http://www.dfid.gov.uk/Media-Room/News-Stories/2010/Mitchell-Private-sector-holds-the-key-to-tackling-global-poverty/ - accessed February 2, 2011

3.1 The recognition of opportunities emerging at the bottom of the pyramid for health

Bottom of the pyramid markets offer significant sources of entrepreneurial opportunities (Hart, 2005; Prahalad, 2006) for private sector businesses with a market-oriented solution. Business models can be adapted to serve the poor and yet provide commercial viability for the enterprise (Prahalad & Hammond, 2002). Public partners and government national health systems could help reduce risk, integrate knowledge and diffuse innovations to achieve social impact (Gardner, Acharya, & Yach, 2007; Hecht, et al., 2009).

For the most part, private entrepreneurial firms have not tackled diseases of the developing world because they have assumed only in developed countries is there purchasing power for technological innovations. However, new studies argue that although consumers at the bottom of the income pyramid have low individual levels of disposable income, on an aggregate basis, consumer demand is extensive (Hammond, Kramer, Katz, Tran, & Walker, 2007; Karamchandani, Kubzanasky, & Frandano, 2009; Prahalad, 2006). It is estimated that populations living in low and middle-income countries comprise a $158 billion market opportunity for healthcare products and services (Hammond, et al., 2007). To access bottom of pyramid consumers, entrepreneurial firms, governments and global aid agencies are exhorted to consider the principles of affordability, access and availability of innovations (Prahalad, 2006). Applying these three principles to health innovations appears to be essential for reducing health inequities.

To address affordability and access, increased funds have been targeted at healthcare logistics and delivery capabilities in resource-poor countries. Of particular interest here, financing incentives have been established to encourage public and private sectors to work together to address availability of drugs and services that target the disease burden in developing countries and overcome the market supply gap (Taskforce, 2009a, 2009b).

New funding sources provide two types of support for entrepreneurial firms: push and pull incentives. Push programs are primarily supply-side grants and subsidies that reduce the costs of research inputs; they include grants to university academics and tax credits for firms engaging in R&D activities. Pull programs operate from the market demand side of the spectrum, increasing the potential rewards for commercialization success and providing a higher payment for research outputs (Kremer & Glennerster, 2004). Examples of pull incentives include a purchase guarantee of a product/service at a certain quantity or at a certain price. Both push and pull methods can be used to spur innovations that serve the

bottom of the pyramid populations (Group, 2010). Large multinational firms have begun implementing the principles of serving the poor profitably (Immelt, Govindarajan, & Trimble, 2009; Webb, Kistruck, Ireland, & Ketchen, 2009), and policy changes to increase funding could also be used to attract smaller entrepreneurial firms.

There has been a shift in public health polices in recognition of the possibility of new business models to deliver healthcare knowledge, goods and services. Push and pull incentives are being provided to enable private partners, small and large, to participate in both knowledge generation and knowledge delivery of health innovations. Entrepreneurial thinking, both from the public and private sectors can extend the boundaries of internal capabilities and add synergies in new resource combinations (Burgelman, 1983).

3.2 The entrepreneurial response to new opportunities through public-private partnerships

As part of the effort to improve healthcare provision, global product development partnerships have developed since the mid 1990s (Buse & Walt, 2000). These partnerships mobilize resources in both the public and private sectors and involve donor countries and foundations united in pursuit of a common health goal. Partnerships for international development between donors and recipient countries is a concept originating from the Pearson Commission of 1969 (Pearson, 1969). In the healthcare context, the World Health Organization describes partnerships with the private sector as a means to "bring together a set of factors for the common goal of improving the health of populations based on mutually agreed roles and principles" (Buse & Walt, 2000). The working definition of public-private partnerships includes three points: partnerships must involve at least one private for-profit organization with at least one not-for-profit organization, core partners provide a joint sharing of efforts and of benefits, partnerships in public health are committed to the creation of social value (aimed at improving health) especially for disadvantaged populations (Reich, 2000).

Increasingly, private philanthropic foundations have operated as catalysts in the funding of global product development partnerships and health aid, reaching 27% ($5.2 billion) of health aid in 2007 (Ravishankar, et al., 2009). Philanthropic foundations and public sector aid donors support the project management infrastructure of the partnerships and create a platform to engage the private sector.

The partnership basis of these global product development partnerships encourages interdisciplinary collaboration in the ecosystem. Push funding derived from partnerships can mitigate product development failure risk as well as provide additional technical support to the entrepreneurial firm. This can reduce some of the risks experienced by firms that need to engage in scientific R&D as depicted by (Pisano, 2010), and extend the reach of entrepreneurial innovation.

Public-private health partnerships also provide pull incentives for the private sector. Partnership stakeholders can play funding roles, technical roles as well as a procurement role for the final product developed. The difficulty in reaching small, segmented markets for health can be overcome with a coordinated approach that can be facilitated by a public-private partnership.

4. Research perspectives from the field of management studies

The research question examined here is as follows: what business models can enable entrepreneurs to provide affordable healthcare innovations on a viable basis? The unit of analysis examined is the entrepreneurial firm within its wider ecosystem. This approach is used as a basis for integrating themes from entrepreneurship, policy, and technology innovation.

The importance for firms of selecting an appropriate business model in creating value is increasingly recognized (Teece, 2010). However, prior research concentrates on innovation in resource-rich environments. Less attention has been paid to innovative business models in developing country contexts. We explore this knowledge gap through the application of a model of entrepreneurial value generation (Figure 1). This is applied here to new and established firms that offer products and services to users at the bottom of the income pyramid. The conceptual model makes it possible to map out the elements of entrepreneurial activity and identify how new firms or units of existing firms may adapt their business models to fit resource-poor settings.

Influential definitions of entrepreneurship focus on economic opportunity (Kirzner, 1979; Schumpeter, 1934) and pursuit (Shane & Venkataraman, 2000). In contrast, it can be argued, following earlier work by Penrose (1995), that the novel ways in which entrepreneurs build resources for their ventures is no less critical to their success (Freeman, 1982). Thus

key features of entrepreneurial innovation are to be found not only in the way opportunities are identified, created and pursued, but in the novel matching of a firm's resources to opportunity in order to create value in new ways (Garnsey, 1998).

Evidence from an entrepreneurial firm active in a wider health partnership (MVP) is presented as an exemplar. A single case study can be justified to inform a conceptual framework. It is not claimed that such a case is representative, but rather that it can provide theoretical and empirical insight: "it is often desirable to choose a particular organization precisely because it is very special in the sense of allowing one to gain certain insights that other organizations would not be able to provide" (Siggelkow, 2007, p. 20). Single case studies have provided insight for influential studies in management studies, e.g. (Penrose, 1960; Schein, 2010).

The case study method is applied to investigate entrepreneurship and global health in this paper. This approach makes it possible to inform a conceptual model with evidence in order to illuminate poorly understood phenomena (Eisenhardt, 1989). Qualitative research can provide rich evidence needed for understanding "why" and "how" questions relating to entrepreneurial motivation and behavior in firms (Yin, 2003). Qualitative research of this kind draws on the inductive and interpretative tradition (Van Maanen, 1983). Primary evidence from face-to-face interviews are particularly valuable (Walsham, 1995), and were undertaken for this inquiry. In selecting interview subjects, researchers are encouraged to find individuals with the requisite experience to offer understanding of the case history through their own experience (Greenhalgh & Taylor, 1997; Patton, 1990). To guard against retrospective bias, such testimonies should be checked against secondary evidence obtained from archives, company documents and press reports. Case evidence was gathered through primary semi-structured interviews with the chief MVP project director and implementation staff of MVP partners. Triangulation was conducted through secondary and archival data research and use of public press releases on the 10-year development timeline of the project.

The case selected provides insight into many dimensions of the issues addressed in this paper. SERUM Institute of India Limited (SERUM's) business model in developing the meningitis A vaccine relies on its mutual cooperation with the Meningitis Vaccine Project (MVP), a public-private development partnership. While maintaining its regular operations, SERUM has been able to diversify into a new disease area (meningitis) with a new vaccination technology. The case shows how product development partnerships may help

firms achieve new business models to generate value for both producers and users. But to accomplish this, they may have to create for themselves a more supportive business ecosystem (Garnsey & Leong, 2008), or identify one that they can enter. The case study shows how MVP has drawn together stakeholders that have provided a supportive business ecosystem for SERUM (Moore, 1996).

5. Conceptual framework: mobilizing resources to create value

Public-private partnerships can create alternative avenues for incumbent firms to venture into new areas with a risk-mitigating and knowledgeable partner in order to achieve entrepreneurial-style innovations. An open innovation public-private partnership business model is a new alternative to the traditional in-house drug commercialization model of healthcare firms. The open innovation business model allows each participant to contribute resources in accordance with their capabilities (Chesbrough, 2003). In any entrepreneurial undertaking whether in a new venture or in an established firm, resources are combined in new ways to create value for the activity (Garnsey, Dee, & Ford, 2006; Penrose, 1995). By viewing entrepreneurial innovation in this light, we aim to extend entrepreneurship theory to the context of global health.

The healthcare ecosystem is complex because of the many interdependent stakeholders involved. To illustrate the role of the firm as a key player within the ecosystem, we draw on two streams of thought: entrepreneurial building of the resource-base (Figure 1) and the innovation value chain (Figure 2), which can provide a supportive ecosystem for an entrepreneurial firm (Figure 3). Entrepreneurial value generation occurs in each of the firms that take part in the innovation value chain, as illustrated in Figure 3, so that the entire value chain becomes a value-adding innovation system.

5.1 Applying the conceptual framework to case evidence

5.1.1 Combining resources

The firm's business model represents the way the firm is organized to create and capture value (Garnsey, 2003; Teece, 2010). This is depicted over the firm's value generation cycle in Figure 1, showing the firm as an input-output system obtaining resources

from its ecosystem and transforming them into outputs of value to customers. The value generation process for given output requires a productive resource base that enables the entrepreneur to be an agent of change. Some innovating firms already have a resource base, while others have to build a resource base, and also access the resources of others in their ecosystem, before they can produce innovative output. Figure 1 depicts the resource base used to create output of value to users/customers, sometimes with the help of partners. The top loop shows efforts at building the resource base, which may be extensive for a new science-business in the life sciences. If the firm's activity is to be sustained, it must capture some of the value created as returns over and above costs; returns may be distributed or reinvested to propel the next phase of the value generation cycle. Because of the challenges they continually face, entrepreneurs often reconfigure their resources and search for opportunities using a different organizational base. Resource constraints both limit and enable enterprise, restricting obvious options but encouraging new thinking outside conventions (Hugo & Garnsey, 2005).

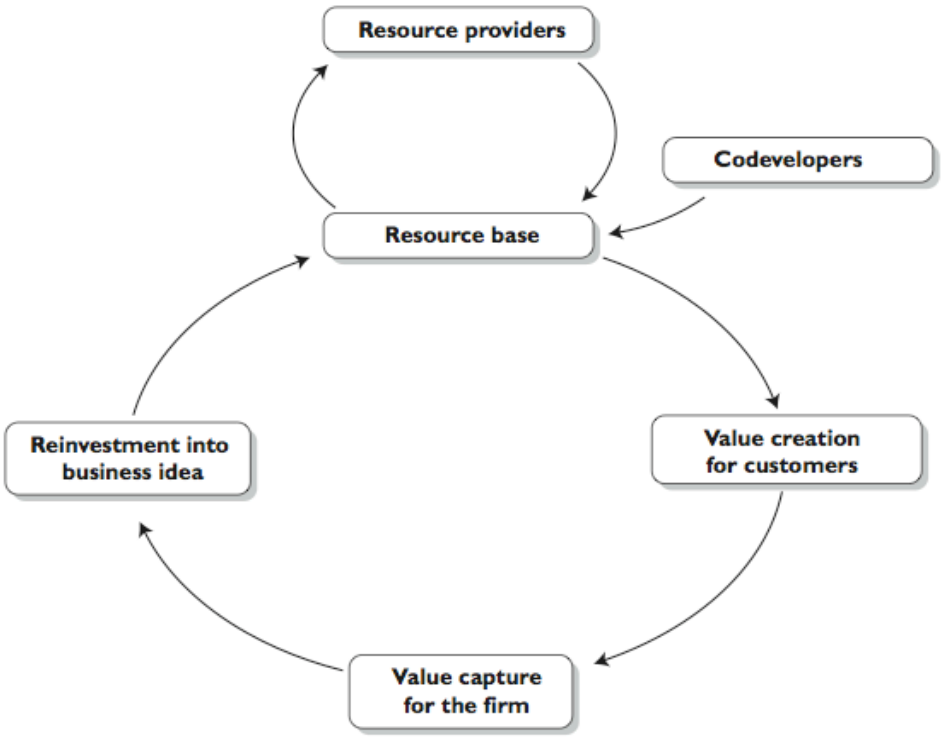

Figure 1: The value generation cycle. Adapted from Garnsey, et al., 2006

An entrepreneurial firm is typically resource-constrained and creates competitive advantage not only from its own resource base, but rather from a unique assembly of resources (Penrose, 1995). These may include critical resources from other organizations

that provide inputs (eg. investment) or help the firm produce its outputs on a complementary or collaborative basis. In the case of global health enterprises, resources and knowledge that the firm does not immediately own may be accessible from resource providers through collaboration (Garnsey & Leong, 2008). The study focuses on ways in which the entrepreneurial healthcare firm may be able to create a supportive ecosystem for itself through public-private partnerships.

The theoretical underpinning of this approach comes from the resource-based theory (RBT) view of the firm, attributing differential firm performance to firms' resource composition (Barney, 1991; Rumelt, Schendel, & Teece, 1991; Wernerfelt, 1984). Additional capabilities within the ecosystem can complement the firm's resource base, while each value-creating firm helps contributes to the shared ecosystem through a process of mutual influence (Garnsey & Leong, 2008). This is a way of operationalizing the notion that entrepreneurs actively utilize their networks to seek out the necessary knowledge and resources to form new combinations of intellectual and social capital (Nahapiet & Ghoshal, 1998).

Thus the value generation model depicts the way firms' inputs (resources) can be organized and translated into outputs of increasing value – Figure 1 is a way of operationalizing the concept of the firm's business model (Johnson, 2010; Teece, 2010). Every successful business model is structured to create value greater than its discrete inputs, and to engage customers prepared to pay for value and convert value to profits (Teece, 2010). The focal point in our depiction of value generation by the entrepreneurial firm is on the resource base that the firm builds and sustains, and how this is extended through collaborations with partners in its ecosystem. It is by using its resources to deliver an offering that is affordable and meets user needs that the firm creates a value proposition for the customer (Johnson, 2010).

Value generation can be seen as an emergent property of the firm as an input-output system. This model builds upon Penrose (1995) who argued that resource asynchronies are drivers of firm growth. In a partnership model, internal firm resource asynchronies may be supplemented by partner sources in complementary combinations to drive new entrepreneurial activity for all participants.

5.2 Contributing to the innovation value chain and capturing value

The innovation value chain involves the transformation of ideas into end products for the customer and requires the integration of idea discovery, idea development and idea diffusion (Afuah, 2003; Hansen & Birkinshaw, 2007). This notion is built upon the manufacturing value chain concept of mapping out processes to transform raw materials into finished goods (Porter, 1980). In a partnership business model, the innovation value chain becomes open to contributors who may specialize in one or more distinctive competencies.

Where there is social as well as economic value to be created, each party may contribute to the mission to which other participants in the value chain are committed. While most work on value creation has a focus on the creation and capture of economic value, increasingly it is realized that the social value created by enterprise and innovation is of no less importance. Value captured by each stakeholder can be a combination of financial, technical and social value (Lepak, Smith, & Taylor, 2007). Lepak's (2007) review proposes two conditions for value creation: first, the monetary amount exchanged must exceed the producer's costs of creating the value and second, the value enjoyed by the consumer must be perceived to be better than the consumer's closest alternative. The financial value captured by the firm is the difference between exchange value and production cost. In addition, intangible value can be built, in the form of knowledge and skills, while social value created is created through the matching of innovation to an unmet consumer need that may result in positive externalities for society.

This concept extends the notion of open innovation value (Chesbrough, 2003) to encompass social value; participants draw on internal and external knowledge and learning to create value while each partner is enabled to capture part of the overall increase in quantifiable economic value and unquantifiable but significant social value.

Figure 2 below shows the innovation value chain as applied to healthcare. This has a translation process from scientific discovery to use, with intermediary phases in clinical development to test efficacy and safety and delivery processes to reach patients in need (Commission on Intellectual Property Rights, 2006). Value can be created and captured at each stage of the innovation value chain through a partnership model.

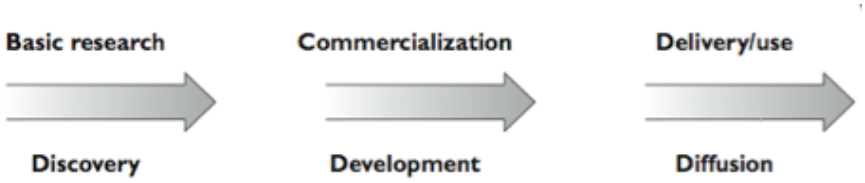

Figure 2: The innovation value chain in healthcare. Adapted from (Commission on Intellectual Property Rights, 2006; Hansen & Birkinshaw, 2007)

Managers who recognize the importance of engaging with other stakeholders realize that there is a bi-directional relationship between the firm and other players in adjoining input-output constituencies (Donaldson & Preston, 1995). Unmet medical needs create a focused direction for innovation and involve primary stakeholders outside the direct chain of suppliers and customers.

5.3 Innovation in the public-private partnership ecosystem

To move from a conceptual scheme to specific instances, we can see for those developing remedies for neglected diseases in various parts of the innovation value chain, private public partnerships can offer resources and project management capability to integrate processes of collaboration.

Figure 3 shows that entrepreneurial firms need not to be active in every stage of the innovation value chain of global heath, but can specialize within a innovation ecosystem towards a shared objective (Adner, 2006; Buse & Walt, 2000). Value created by specialist firms at the discovery and development nodes of the innovation value chain can be transferred to delivery partners. This occurs where there is disintermediation (the reverse of vertical integration) among producer firms in the value chain. The firms can draw on their resource base to create value for their customer, and also capture value in order to remain viable. The firm's customer may not be the final customer, but could be another intermediary participant in the overall innovation value chain. Value creation along the innovation value chain, potentially involving more than one enterprise, can collectively generate value in a safe and efficacious therapeutic solution. Central to the firm's operations are its transaction partners, including suppliers, customers, co-innovators and resource providers. Resource providers can provide support to several participants in the innovation ecosystem, together in pursuit of a common mission.

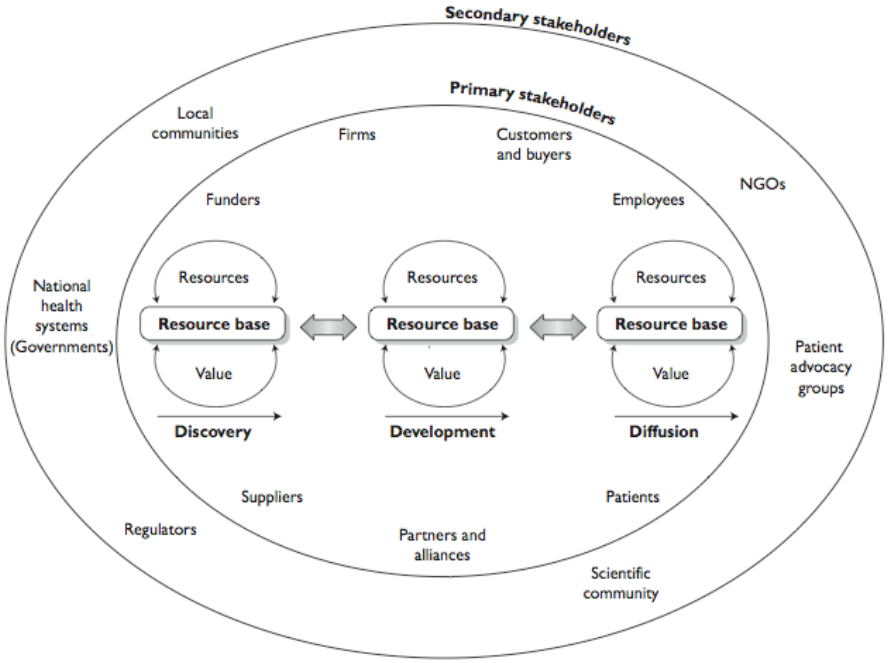

Figure 3: Value generating firms taking part in the innovation value chain of the global health innovation ecosystem

In addition to the firm's transaction partners, who can be thought of as primary stakeholders, the firm's secondary stakeholders play an increasingly important role (Waddock, Bodwell, & Graves, 2002) in the business ecosystem but are often more difficult to identify (Hall & Martin, 2005). Regulators, trusts and non-governmental organizations (NGOs) can directly impact firms' activities and occupy both primary and secondary stakeholder positions. Secondary stakeholders can also contribute to or disrupt competencies of the innovation value chain. For example, the wider scientific community is affected by the commercialization of other health research, as discoveries and lessons are shared within the community generating positive externalities. NGOs and advocacy groups take up causes and needs of the poor and raise awareness of commercially neglected issues.

6. Public-private partnership ecosystem: the case of SERUM within the Meningitis Vaccine Project

In what follows this conceptual framework is informed by evidence from a global public-private partnership, the Meningitis Vaccine Project (MVP) that produces MenAfriVac™[5], the world's first meningococcal serotype A conjugate vaccine. MVP is a

[5] MenAfriVac™ received WHO prequalification and approval status on June 23, 2010

partnership coordinated by the United Nations World Health Organization (WHO) and Program for Appropriate Technology in Health (PATH). The vaccine obtained WHO approval on June 23, 2010 and launched its first mass vaccination campaign in Burkina Faso on December 6, 2010[6].

The Need

Meningococcal meningitis occurs when viruses or bacteria invade the protective membranes of the central nervous system and cause an adverse inflammatory response. Bacteria that penetrate the meninges have passed the crucial blood- brain barrier and can cause permanent damage to neural functions. Even with aggressive treatment, case mortality is high, reaching up to 25% globally (Greenwood, 1999; Jodar, LaForce, Ceccarini, Aguado, & Granoff, 2003). However, this may be underestimated due to the high number of cases in resource- poor settings where the patient does not reach the hospital-level for appropriate treatment and therefore no record is kept.

In sub-Saharan Africa, *N.meningitidis* is of particular concern and is the bacteria with the greatest potential to cause epidemics in the semi-arid region stretching from Senegal (West Africa) to Ethiopia (East Africa) in what is known as the "African meningitis belt". Meningitis bacteria are spread via sneezing and coughing and are perpetuated across African countries during the hot, windy season where cyclical epidemics affected up to 250,000 people.

Monitoring and evaluation of immunization schedules in developed countries have demonstrated efficacy as pharmaceutical companies responded to public health concerns (Trotter, Andrews, & Kaczmarski, 2004). The meningococcal C conjugate vaccine was added to the UK immunization schedule in 1999 and Trotter's study (2004) found a significant drop in meningococcal C disease after immunization and confirmed persistent vaccine effectiveness (90% at 4 years). By contrast, no private manufacturer was willing to develop a meningococcal A conjugate vaccine, which is the serotype which predominately affects sub-Saharan Africa. In 2000, a WHO report found that existing intellectual property on conjugation technology for a group A vaccine existed and if paired with international funding, a low-cost, high quality vaccine could be produced for Africa at a target price of US$0.40 per dose or less (LaForce, Konde, Viviani, & Preziosi, 2007).

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http://meningvax.com/

[6] MVP Press releases - http://meningvax.com/ accessed December 16, 2010

The Response: recognizing an opportunity and mobilizing resources

Upon the 2000 issuance of the WHO recommendation, the Bill and Melinda Gates Foundation awarded a $70 million USD, 10-year grant to WHO and PATH to coordinate a global public-private partnership effort to eliminate meningococcal epidemics in the "African Meningitis Belt".

The MVP team chose the contract manufacturing approach to consolidate the intellectual property, technology and know-how to commercialize the vaccine. In-depth discussions were held with WHO and African public health officials who emphasized that the commercial cost of the vaccine needed to be kept low to ensure wide patient access in endemic countries. MVP signed up its first three commercialization partners in spring 2002 (LaForce, et al., 2007). SynCo Bio Partners, a Dutch biotechnology firm was to supply the meningococcal group A polysaccharide and the Centre for Biologics Evaluation and Research of the US Food and Drug Administration (CBER/FDA) was the lead on the technology transfer of conjugation technology. The manufacturer position was chosen to be SERUM Institute of India, an emerging market supplier, prequalified and certified by WHO to make high quality vaccines. SERUM was founded in 1967 in Pune and is a member of the Poonawalla Group of Companies and fully owned by founder/owner Cyrus Poonawalla[7].

An Entrepreneurial Innovator: SERUM Institute

SERUM's competitive advantage in the vaccine business is in that it sells high quality vaccines at low cost. Its central tenet is manufacturing capacity; economies of scale and low cost are top priorities (Mahalingam, 2008). SERUM invests in additional infrastructure and capacity ahead of the market demand curve; thus its strategy is to be able to respond to surges in international demand ahead of its immediate competitors. SERUM continuously devotes R&D funding resources towards improving its product portfolio and the MVP project was a strategic fit for its new areas of research and collaboration[8].

SERUM had developed high quality, low cost vaccine products for over four decades. SERUM was able to attract and retain talented personnel to work on a wide range of vaccine products. Cyrus Poonawalla and his long-serving staff at SERUM are well-known in the industry for their strong commitment to social values and interest in improving health

[7] http://www.poonawallagroup.com/ - accessed January 10, 2010
[8] Discussion with MVP Lead, Dr. Marc La Force February 2010 and corroborated by R&D technical section on Serum website http://www.seruminstitute.com/ accessed February 2010

outcomes. SERUM understood both the social need of the MVP project and the benefits of collaboration[9]. The WHO strategy for meningitis control prior to the commercialization of MenAfriVac™ was reactive mass vaccination with polysaccharide vaccines, but control was difficult due to timing and unreliable epidemiological surveillance (LaForce, Ravenscroft, Djingarey, & Viviani, 2009). With the MenAfriVac™ proactive vaccination approach, there is greater chance of inducing herd immunity and saving more lives.

MVP was organized on the basis of a division of labour in the innovation value chain. Basic discovery had been completed years prior through scientific efforts in commercializing other serotypes of meningococcal bacteria. SERUM was chosen to do new product development for meningitis serotype A. SERUM worked closely with co-developers SynCo who provided high-grade contract group A polysaccharide, and scientific partners in MVP from US, UK, Norway, Italy and Senegal. Further clinical work was conducted in India, Kenya, the Gambia, Senegal and Ghana. Development took place at SERUM headquarters, but a global effort was required to advance the vaccine through clinical trials and regulations.

6.1 The entrepreneurial process and creating value through partnership

Aggregating resources and capabilities to create value

The Gates Foundation grant provided push funding for MVP to progress its work and MVP also benefitted from SERUM's existing infrastructure. SERUM as a stand-alone organization prior to MVP collaboration already possessed a reputation for R&D innovation and high quality standards. As a private enterprise with one sole owner, SERUM was able to streamline the decision-making process, allowing MVP to work immediately upon release of funding.[10]. This proved attractive to external public partners and PATH, the chief product development coordinator.

SERUM's participation in the Meningitis Vaccine Project and its mode of innovation show a entrepreneurial matching of resources and opportunities, as described by Penrose (Penrose, 1960). SERUM adapted its internal resources to shift to a new area of vaccine development (meningitis A). The MVP product development partnership model allows for collaborative sharing of knowledge by stakeholders within the innovation value chain. Stakeholders can be private firms (such as SERUM) or public health delivery partners such

[9] Discussion with MVP Lead, Dr. Marc LaForce February 2010
[10] Discussion with MVP Lead, Dr. Marc La Force February 2010

as UNICEF and Medicines Sans Frontiere (Doctors without Borders)[11]. The public-private partnership structure can be configured to act as a long-linked value chain in which core activities are split between contributors in idea discovery, development and diffusion. Partnership project management by PATH and WHO covers support functions of overall logistics (Porter, 1980; Stabell & Fjeldstad, 1998). The firms within the ecosystem are differentiated by individual competencies (Barney, 1991), but they can create value for each other within the innovation value chain of the partnership when they share a common goal.

SERUM is an established firm and shows ability to continuously renew its capabilities. The founder is actively involved in daily operations and drives the entrepreneurial process of matching opportunities with available resources and prior knowledge. The founder is able to combine social capital and intellectual capital through long-term commitments to their ventures and to their people (Garnsey & Heffernan, 2005). Firms are natural institutional settings conducive to the development of social capital that bind stakeholders of each project (Nahapiet & Ghoshal, 1998).

The MVP partnership supports an ecosystem of public and private resources that has allowed for MenAfriVac's commercialization. SERUM has invested its own internal resources in building the manufacturing facility for the MenAfriVac™ vaccine. SERUM reduces its development risk and financial risk by being part of MVP ecosystem. MVP links together project management and provides SERUM access to discovery (upstream) and delivery (downstream) partners for the eventual product launch.

Partnerships and external collaboration often result from the need to mitigate risk in the pioneering technical stages of product development (Eisenhardt & Schoonhoven, 1996). A unified medical and social mission binds together internal and external competencies of the firms within MVP. SERUM draws upon the expertise from its MVP partners and suppliers as well as its coordinating partners PATH and WHO. Establishing strategic alliances is a central function for many firms (Harrigan, 1988; Parkhe, 1993) to conserve resources and share risks (Hamel, Doz, & Prahalad, 1989). Many advantages of risk sharing have been identified by global health funding and coordination bodies (Buse & Walt, 2000) to increase legitimacy for firms (Baum & Oliver, 1991) as allowing for opportunities to gain new competencies (Dyer & Singh, 1998; Hagedoorn, 1993). MVP maintains the value network of

[11] For full listing of Meningitis Vaccine Project partners please see http://meningvax.com/partners.php -- accessed November 1, 2010

international alliances and processes of work distribution to leverage limited resources and knowledge.

The partnership business model allows SERUM to overcome the long-term risk facing science-based business and to achieve the required knowledge integration and learning advocated by Pisano to make them viable (Pisano, 2010). MVP is able to mitigate and reward long-term risk to ecosystem stakeholders through the resources pooled within the partnership. It is also able to integrate across technical within a value chain to which stakeholders share information and share commitment to the mission. Learning and knowledge are also achieved collectively among the MVP partners, because intellectual property and expertise are held by the partnership and not by any individual stakeholder. All technical stakeholders are able to share lessons learned from failures and contribute technical resources to progress future iterations.

Accessing resources in the MVP global health ecosystem

The resources of the MVP network open to SERUM provided technical advice, distribution advice and project management timeline guidance, further reducing risk and assisting knowledge integration. The diagram below depicts the key resources assembled at SERUM for successful MenAfriVac^{TM} development.

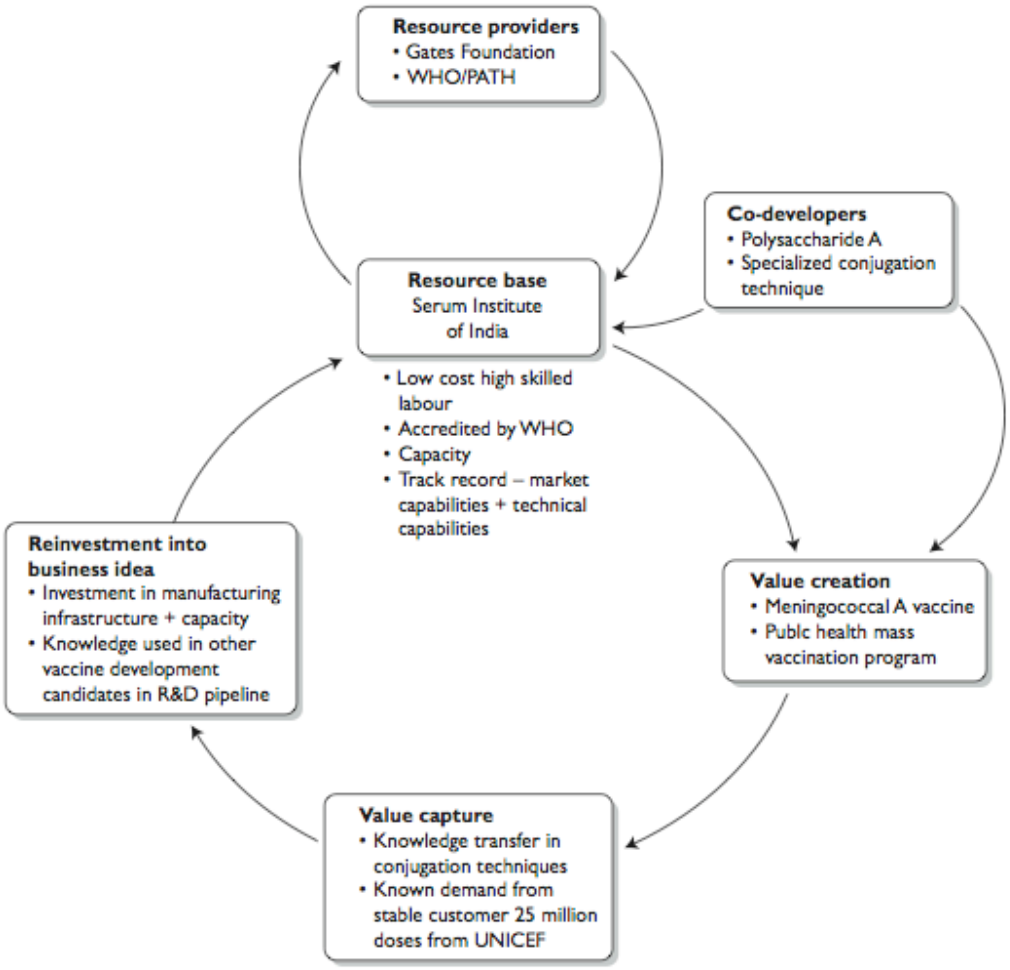

Figure 4: The value generation model applied to SERUM Institute of India (SIIL) Ltd

The constructs of the value generation model in Figure 1 are informed by case evidence from MVP in Figure 4 above. The resource base for SERUM combines both technical capabilities and market capabilities as a direct result of its central participation in the Meningitis Vaccine Project. SERUM's role in the innovation value chain was based on its competitive advantage and knowledge of product development. Value creation for the customer solidified when pre-qualification was approved by WHO on June 23, 2010 specifying that individual vaccines produced met international standards of quality, safety and efficacy[12]. Value has been captured by SERUM because the price on offer is above their costs and moreover they have gained on a learning curve as a result of knowledge transfer and technical expertise gained from the MVP ecosystem, especially the conjugation techniques from CBER/FDA. This learning can be applied to future projects in SERUM's

[12] PATH press release June 23, 2010 http://www.path.org/news/an100623-menafrivac.php - accessed July 29, 2010

internal pipeline. SERUM's future value capture is ensured by margins expected from stable, long-term demand of MenAfriVac™ from international agencies. The price for the first 25 million doses of MenAfriVac™ is sold by SERUM at $0.396 USD, under original target profile mandate of < $0.40 USD (LaForce, et al., 2007). There is also a governance process to monitor future price changes requiring price increases to be justified through a review process that includes PATH and WHO as coordinators of MVP. For example, the per dose cost after the first 25 million doses will rise to $0.49 USD per dose based on increases of operational costs and raw materials[13]. The technical knowledge achieved by SERUM as a further form of value capture from the MVP partnership is reinvested back into R&D product pipeline development and the financial value captured is reinvested in development of their manufacturing capacity.

SERUM has harnessed existing prior intellectual property in vaccine conjugation techniques from the partnership. SERUM's key task was to tailor the vaccine to the meningitis A serotype and work with its clinical partners within MVP to demonstrate safety and efficacy. Vaccine distribution and delivery is transferred to additional global partners such as NGOs and WHO working together with governments where the disease is endemic to conduct mass public health vaccination programs. There is little global marketing and sales responsibility incumbent on SERUM. MenAfriVac™ occupies a niche within the vaccine market and the MVP ecosystem ensures that the stakeholders in that market are coordinated and work collaboratively.

[13] Per discussion with MVP Lead, Dr. Marc La Force March 2011

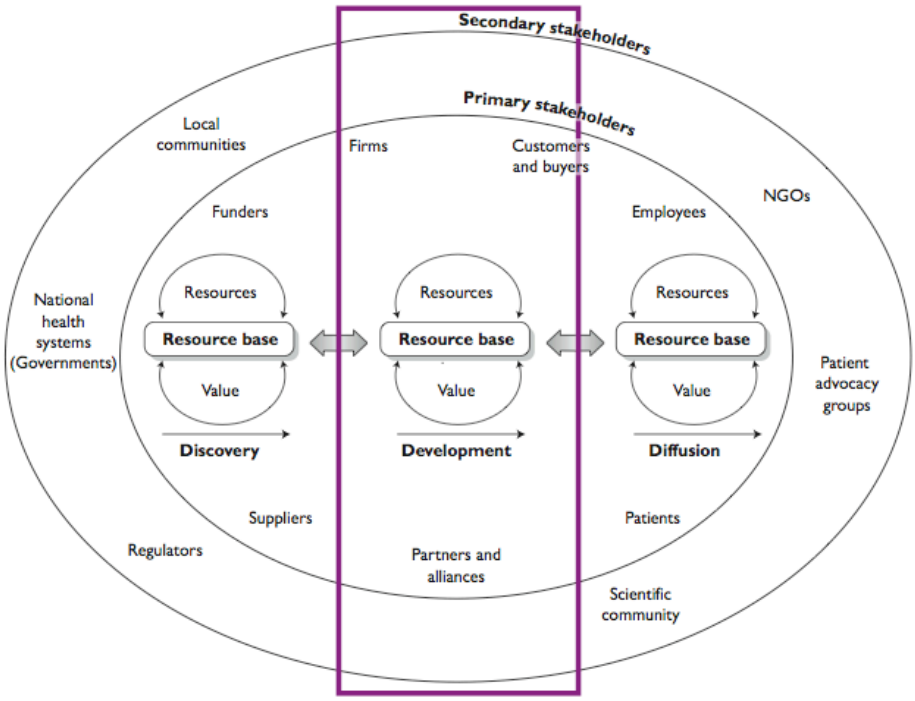

Figure 5: SERUM occupies a development role in the innovation value chain for MVP, involving both primary and secondary stakeholders.

Figure 5 illustrates SERUM operating at the development node of the innovation value chain. Other organizations are operating along the value innovation chain to create complementary elements that contribute to the overall mission. Figure 5 also shows that SERUM, as the entrepreneurial firm in the centre of the ecosystem, both affects and is affected by other stakeholders (Garnsey & Leong, 2008). For example, SERUM strengthens its resource base with technology found in the discovery phase of the innovation value chain being used in the development phase. In turn, SERUM's commercialization work feeds into the resource base of MVP's delivery partners. Secondary stakeholders also affect the innovation value chain through external regulatory and policy control. Public policy by countries affected in the African Meningitis Belt aim both to support R&D innovation of new vaccines (inputs), and to build the complementary assets such as underlying public delivery infrastructure (Teece, 1986). In the case of the Meningitis Vaccine Project, no developing government directly contributed funds for the development partnership. However, it was MVP coordinators, PATH and WHO, that contacted national governments during the development phase to enlist them to collaborate on vaccine roll-out strategies and open access for quick-country uptake upon approval[14].

[14] Per discussion with WHO Implementation Officer Dr. Carol Tevi-Benissan May 2010

Using the ecosystem to generate and capture value

Value creation based on SERUM's resources and capabilities made it possible to provide an offering meeting customer needs (Lepak, et al., 2007). The value generation model summary (Table 1) demonstrates how SERUM achieved value creation as specified by criteria set out by Lepak (2007). SERUM achieved monetary returns greater production costs and the social value enjoyed by the consumer is above that of the closest available alternative.

Table 1 below summarizes the constructs of the value generation model, applied to SERUM.

SERUM Institute of India Ltd (SIIL)	
Year Founded	1967
Health intervention	Vaccines
Resource base	- Science and technology - People / founder
Resource providers	- Catalyst grant from Gates Foundation to establish MVP partnership - Internal resources
Partners	- MVP Team (21 primary stakeholders)
Value creation (revenues generated)	- Yes. Sales of meningococcal A conjugate vaccine MenAfriVac™
Value captured (profit)	- In prospect through long-term contract with UNICEF - Intellectual property rights all housed within MVP with no imminent competitors - New knowledge transferred to SERUM
Reinvestment in business idea	- New vaccines in R&D pipeline - Manufacturing capacity

The table illustrates the SERUM's alignment of internal values and capabilities at SREUM with external incentives provided by MVP. While Dr. Poonawalla, as the scientist entrepreneur, is interested in utilizing SERUM's technology for alleviating social problems, to make the product development process viable, he has to mobilize additional resources from the supporting ecosystem.

SERUM's integration into the public-private partnership ecosystem helps the firm create and capture value. The Meningitis Vaccine Project tied 21 primary stakeholders together in pursuit of a common purpose and allowed SERUM to match its capabilities with the opportunities offered by the partnership ecosystem. SERUM's technical risk was reduced by involvement of development partners including US Food and Drug Administration and Dutch polysaccharide developer, SynCo Bio Partners in MVP and weekly and monthly review meetings with MVP coordinators at WHO and PATH. Leveraging existing technology brought into the partnership by other partners and funding from the Gates Foundation grant lowered financial investment requirements for SERUM. Delivery and distribution partners in MVP also ensured SERUM did not have to build a sales and marketing force. Along with financial and intellectual property value garnered from MVP, the social value captured by the firm involves utilization of the vaccine in the sub-Saharan African Meningitis Belt, reducing meningitis fatalities. The public health goal is to vaccinate 300 million people living in the African meningitis belt by 2015 and thereby ridding the region of meningitis A[15]. SERUM has also been able to achieve a positive international media image through its participation in the MVP partnership and further enhance its profile as a quality vaccine manufacturer.

SERUM actively contributed back to the MVP ecosystem. SERUM's participation allowed MVP coordinators to negotiate a cost-plus price for the final product and reach a target product profile of a vaccine with a specified low-price. This had not proved achievable in 2002 in negotiations with other fully-integrated vaccine manufacturers. SERUM contributed manufacturing expertise and made its own investment into upgrading capacity for final vaccine production, which allowed ecosystem delivery partners to concentrate on distribution.

SERUM is able to reinvest back into its operations monetary, technical and social value sourced from its adapted business model. The literature suggests that firms are more likely to innovate and match resources with opportunities in new ways when they face uncertain environments and are managed by entrepreneurial managers (Brown & Eisenhardt, 1997; Smith, Collins, & Clark, 2005). Although SERUM has long-standing operations in the vaccine industry, technological innovation in new scientific areas is a still high-risk proposition. The owner and founder, Dr. Poonawalla, has extensive social networks and

[15] Mission statement per MVP Project http://meningvax.org/

builds on a track record of innovation. However the creation of new knowledge through interactions and sharing of knowledge both internally and externally with partners has been further stimulus and support to entrepreneurial innovation, as it could be elsewhere (Nahapiet & Ghoshal, 1998).

7. Implications and conclusions

A conceptual framework setting value generation by the innovator firm in the context of its ecosystem allows issues of entrepreneurship, innovation and ecosystem stakeholders to be examined on a coherent basis. The conceptual lenses of value generation and the business ecosystem provided us with focus on what was initially very involved and unclear evidence. Our evidence showed how a enterprise-based solution was reached for vaccine development by a company that drew on an innovative ecosystem in assembling the resources required. This provides some generic lessons from a specific instance.

The evidence illustrates how resources and capabilities can be developed by an enterprising healthcare business, even in the face of considerable constraints, through integration of resources within a supportive ecosystem (Conner & Prahalad, 1996; Grant, 1991). The public-private product development partnership model coordinates the activities of the individual firm within the innovation value chain and allows each stakeholder to both create and harness value. However this required initiative and vision from the various parties involved. Whether the partnership model is an effective catalyst of entrepreneurial activity in all other disease areas is an avenue for future research.

Resource-based theory is often applied to innovative firms in resource-rich environments and infrequently mentioned in development or bottom of pyramid research literature. In examining the value generation cycle for SERUM within the public-private partnership model, we have addressed two specific aspects of the resource-based perspective of the firm and extended conventional entrepreneurship theory to global health. The value generation model made it possible to map the development of distinctive resources by SERUM (Garnsey, et al., 2006). SERUM has become the global supplier of the Meningitis A vaccine by assembling a unique set of resources and capabilities (Penrose, 1995) within a configuration of partnerships - a form of open innovation. SERUM has extended its original R&D activities and internal competencies in vaccine production to address a new disease

area. The participation within the MVP partnership has encouraged entrepreneurial activity in extending firm capabilities (MacDonald, 1985).

The logic of inquiry is to examine the positioning of the main unit of analysis within the innovation value chain and in relation to other units of the global health ecosystem. SERUM is not threatened by its participation in open innovation because it built unique resources which operate as entry barriers because they are hard-to-imitate and non-substitutable (Barney, 1991) and thus a basis for sustaining value generation. Under the direction of the entrepreneurial founder-manager, SERUM provided an offering of value to users and the ecosystem (Bowman & Ambrosini, 2000; Lepak, et al., 2007). Entrepreneurial activity has taken place within a business ecosystem that was itself enacted by the impetus of innovative participants (Rumelt, 1997).

Economic incentives for commercial firms in the area of global health have long been unfavourable (Buse & Waxman, 2001). However, risk-mitigating R&D funding can improve incentives for entrepreneurs (Karamchandani, et al., 2009; Ravishankar, et al., 2009) resulting in increased investments (London, 2009). Government and donor policy have greatly increased push and pull mechanisms encouraging new ideas, initiatives and alliances. The healthcare value chain can be supported by public grants that decrease the entry risk barriers for entrepreneurial firms. In a field where private-sector entrepreneurship had previously been lacking, the SERUM case illustrates the founder/entrepreneur's ability to draw on personal and extended networks (Dubini & Aldrich, 1991) to keep human capital motivated and establish legitimacy (Aldrich & Fio, 1994). The MVP program has created an innovation ecosystem by uniting primary and secondary stakeholders in global health. The ecosystem is able to pull together resources enabling the innovation value chain to draw on multiple resources to develop an effective vaccine.

There is growing recognition that entrepreneurial healthcare firms can make contributions to the global health ecosystem and respond to growth opportunities at the bottom of the pyramid. We have outlined the global need to fight health inequities, pointed to changes in global incentives and illustrated a commercialization business model based on catalyzing the ecosystem as a whole. How will future innovators and entrepreneurs respond to the grand challenge of global health? What kinds of new business models will emerge to provide affordable healthcare for the poor? What financing mechanisms can support the

reconciliation of innovation and access along the innovation value chain? These questions underlie the importance of research on entrepreneurship and global health.

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