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New drugs and health technologies for low income populations: Will the private sector meet the needs of low income populations in developing countries?

Dinar Kale
ESRC INNOGEN
Open University,
Walton Hall
Milton Keynes, MK7 6AA, UK
D.Kale@open.ac.uk

Rebecca Hanlin
ESRC INNOGEN
Open University,
Walton Hall
Milton Keynes, MK7 6AA, UK
R.E.Hanlin@open.ac.uk

Joanna Chataway
RAND Europe
Westbrook Centre
Milton Road
Cambridge CB4 1YG, UK
chataway@rand.org

and
ESRC INNOGEN
Open University,
Walton Hall
Milton Keynes, MK7 6AA, UK
J.C.Chataway@open.ac.uk
Abstract

This paper argues that the development of targeted health technologies for poor people will require a new mix of technology, organisations and institutions which we conceptualise as new social technologies. Using a technology-market matrix we explore these new social technologies which may sometimes include MNCs but are also associated with developing country private sector firms and not for profit Product Development Partnerships (PDPs). The paper argues that these collaborative forms of social technology are most likely to generate and deliver new physical technologies and innovations processes required by low income users.
1. Introduction

The term "10/90 gap\(^1\)", while not representing an accurate current quantitative measure, has become a symbol of the continuing mismatch between needs and investments. Between 1974 and 2004 only 1.3% of the 1,556 new drugs approved by the FDA were for tropical diseases (see Frew et al., 2009 for more discussion of this disparity) and this has not improved substantially since. However, only US $3 billion was spent on neglected diseases in 2011 (Policy Cures, 2012). Whilst investment in neglected diseases and addressing the healthcare priorities of low income users continues, there is still a long way to go before the health needs of poor people are addressed. The question is: How will poor people’s health needs be met?

Prahalad argues in his book *The Bottom of the Pyramid* (2004), large western multi-national companies (MNCs) should wake up to the possibilities of low income markets. In the case of the pharmaceutical sector one outcome of such reorientation might be that more R&D resources are directed towards the needs of this ‘bottom’ market segment. Is this possible in the context of such a highly research intensive sector? One alternative might be that solutions might emerge as a result of R&D investments of companies in emerging economies such as India, China, South Africa and Brazil. Or will the most likely alternative for new technologies be the complex emergent networks forming around the current generation of public-private-partnerships (PPPs) and particularly, their product-development Partnerships (PDPs)? This paper discusses these three different alternative approaches and their role in generating and delivering new ‘physical technologies’\(^2\) and innovation processes needed by low income users. Specifically, this paper reviews the potential for new ‘social technologies’ or innovative institutional and organisational forms and divisions of labour, to provide a way forward to improve the development and delivery of physical technologies in the area of global health research. It does this through a conceptual analysis of how social technologies fit into the current dominate technology-market mix within the global health research and pharmaceutical arenas.

In this paper we use the idea of a ‘Technology-Market Matrix’ to add conceptual specificity with regard to where private firms are most likely to contribute to meeting needs in developing countries and where not for profit PDPs and other new forms of social technology’ are more likely to meet unmet needs.

The term ‘social technology’ is not new. Richard Nelson defines social technologies by using an analogy to the limitations of written recipes for food preparation, “it might be useful to call the recipe aspect of an

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\(^1\) Only 10% of global health research investment is directed towards 90% of global disease burden (Drugs for Neglected Diseases Working Group, 2001)

\(^2\) The distinction between physical and social technologies is explained later in the paper.
activity its “physical” technology, and the way work is divided and coordinated its “social” technology” (Nelson, 2008:11).

To explain the social technologies concept further Nelson (2003) revisits the concept of routines as a way of doing something; a course of action. He points out that any routine involves two aspects: a recipe and, second, a division of labour. It also requires a mode of coordination. He argues that the recipe aspect of the routine can be likened to the 'physical technology' while the ‘social technology’ relates to a division of labour and modes of coordination among them.

Nelson (2002) proposes the concept of social technology as a way of refining the concept of 'institution'. He argues that similar to North’s (1990) concept of the ‘institution’, social technologies are defined by and define the 'rules of games' or in terms of Williamson’s (1985) notion of an ‘institution’ they can be viewed as “modes of governance” and ways of implementing organisational structures and processes and particular divisions of labour. Social technologies can be thought of as institutional arrangements that relate to a particular project or initiative and therefore in the context of more general institutions. Nelson (2002) compares social technologies to a paved road across a swamp; without that road getting across will be impossible. Chataway et al. (2010) points out that the social technologies concept embraces the importance of human agency and corresponding social, political and organisational processes. The concept portrays the evolution of innovation as the interaction between social technologies (particular institutional arrangements to bring people together around specific aims, projects and initiatives), physical technologies and general institutions.

In relation to health innovation, the concept of social technologies is particularly useful because it moves us beyond thinking about the development of technologies and products as input components of health systems and apparent market failures. It emphasizes the need to look at efforts to improve healthcare through organisational and institutional innovation more widely throughout the healthcare and innovation systems. Thus social technologies provide a framework to explore interactions between the creation of a tangible technology and the mix of organisations and institutions which will undertake the work (Chataway et al., 2010) and in relation to the themes of this paper, are used to bring health technologies and products to poor people in developing countries.

Although further empirical work to test our hypothesis regarding the importance of the social technology in developing physical technologies for global health is needed, this paper, based on the case studies reviewed in this paper and experience of 20 years researching this area, concludes that these new social technologies may constitute the basis of new production and innovation systems which could better serve the needs of low income populations. Additionally it makes the point that large pharmaceutical firms and firms in emerging economies which are engaging seriously in drug priorities and agendas for low income users are
predominantly doing so by engaging with new social technologies rather than changing their business models.

2. The pharmaceuticals and health technologies: Science and technology driven or subject to many influences?

The last 30 years have witnessed significant changes in the organisation of industrial enterprise and production. There is now a greater responsiveness amongst producers, new capabilities allowing for ‘just-in’ time production and interdisciplinary teams feeding customer feedback back into the production process. This change has delivered enormous benefits to consumers in Western countries. However, as Christensen (1997) has pointed out, whilst this produces efficiency and increased focus on users in many respects it also leaves firms vulnerable to disruption from new technologies; firms become so involved in their own processes, products and customers that they are blind to challenges which appear to come from ‘left field’.

At a very general level, the result is that most large MNCs and companies based in industrialised developed country contexts are not interested in the large low income market that exists in developing countries. This is the basis of Prahalad’s analysis resulting in his book The Fortune at the Bottom of the Pyramid (Prahalad, 2004). Companies have based their processes and products on serving the needs of higher income populations in developed countries.

Another way of seeing this is that firms producing for, and serving, a particular set of users create ‘social technologies’ around those users. Not all firms and initiatives will have identical social technologies and there will be a wide range of ways in which work is divided within organisations and between organisations and institutions. Often social technologies occur in a latent/implicit manner that in future ensures ‘lock in’ or path dependency activities towards traditional markets, users and consumers. In the case of large pharmaceutical firms most if not all have as their core users relatively wealthy patients predominantly in industrially developed countries. Their social technologies are anchored in this user base.

For some the argument that pharmaceuticals and health technologies sectors fit into the characterisation as a sector locked-in their own processes, products and customers and not geared to low income markets will be controversial. Pharmaceuticals in particular are often thought of as being supply driven to a much greater degree than other manufacturing sectors. There is significantly higher spending on R&D than in many other sectors and the progression of science and basic technologies impacts in fundamental ways on the evolution of products and processes in the sector (Henderson and Cockburn, 1996).

In developing and developed countries close interaction with policy in some instances and health systems in others has mattered enormously in shaping the evolution of pharmaceutical firms (Chataway et al., 2007).
Some analysts consider that it is regulation which largely shapes the structure of the industry (Taït et al., 2009). It is a structure which has certainly not helped in serving the needs of low income users and has been extremely controversial because of this. The Indian pharmaceutical sector points to the significant impact policy frameworks and regulation can have in the development of the pharmaceutical industry.

2.1 Policy impact on pharmaceutical industry growth: A brief history of the Indian pharmaceutical industry

One example of the way in which policy and regulation have impacted on the evolution of the sector is provided by the Indian government’s decision to intervene to create an industrial apparatus to better serve the needs of its people (Chataway et al., 2007). Shifts in policy and investment encouraged the growth of an industry focused on the needs of low-income users. We would argue that we can see a new social technology having emerged as a result that was closer to these users and better able to address local priorities. It is worth looking in some detail at first, how the Indian pharmaceutical story evolved as it does relate closely to the argument that large MNCs in their current form were and perhaps still are unable to address the needs of low income users. Secondly, the rate and direction of innovation in pharmaceutical is very far from being determined only by scientific and technological or market factors.

Adoption of weak patent laws in 1970s propelled Indian firms onto a reverse engineering³ path and laid the foundation for a strong domestic industry. The resulting ‘imitative’ follower trajectory, facilitated by the lack of intellectual property rights, differed greatly from the technological trajectories followed by firms in the US and Europe (Kale and Little, 2007).

Over the past 50 years, policy intervention from the Indian government steered firm level strategies and gradually Indian firms have gone from being weak followers in the 1970s to partners of choice for multinational companies in their drug discovery research and development efforts (Athreye et al., 2009). Post 1990 India emerged as a cheap and efficient supplier of bulk drugs and formulations to countries from the developing and developed world. The pharmaceutical industry started to really take notice of the Indian pharmaceutical industry’s generic and manufacturing capabilities when in 2001 Cipla, one of the largest Indian emerging manufacturers, announced a major price reduction for Triomune, a first-line combination HIV therapy. The impact of Cipla’s offer was immediate and significant; alternative AIDS treatment cocktails were selling at $10,000-$15,000 (per patient per year) in the advanced countries at the time. International pressure forced large pharmaceuticals firms to cut the price of their own drugs - by up to 90 per cent - making them also affordable to developing country governments. As we can see in this case, regulation and policy change along with the dynamic response of Indian firms made a serious contribution to improving the supply and access of medicine to poor populations in developing countries.

³ Reverse-engineering R&D involves imitating a product by modifying existing process or developing it by using new process
2.2 Plus ca change?

Despite, a few rare examples such as the Indian case study above, there can be little doubt that market constraints play a role in on-going health inequalities and very slow progress in developing sorely needed treatments and vaccines for low income populations in developing countries. A large literature analyses neglected diseases and neglected patients from this perspective.

The ‘pull’ mechanisms designed to provide demand incentives for companies to invest in product development are proposed either as a complement or an alternative to ‘push’ programs and initiatives. The latter propose to resolve market failure through large government and philanthropic foundation investment push in science, R&D and product development. The logic here is that if market failure means lack of private investment in basic science and R&D, then where compelling social and political reasons exist, the public sector should step in (Archibuigi, 2006).

While pull mechanisms may be necessary, pull or demand based mechanisms do not necessarily signify a link to users and a more low income driven user-focus as argued in the previous section. This is important because it is very likely that one issue that hinders pharmaceutical companies in developing products for lower income users is effective distribution and feedback loops or, put another way, an effective value chain. The link between an individual’s health and the innovation and healthcare systems that could contribute to a value chain which would serve the needs of low income users more effectively is lacking in many cases. This in part explains why a powerful Indian pharmaceutical sector does not equate with drastically improved health outcomes for poor Indians (Chaturvedi et al., 2007)

Thus there are good reasons to believe that neither demand pull or supply push will (on their own or in combination) solve the problem of health innovation for low income countries. The problem may take longer to resolve as it almost certainly requires new institutional and organisational forms which can address the needs of low income users as their core concerns and it requires new systems and new interactions built on the back of them. There is now a plethora of new institutions and organisations involved in global health and related R&D and product development and a very significant increase in funding available for research in this area.\(^4\) Simply putting additional finance into drug development, whether it is in the form of push or pull mechanisms will not solve the need to create more responsive organisations that have as their key concern the needs of low income users. The question remains whether the new constellation involved in the production of vaccines and other drugs will prove any more successful over the medium and longer term than previous institutional infrastructures.

\(^4\) We should point out that the increase in funding has occurred over the last 15-20 years although in recent years the relative rate of increase in funding has declined and in some cases reduced as a result of the economic crisis.
3. Healthcare needs of low income populations

The past two decades have seen considerable innovation in the spectrum of organisations and institutions involved in global health. There is also some evidence that the geographical shift in capabilities in pharmaceuticals, of which emerging countries such as India and China are a part, is having some effect on who does the work involved in developing new drugs for developing countries’ needs and how the work gets done. We now try to consider these changes – taking a social technologies perspective as a base – through the conceptual analysis of the field using a Technology/Market Matrix.

The matrix (presented in Figure 1) divides technologies and users into four different quadrants using traditional/new levels of market and technologies from the perspective of meeting health needs. In the matrix technology is used as an overarching concept covering both physical technologies and social technologies. Considering these changes using this matrix helps us to conceptually think about the relationship between technologies and the ‘market’ and to give further specificity to the analysis of how markets and technologies intersect. As seen from the above, the debate from an innovation perspective as well as from an access to medicine perspective is often conceptualised in relation to these two starting points (even when there is recognition of the social, political, economic and cultural complexities) with the issue of markets often simplified into supply vs. demand. The key concerns of this paper fall on the right hand side of the matrix and particularly the issue of who will develop new ‘western’ medicines for poor consumers identified in the bottom right hand box of the matrix; that is social technologies for new markets. By highlighting the relationship between different types technologies and markets, the matrix highlights the value of the social technologies approach. Social technologies of different types can be seen as the road connecting physical technologies and markets.

[Fig. 1 here]

3.1 Traditional Technology/Traditional Market

This quadrant represents conventional treatments for the ‘rich’ mostly for consumers in advanced markets (such as heart disease, cancer). For example analysis of the large pharmaceutical sector’s R&D pipeline suggest that future R&D investments are still tuned to tap traditional pharmaceutical markets, while the sales figures of the top 20 large pharmaceutical firms’ in 2009 shows that major markets for these firms are still in the USA, Western Europe and Japan (Table 1).

[Table 1 here]

Similarly, Indian firm’s generic market strategy and R&D pipeline shows a strong basis towards advanced country markets (Table 2). Since 2000 Indian firms have adopted overseas acquisitions as a key strategy to acquire knowledge regarding advance markets, technology and regulatory skills. The value of the Indian
pharmaceutical industry’s overseas acquisition has grown from just US$ 8 million in 1997 to $116 million in 2004 (Bloomberg, 2005). Geographically the overseas acquisition by Indian pharmaceutical firms continues to be directed at developed countries specifically the US and Europe.

[Table 2 here]

3.2 Traditional Technology/New Market
The Traditional Technology/New Market quadrant represents generics for neglected diseases, new distribution channels for drugs developed in the West and traditional healthcare in developing countries. In the last decade large pharmaceutical firms are investing heavily in emerging markets and taking their mainstream technologies and products to new markets. With the growth of the middle class in developing countries there has been a very significant change in large pharmaceutical’s strategies for emerging markets, including as the prevalence of chronic diseases has risen. Both as producers and consumers of healthcare, emerging markets are now extremely important in the global context. According to an IFC report (2009) the combined health market in Africa (12 countries), Asia (9), Eastern Europe (5), Latin America and the Caribbean (9) is US $ 158.4 billion accounting for spending of 3.96 billion people. An IMS Health Report (2010) suggests that 17 high-performing emerging nations, amounting to around 16% of the total world market or US$123 billion in 2009, are set to form new growth markets for the pharmaceutical industry overturning the established pharmaceutical order.

3.3 New Technologies/Traditional Market
This quadrant concerns the important 10-90 issue whereby most R&D spend goes to develop new drugs for a small percentage of the world’s population in that most investment in health technologies is geared to traditional markets. The emergence of biotechnology and genomics has revolutionised drug discovery and brought a model of technical change. These new technologies are expected to bring about radical change in healthcare, involving a shift from reactive to preventative and more personalised medicine (Nightingale and Martin, 2004). It gave rise to a trend towards proteomics, stem cells and synthetic biology. These technologies have potential value in providing effective healthcare solutions to patients; however, the significant cost associated with their implementation would seem to make them unaffordable to vast poor populations of developing countries.

3.4. New Technologies/New Market
The New Technologies/New Market quadrant represents new social and physical technologies; a new mix of technologies, organisations and institutions that are delivering healthcare solutions to poor populations of developing countries. This quadrant also includes indigenous and traditional cures supplied to consumers in developing countries.
Fig. 2 represents three different potential types of actor or social technology solution that have the ability to develop new western medicines for poor consumers in developing countries (New Technologies/New Markets quadrant):

a. large pharmaceutical firms,
b. emerging country firms and
c. PDPs.

Section 4 below discusses their ability to operate in this quadrant in more detail.

4. Solutions to meeting the new technology needs of low income populations in developing countries

This section discusses contributions to meeting new technology based on the needs of low income populations in developing countries. We begin by looking at emerging market activities of purely private sector firms both in industrially developed contexts and industrially developing country contexts. As the following section shows, there is evidence that large pharmaceutical companies are collaborating with other types of actor to engage more effectively with low income users and address the New Technology/New Market needs as identified in the lower right quadrant of the Market-Technology Matrix.

4.1 Large western pharmaceutical firms

In the last two decades large pharmaceutical companies increasingly frequently have offered to provide a narrow range of cheap medicines to the world’s poorest countries - notably anti-retrovirals for HIV, spurred on by the Cipla decision discussed earlier. These types of deals and the partnerships that result derive from political pressure, corporate social responsibility and perhaps sensing a need to do business more inclusively. They are, in our terminology, forming new social technologies to develop new technologies and products which respond to the needs of low income users.

Many large firms are now making concerted efforts to work with firms and research institutes from developing countries on diseases which afflict low income populations. Examples include GSK’s partnership with Fiocruz, a public sector research institute in Brazil, a deal with China’s Shenzhen Neptunus to develop and manufacture flu vaccines and an R&D deal with Indian firm Ranbaxy.

Large pharmaceutical firms are remixing prices, products and marketing approaches to address needs of low income consumers. For example, in Brazil Novo Nordisk supplies at much lower cost older generation insulins, which are paid for by the government while GSK is using a discounts strategy to make off-patent branded generics and dermatological “over the counter” products affordable to local populations (Financial Times, 2012).
GSK reports its strategy as shifting from a traditional blockbuster model and towards driving growth from new products, emerging markets and its consumer business. Adapting to requirements of emerging country markets GSK plans to significantly reduce prices of its medicine in emerging economies in 2010. GSK has made several moves to build its presence in emerging regions around the globe (Table 3) and as a result of these activities GSK is named as the industry leader for improving access to medicines.

[Table 3 here]

But while the pharmaceutical industry is clearly serious about investment in emerging markets, this change must be kept in perspective. Large firms often lack the incentive or perhaps the organisational and institutional focus, in other words, the right mix to create the best ‘social technology’ to prioritise health problems that most worry developing countries. Quite naturally the focus on wealthier users in wealthier countries (which was and still is at the core of most large MNCs business organisation) was not appropriate for dealing with the very different challenges of developing country health care needs.

4.2 Firms from emerging economies

If large pharmaceutical companies are unable to incorporate the needs of low income users into its basic business model, what about firms from developing countries? In the post-TRIPS era Indian industry has emerged as one of the main producers of cheap generic drugs. The Indian pharmaceutical sector achieved an incredible feat in building an industry to challenge western firms. Having built competences and knowledge capabilities over the years Indian firms now have the internal resources to begin developing new drugs. However, regulation, trade policy and the lack of effective markets make it difficult for firms to devote expensive R&D and drug development to developing country priorities. This argument rests on a perceived market failure. Put simply, as with large pharmaceutical firms in developed countries, high R&D and development costs combined with poor market prospects do not give firms sufficient incentives to invest in new treatments and drugs which will be relevant mainly to developing countries.

It may be that biotechnology small and medium sized companies (SMEs) in developing countries have substantial and central commercial interest in low income patient needs. In a study of 78 ‘home-grown’ small to medium sized health biotechnology companies in the emerging economies of Brazil, China, India and South Africa excluding manufacturers and domestic subsidiaries of MNCs, these companies were innovating in the area of biologics, biopharmaceuticals, diagnostics and related technologies and services apparently targeted to address domestic needs (see Frew et al, 2009). The firms have a collective pipeline of nearly 500 products for more than 100 indications. This pipeline consists of novel and other products but it may be that the majority are adaptations of existing drugs. About half of these have received domestic regulatory approval. Frew et al do not specify whether it is the local SMEs who have sought and gained this approval but even in the case that other parties took the drugs through regulatory procedures, the point is clear that
these firms may well constitute a vital part of the ‘social technologies’ needed to deliver drugs to low income users.

The picture portrayed by this research is that SMEs in emerging economies view low income user markets as an attractive business proposition and see them as an entry point into international markets. Drugs and technologies in development include diagnostics (some of which might be considered low tech but offer very important new technologies for diagnosis and dedication), vaccines and therapeutics. It may be that SMEs in developing countries do constitute an important element in the range of organisations and institutions involved in developing new physical technology and innovation for low income populations. It is unlikely however that they will be able to develop new drugs from research all the way through to marketing and distribution and this is the limitation of their current social technology or mix of organisations and institutions.

Another trend observed is the acquisition of emerging country firms by large pharmaceutical firms to set up sometimes joint generic product development and manufacturing facilities (Table 4).

[Table 4 here]

These acquisitions of emerging country firms or parts of their business by large multinational firms may point towards the emergence of new social technologies that can emerge as a supplier of cheap and affordable drugs to developing countries.

Whilst both large pharmaceutical firms and those in emerging economies are engaging with diseases afflicting low income populations in developing countries they are doing so in conjunction with public or not for profit sectors. This paper does not argue against a role for the private sector to play in constructing new approaches to engaging with the health needs of low income users in developing countries. However, it is questioning whether the private sector alone can provide a durable innovation architecture or the right set of social technology which will deliver on-going benefits and engagement over time.

5. Product-development-partnerships

Given what has been said in the previous section, a question arises as to whether PDPs more specifically can provide a more appropriate social technology to enable development of physical technology and successful innovation for low income populations. PDPs are relatively recent phenomena but quite a few such partnerships have been working on issues of global health. PDPs are defined as “a project or portfolio of projects in which public or philanthropic funds and resources are combined to discover and/or develop a product (medicine, vaccine, diagnostics) to meet a public health need” (Zimba, 2005;10). We would argue
they also include a strong element of organisational (re-structuring) and power relations (Chataway et al., 2009). Their starting point of the needs of low income users of physical technologies (namely drugs, diagnostics and vaccines) together with the way they are able to combine the various organisations and institutions involved in product development mean that they have been highly successful in their overarching missions of developing and delivering affordable medicines to the poorest.

5.1 New technologies in development of products by PDPs
Several studies have shown that PDPs offer advantages over the private sector or public sector when they act alone (Moran et al., 2005; Chataway et al, 2010). PDPs are a complex mix of NGO, private and public sector organisations and at best they work to maximise each other’s contribution. Table 5 presents a list of PDPs involving large pharmaceutical firms and their outcomes. All PDPs listed have a large pharmaceutical firm along with either local NGO/institute/university working in developing countries and the World Health Organisation or charity foundations such as the Bill and Melinda Gates Foundation as key partners. These PDPs cover a wide spectrum of health care needs from anti-malarial drugs to insecticide kits for nets. This section discusses one PDP in detail to exemplify the ways in which they work, exemplifying the way a social technologies approach can work within this new technologies/ new markets quadrant of our matrix.

[Table 5 Here]

Medicines for Malaria Venture and Ranbaxy
MMV was officially launched on 3 November 1999 as a non-profit foundation dedicated to reducing the burden of malaria in disease endemic countries by discovering new affordable anti-malarials through effective public-private partnership. MMV in its first three years of operation was managing a portfolio of over 14 projects in different stages of Drug Research and Development.

In 2003 Ranbaxy as a part of the MMV partnership took over a project for a key new anti-malarial drug from leading research-based healthcare company Roche for further development. Initially Roche worked with the MMV project to develop this new drug, and then passed it onto Ranbaxy to bring it to the market with the continued support of MMV. In 2009 Ranbaxy Laboratories Limited started Phase-III clinical trials for its new anti-malaria combination drug, Arterolane maleate + Piperaquine phosphate in India, Bangladesh and Thailand. The drug is targeted at patients in developing countries with the aim of significantly improving upon the conventional options available for the treatment of P. falciparum malaria.

The original discovery team for this innovative molecule comprised leading scientists from the University of Nebraska Medical Centre, Monash University and the Swiss Tropical Institute with active participation and support of Roche, working on the MMV’s partnership model.
Ranbaxy’s R&D strengths in process chemistry, formulation development and other preclinical expertise, strong regulatory submission capabilities and cost effectiveness were the key considerations for MMV to partner with the company. Ranbaxy’s presence in several African countries will help in delivery of needed medicine to the disease endemic countries, at affordable cost, once testing is complete.

This collaboration also provided Ranbaxy with an opportunity to work with leading scientists working in anti-Malarial research and create a stronger portfolio in this segment of the market. Ranbaxy aims to market the drug in malaria endemic geographies of India, Africa, Latin America and the Asia Pacific.

5.2 Key Characteristics of PDPs as social technologies

Through this case study, we can see how PDPs are development and innovation actors plus 'assemblages' that work through global networks. It is the combination of these two spheres of activities around concrete product development agendas which is, in part at least, why PDPs have attracted widespread support and have secured financial resource; PDPs bring together a range of actors in public, private and NGO sectors with a targeted mission of introducing, developing and making accessible new technologies and treatments to those who need them in poor countries. Their efforts have had to include support for new science, technology and product development and a range of brokering and capacity building activities around defined product development activities including clinical trials.

This new approach of integrating innovation with development is a PDP’s social technology innovation and this is why PDPs are widely considered appropriate vehicles for the development of new physical technologies. Other public, private and charity organisations can undertake activities in discrete segments of the value chain and have specific capabilities but PDPs have introduced a coherent organisational, management and cultural approach to assemble innovation and development under one organisational banner in a targeted way that has moved things forward more rapidly than the alternatives (Moran et al, 2005).

PDPs may share characteristics but they are not of course identical. For example the International AIDS Vaccine Initiative (IAVI) and the Malaria Vaccine Initiative (MVI) are similar in overall goal and mission: both are PDPs aiming to develop and make accessible to poor people in developing countries vaccines for major neglected diseases (Chataway et al., 2010). However, IAVI is at a different stage of product development than MVI which has a product in stage III clinical trials. MVI’s activities are now increasingly concerned with establishing the distribution and clinical networks needed to make a malaria vaccine available to those who need it now trials are proving successful.

5.3 Using PDP social technology for serving the needs of poor

Many PDPs, including MVI and IAVI are in a good position to learn about local contexts and innovate in the area of social technologies on the basis of local knowledge. This social technology will be invaluable in devising plans for the production, distribution, acceptance and use of new treatments and drugs. It is clear
from many studies that have been carried out that vaccines and other drugs are at times rejected because not enough resource is devoted to understanding local contexts (Leach and Fairhead, 2007). Moreover, the structure of local distribution channels impacts significantly on the way drugs and treatments are consumed (Mackintosh and Mujinja, 2008). By using their connections and networks which span local contexts and global product development, PDPs can hopefully give rise to further social technology innovations which will contribute to making new products and technologies more accessible.

This more user-led innovation process involving poorer consumers in developing countries focuses on the demand side of innovation (issues of access and affordability) and not just supply. It involves a range of unseen activities in the setting up of durable innovation infrastructure which has low income users as a central focus and thus has the potential for productive innovation over the longer term for poor users and consumers. This type of activity is difficult for large powerful pharmaceutical players in emerging economies to undertake due to their path dependency and business trajectories discussed in earlier sections of this paper. We would argue the problem for big pharmaceutical in both established high income markets and emerging economies is a 'double whammy' – both non-linear user-led innovation processes and non-market pull for the innovation. The evidence seems to suggest that this tricky selection environment for the innovation requires a new social technology - a mix of public, private and not for profit actors.

6. Conclusion

Large numbers of people from developing countries are living in absolute poverty and with varied and severe unmet health needs. In recent years this population has been viewed as a US $ 5 trillion bottom of the pyramid consumer market and various business managers from large pharmaceutical firms as well as emerging country firms are devising various product and process strategies to reach this potentially significant market. However, this paper has argued that large multinational firms are more likely to engage with a range of other stakeholders to undertake this work rather than reorient their core business models. These emerging configurations can be thought of as new social technologies.

Some large pharmaceutical firms are focusing more on the emerging country markets and adjusting their products and their costs to suit to consumers in these countries. However involvement of large pharmaceutical firms becomes viable and fruitful only when a certain level of commercial viability is reached. In the last decade emerging countries’ pharmaceutical firms have contributed to the reduction of drug prices but with the current strengthening of regulation are mainly targeting the development of products for advanced markets. Emergence of user-driven innovation in firms and demand-driven strategies often results in development of innovative products however it also results in firms getting locked-in to a specific customer base.
Thus this paper argues that whilst large pharmaceutical companies and the private sector more generally will be important partners and providers of drugs for wealthier segments of the population in developing countries, they will have a limited role in satisfying healthcare needs of poor populations. Meeting the needs of lower income populations will more likely be met by new mixes of organisations and networks that contain public and private actors. Some of these strategies include participation in new social technologies better connected to local contexts and firms and are in the form of PDPs.

This paper has come to these conclusions through the conceptual use of a Technology-Market matrix to explore the contribution being made by different combinations of social technology and particularly the role of not-for-profit PDPs to meet the health needs of low income people in poor countries. Unlike other arrangements PDPs introduce a coherent organisational, management and cultural approach to bringing together development and innovation. Some PDPs are able to learn about local contexts and innovate on the basis of local knowledge and this allows PDPs to play an invaluable role in devising plans for the production, distribution, acceptance and use of new treatments and drugs. By using their connections and networks which span local contexts and global product development, PDPs have shown potential to contribute to making new products and technologies more accessible.

Analysis presented in this paper shows that the emergence of new social technologies, such as PDPs may respond to low income users in developing countries more effectively than the traditional private sector or public sector actors. Our research on PDPs shows that such activities can result in creative ways to refocus marketing and production activities towards the needs of the poor in a way that currently pharmaceutical firms in both developed and emerging economies are less able to do. However, to be effective, PDPs need to operate in the context of effective and productive broader institutions and the dynamics between the regulatory and funding environment and ‘social technology’ options open to those engaged in major neglected disease initiatives is an area that warrants more attention than it currently receives.

7. References


Bloomberg (2005) Big Pharma's Shameful Secret. New York,


## Figure and Tables

### Fig 1 Technology v/s Market Matrix

<table>
<thead>
<tr>
<th>Technology</th>
<th>Traditional</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional</td>
<td>Old treatments for ‘rich’ consumers mainly in West. Heart Disease, Cancer are some of the major targets. Indigenous and traditional cures supplied to their traditional consumers in developing countries</td>
<td>Generics for neglected and diseases New distribution channels for old Western developed drugs and indigenous and traditional healthcare in developing countries</td>
</tr>
<tr>
<td>New</td>
<td>The 90/10 issue – most R&amp;D spend going to developing new drugs for a small minority of the world’s population. Includes trends toward pharmacogenomics, personalised medicine and new developments in synthetic biology, stem cells.</td>
<td>New Western medicines for poor consumers in developing countries – for example, vaccines for neglected diseases. Mix of ‘indigenous and traditional medicines and new consumers/users of those products</td>
</tr>
</tbody>
</table>
Fig 2 New markets: where will solutions come from?

Low income population’s health needs

New social technologies

Large pharma firms

PDPs

Emerging country firms
### Table 1 Top 15 Global Pharmaceutical Companies in 2009
(Source: IMS Health Midas, December 2009, Annual Reports, 2009)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Sales ($ US Mn)</th>
<th>Sales from emerging countries %</th>
<th>Total R&amp;D (US $ Mn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Pfizer</td>
<td>57024</td>
<td>14.2</td>
<td>7845</td>
</tr>
<tr>
<td>02</td>
<td>Merck</td>
<td>38963</td>
<td></td>
<td>4805</td>
</tr>
<tr>
<td>03</td>
<td>Novartis</td>
<td>38460</td>
<td>8.9</td>
<td>7217</td>
</tr>
<tr>
<td>04</td>
<td>Sanofi-Aventis</td>
<td>35524</td>
<td>~22</td>
<td>6731</td>
</tr>
<tr>
<td>05</td>
<td>GSK</td>
<td>34973</td>
<td>10</td>
<td>6599</td>
</tr>
<tr>
<td>06</td>
<td>AstraZeneca</td>
<td>34434</td>
<td>13</td>
<td>5179</td>
</tr>
<tr>
<td>07</td>
<td>Roche</td>
<td>32763</td>
<td>11</td>
<td>8194</td>
</tr>
<tr>
<td>08</td>
<td>Johnson &amp; Johnson</td>
<td>26783</td>
<td>~16</td>
<td>6986</td>
</tr>
<tr>
<td>09</td>
<td>Eli Lilly</td>
<td>20310</td>
<td>~10</td>
<td>4326.5</td>
</tr>
<tr>
<td>10</td>
<td>Abbott Laboratories</td>
<td>19840</td>
<td>~20</td>
<td>2255</td>
</tr>
<tr>
<td>11</td>
<td>Teva</td>
<td>15947</td>
<td>14.6</td>
<td>802</td>
</tr>
<tr>
<td>12</td>
<td>Bayer Schering</td>
<td>15711</td>
<td></td>
<td>2266</td>
</tr>
<tr>
<td>13</td>
<td>Boehringer Ingelheim</td>
<td>15725</td>
<td>~20</td>
<td>2215</td>
</tr>
<tr>
<td>14</td>
<td>Amgen</td>
<td>15038</td>
<td></td>
<td>2739</td>
</tr>
<tr>
<td>15</td>
<td>Takeda</td>
<td>14352</td>
<td>1.9</td>
<td>2690</td>
</tr>
</tbody>
</table>

### Table 2 Leading Indian pharmaceutical Firms (Annual Reports, 2008)
<table>
<thead>
<tr>
<th>Firm</th>
<th>Total Sales (Rs. Million, 2008)</th>
<th>% from Overseas (high-income) markets</th>
<th>Overseas acquisitions (post 2000)</th>
<th>Out-licensing deals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>44814</td>
<td>82</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>DRL</td>
<td>69440</td>
<td>67</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>15454</td>
<td>73</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>PIH*</td>
<td>32811</td>
<td>~ 40</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Glenmark</td>
<td>21160</td>
<td>~ 60</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Cipla</td>
<td>44290</td>
<td>55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aurobindo</td>
<td>23,511</td>
<td>60</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Sun</td>
<td>34606</td>
<td>55</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Torrent</td>
<td>9959</td>
<td>24</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Lupin</td>
<td>27730</td>
<td>65</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

* Piramal Healthcare formerly known as Nicholas Piramal (I) Ltd

Table 3 GSK’s activities in emerging markets (Source: GSK website, Annual Report, News reports)

<table>
<thead>
<tr>
<th>Country</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>In 2009 GSK signed a deal with Aspen, a South Africa-based pharmaceutical company buying 16% of Aspen and selling it a number of specialty medicines along with a German manufacturing site. The two companies plan to commercialise products in sub-Saharan Africa. In South Africa, GSK will transfer marketing and distribution rights to Aspen for its pharmaceutical products.</td>
</tr>
<tr>
<td>India</td>
<td>In 2009 GSK set up a deal with Dr. Reddy’s Laboratories (a leading Indian firm). GSK will get access to more than 100 branded drugs to market in Africa, the Middle East, Asia and Latin America. They will be manufactured by Dr. Reddy’s with shared revenues.</td>
</tr>
</tbody>
</table>
Pakistan

In 2009 GSK picked up Bristol-Myers Squibb’s Pakistan business

Egypt

GSK picked BMS’s mature products (20 branded products) and high quality manufacturing facility

Lebanon, Jordan, Syria, Yemen

In 2009 GSK acquired Bristol Myers Squibb’s branded generics business (13 branded products) in Lebanon, Jordan, Syria, Libya and Yemen.

Other emerging markets

In 2009 GSK acquired rights in emerging markets for several products from UCB Pharmaceutical

<table>
<thead>
<tr>
<th>Large MNC firms</th>
<th>Emerging country firms</th>
<th>Year</th>
<th>Deal type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mylan Labs</td>
<td>Matrix Laboratories (India)</td>
<td>2006</td>
<td>Company Acquisition</td>
</tr>
<tr>
<td>2. Daichi Sankyo</td>
<td>Ranbaxy Laboratories (India)</td>
<td>2008</td>
<td>Company Acquisition</td>
</tr>
<tr>
<td>3. Frensenius Kabi</td>
<td>Dabur pharma (India)</td>
<td>2008</td>
<td>Company acquisition</td>
</tr>
<tr>
<td>4. Hospira</td>
<td>Orchid Chemicals (India)</td>
<td>2009</td>
<td>Injectable business</td>
</tr>
<tr>
<td>5. Sanofi-Aventis</td>
<td>Shanta Biotech (India)</td>
<td>2009</td>
<td>Company Acquisition</td>
</tr>
<tr>
<td>6. Sanofi-Aventis</td>
<td>Medley (Brazil)</td>
<td>2009</td>
<td>Company Acquisition</td>
</tr>
<tr>
<td>7. Sanofi-Aventis</td>
<td>Kendrick (Mexico)</td>
<td>2009</td>
<td>Company Acquisition</td>
</tr>
<tr>
<td>8. Perrigo</td>
<td>Vedant Drugs and pharmaceuticals (India)</td>
<td>2009</td>
<td>Company acquisition</td>
</tr>
<tr>
<td>9. Mylan Labs</td>
<td>Famy Care (India)</td>
<td>2009</td>
<td>15% stake</td>
</tr>
<tr>
<td>10. GSK</td>
<td>Aspen Laboratories (South Africa)</td>
<td>2009</td>
<td>16% stake</td>
</tr>
<tr>
<td>11. Sanofi_Aventis</td>
<td>Zentiva NV (Czech Republic)</td>
<td>2009</td>
<td>Company acquisition</td>
</tr>
<tr>
<td>12. Abbot Laboratories</td>
<td>Piramal Healthcare Ltd</td>
<td>2010</td>
<td>Formulation business with</td>
</tr>
<tr>
<td>No</td>
<td>PDP name</td>
<td>MNC firm</td>
<td>Date of starting</td>
</tr>
<tr>
<td>----</td>
<td>----------</td>
<td>----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>1</td>
<td>Action TB Programme (ATBP)</td>
<td>GSK</td>
<td>2003</td>
</tr>
<tr>
<td>2</td>
<td>Dengue Vaccine Project (DVP)</td>
<td>Aventis-Pasteur</td>
<td>1989</td>
</tr>
<tr>
<td>3</td>
<td>Diflucan Partnership Program</td>
<td>Pfizer</td>
<td>2000</td>
</tr>
<tr>
<td>4</td>
<td>Eli-Lily multi Drug Resistant Tuberculosis Partnership (MDR-TB)</td>
<td>Eli-Lily</td>
<td>2003</td>
</tr>
<tr>
<td>5</td>
<td>GSK African Malaria Partnership</td>
<td>GSK</td>
<td>2002</td>
</tr>
<tr>
<td>6</td>
<td>Global Alliance for the elimination of Lymphatic Filariasis</td>
<td>GSK, Merck</td>
<td>2000</td>
</tr>
<tr>
<td>7</td>
<td>Global Alliance to Eliminate Leprosy</td>
<td>Novartis</td>
<td>1999</td>
</tr>
<tr>
<td>8</td>
<td>Global Guinea Worm Eradication Program (GWEP)</td>
<td>Dupont/American Cynamid (BASF)/Johnson &amp; Johnson</td>
<td>2000</td>
</tr>
<tr>
<td>9</td>
<td>Global public-private partnership for Hand Washing with Soap</td>
<td>Colgate-Palmolive</td>
<td>1998</td>
</tr>
</tbody>
</table>

Table 5 PDPs involving large pharmaceutical firms (data from [www.health-partnerships-database.org](http://www.health-partnerships-database.org), accessed 10/12/12)
<table>
<thead>
<tr>
<th></th>
<th>Program Name</th>
<th>Year</th>
<th>Company</th>
<th>Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Infectious Disease Research Institute (IDRI)</td>
<td>1994</td>
<td>Corixa corporation</td>
<td>Leishmaniasis treatment</td>
<td>On-going</td>
</tr>
<tr>
<td>11</td>
<td>International Trachoma Initiative (ITI)</td>
<td>1998</td>
<td>Pfizer</td>
<td>Improved drugs for Trachoma (blindness)</td>
<td>Reduced disease in Tanzanian, Ghanaian and Vietnamese children</td>
</tr>
<tr>
<td>12</td>
<td>Malarone Donation Program</td>
<td>1997</td>
<td>GSK</td>
<td>Preserve utility of Malarone as anti-malarial agent</td>
<td>Ongoing</td>
</tr>
<tr>
<td>13</td>
<td>Global elimination of Maternal and Neonatal Tetanus</td>
<td>1998</td>
<td>Becton Dickinson &amp; company</td>
<td>Reduce Tetanus infections in women and children</td>
<td>33 million women protected since 1999</td>
</tr>
<tr>
<td>14</td>
<td>Mectizan Donation Program</td>
<td>1987</td>
<td>Merck</td>
<td>Eradicate River blindness</td>
<td>250 million doses were donated to more than 30 million people in 34 countries</td>
</tr>
<tr>
<td>15</td>
<td>Net Mark Plus</td>
<td>1999</td>
<td>BASF/Bayer AG</td>
<td>Malaria prevention</td>
<td>Increased access to insecticide-treated nets</td>
</tr>
<tr>
<td>16</td>
<td>Secure the Future</td>
<td>1999</td>
<td>Bristol-Myers Squibb</td>
<td>Provide care and support for women and children with HIV-AIDs</td>
<td>Over 150 projects have been funded in South Africa, Botswana, Namibia, Lesotho and Swaziland</td>
</tr>
<tr>
<td>17</td>
<td>Step Forward Programme</td>
<td>2000</td>
<td>Abbott Laboratories</td>
<td>Provides support to children affected by AIDS</td>
<td>On-going</td>
</tr>
<tr>
<td>18</td>
<td>WHO Programme to Eliminate Sleeping Sickness (WPRESS)</td>
<td>2001</td>
<td>Aventis SA and Bayer AG/ Bristol-Myers Squibb</td>
<td>African trypanosomiasis elimination</td>
<td>On-going</td>
</tr>
<tr>
<td>19</td>
<td>WHO/Novartis Coartem</td>
<td>2001</td>
<td>Novartis</td>
<td>Malaria drug development</td>
<td>On-going</td>
</tr>
<tr>
<td>20</td>
<td>LAPDAP Anti-Malarial Drugs</td>
<td>2003</td>
<td>GSK</td>
<td>Malaria drug development</td>
<td>Drug under Phase IV studies</td>
</tr>
</tbody>
</table>