Linking Innovation Process to the Provisioning of Public Goods: The Case of Neglected Diseases

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ABSTRACT

The literature on the role of firm level innovation process mostly deals with the production of private goods as opposed to public goods. The innovation paradigms that are currently being encountered endow us with an opportunity to design a framework leading to a model of enabling firms to produce public goods. Public goods face two kinds of problems: one arising due to lack of either administrative or market oriented incentives, as the dearth of drugs for infectious diseases suggest, and the other arising due to restrictions in their use, as for example, controlling access to information over the internet. We would like to examine in particular the first set of issues arising out of a virtual neglect in the production of public goods. The production of public goods is facing an impasse due to the nature of the neo-liberal economy, where the state gradually seeks to withdraw itself from the economy without adequate replacement. We seek specifically to closely examine the role of the innovation process as a clear visible expression of the knowledge production occurring in a firm towards the production of drugs for infectious diseases. We have chosen 'drugs for infectious diseases' as the public good for closer examination as it rises several interesting questions. Has the public goods nature of drugs for such infectious diseases reduced the innovativeness of the relevant firms? Are there any policy levers available that will incentivise production of such goods? We specifically examine how redesigning the innovation process can help firms and the state in accomplishing the production of such public goods – hitherto made rather onerous. Through this work, we seek an answer to the question "Under what kind of innovation process would an entity produce a public good?"

Keywords: Innovation Process, Neglected Diseases, IP, Public Goods, Incentive frameworks, R&D

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Introduction

Are research and development (R&D) practices, the world over, becoming sufficiently open and flexible in acknowledging new innovation processes? We explore this issue with respect to public goods, by taking drugs for neglected diseases as a specific example. The literature on drugs for neglected diseases shows a marked indifference to its development both from the state and private firms. In a globalised world how does one seek to address such problems of both 'state' and 'market' failure? How can innovation processes be better organized, whether in private or public spheres, as we attempt to grapple with the issue of public goods production and access within the larger context of state and market failure?

Various definitions for innovation in the literature from Schumpeter (1934), Rogers (2003), Malerba (2000) identify appropriation mechanisms as a critical component to complete the cycle of innovation. Intellectual property (IP) is one example of an appropriation mechanism that organisations prefer. IP is a state guaranteed instrument that attempts to balance the static equity (monopolistic power to the innovator) with a dynamic efficiency (knowledge available to the public to further research developments) for a fixed period of time (Stiglitz 1999). We believe that the nature of the good being innovated plays a deciding factor in the innovation process of a firm which subsequently affects the design of the appropriation mechanism.

Given the putative difference in the characteristics of certain goods, how does a firm establish a framework that acknowledges and internalises such differences within its innovation processes? To a considerable extent, the motivation towards production of any good is largely subservient to serve the robustness of market conditions. For instance, healthcare for life-style diseases has expanded tremendously whilst many other infectious diseases are usually neglected due to allegedly poor market size[1] and the rather inadequate purchasing power capability of the concerned people.[2] Public goods therefore, due to their specific characteristics as explained in greater detail below, require continuous forms of support from various concerned actors.

IP, in its conventional form, as a proxy and motivator for a firm's ability to extract value, fails in addressing the cause of neglected diseases.[3] We argue that the health industry requires a more innovative role to be played by IP different from its present customary role of enhancing static equity (a protective role enabled through monopoly) by rather moving towards enhancing dynamic efficiency (enabler of knowledge accessibility). This is possible by a more close understanding of the progressively more complex processes of product creation. The R&D efforts have, we argue, acquired considerable complexity for a mere single firm to undertake the comprehensive development of a new drug. Can appropriately designed innovation processes help to internalise the characteristics of public good and enable its production rather than depending on external incentives?

The paper is structured in the following way. We introduce the 'nature of goods' in specific relation to health goods and global public goods and examine their impact on neglected diseases. We next present the transitions occurring in the nature of the good and its management through various current incentive models. We finally propose a multi stage innovation process within the firm to internalise the complex nature of producing public goods. The work concludes by mapping the case of production of neglected drugs to the proposed framework.

Nature of the goods – private versus public

Access to seeds and food, energy, water, internet or neglected areas like drugs for infectious diseases are examples of goods that face a continuous pull between providing adequate market based incentives to innovate on the one hand versus their accessibility and affordability to the public at large. Neither the state, as a result of neo-liberal growth patterns, nor the private sector due to lack of alleged 'proper incentives'[4] are adequately forthcoming in producing the specific public good.

All goods have the dual characteristics of private and public built into them, differentiated primarily through their non-rivalrous and non-excludable nature. A good is therefore identified based on the above mentioned dominating characteristics. Public goods are goods in the public domain – available for consumption by all and hence potentially affecting all (Kaul et.al. 1999a). The public good characteristics[5] arise from the core principle of indivisibility of costs or benefits for the public at large and may be public at either a global[6] or regional level. On the contrary however, private goods can be made excludable in consumption and usage by associating them with clear property rights.

We know that one of the chief characteristics of knowledge as a good is that it can be 'shared' with as many people as possible without the producer necessarily having any less of the original knowledge.[7] The non excludability element suggests that raising prices may lead to potential free riding. The non rivalry element suggests that with marginal costs close to zero, there exists the inability to recoup R&D costs, leading to less than optimal supply.[8] Hence certain incentives appear relevant for sustaining the generation of knowledge.[9] In such a framework, IP provides the missing incentive by attempting to balance both the access and efficiency requirements. Knowledge thus becomes an enduring example of a non-rivalrous product, made exclusive through the use of IP (Stiglitz 1999). Stiglitz (1995) identifies five examples of global public goods: international economy; security and stability, environment, humanitarian and knowledge. The health of an individual, although considered as a private good, can under certain conditions become a public good due to the positive externalities that it generates. The cumulative impact of the individuals' health on the nation's epidemiology (negative externalities) makes health a global public good.[10],[11]

Neglected Diseases (ND)

Currently, over 1 billion people, nearly one-sixth of the world's population are affected by ND.[12] HIV/AIDS, malaria and TB have dominated the funding share for neglected diseases (Molyneux et al 2005). Lacking public infrastructure coupled with vector carriers' growth help ND to proliferate. It is suggested that investment in control/elimination of these diseases can produce an enhanced economic rate of return of 15%–30%, and is capable of delivery on a large scale (Molyneux 2004).

Innovations across the board of diagnosis, treatment and control are required to check the impact of ND. Taking into account the overwhelming characteristics of societal health being a global public good, firm level incentives are necessary for private players to directly contribute.[13] This is precisely where the nature of IP (through the role of the state) can play a most significant role. We would like to stress that an IP system based on an innovation process that enhances accessibility (dynamic efficiency) would be more appropriate for addressing issues faced by global public goods, than an innovation process that emphasises a more restrictive and protective IP system (based on static efficiency).

We next examine the public-private transition in the nature of the good and subsequently explore the various incentive models proposed in the literature to tackle the pressing problem of access and availability of drugs for neglected diseases.

Transitions in the Nature of the Good

Figure 1 represents the shifting nature of the good throughout its lifecycle by mapping a typical drug creation process. The starting point is the conception of knowledge as a public good and the creation of the tangible elements (drugs in this instant) as a private good. The accessibility segment due to the positive externalities that is created is identified as a public good. The dotted lines in Figure 1 represent the intended link whilst the thick lines represent the presence of an established link.

There is a clear lacuna in the creation stage itself (a lack of interface between the R&D level and medical knowledge as shown in Figure 1). The initial R&D stage in a typical production cycle appears oblivious of the demands of a public good [link K1]. It is only when the production cycle is completed [link D1] and reach the market, that firms begin to realise the necessity to engage with appropriate government policies (for instance, compulsory licensing) for addressing the public nature of the goods [link M1]. We argue that such a belated or deferred R&D product strategy introduces certain imperfections in the development process. Firms appear therefore to justify their unrelenting intent in exacting as much appropriation as possible to justify the internal risks of their R&D activities, as opposed to possibly re-examining new innovation processes that could address this anomaly. This could also be understood by referring to Figure 2 which captures the inflated role of IP as a necessary motivator of innovation. This figure refers to Heller's work, where he has argued eloquently about the potential threat of the anti commons. Transaction costs could be seriously raised for, say drug development, as the potential for splintered ownership of several patents becomes the norm (Heller 1998).

The developments that are indicators of such inflation include the widening of patentable subject matter (including the basic building blocks, gene sequences, diagnostics sequences and methods, data protection policies[14] among others) and a rather lenient approach to novelty. Such widening creates proliferation in the nature of IP ownership leading eventually to the inhibition in the licensing of goods. The dotted arrow in Figure 2 reflects the current transition occurring in the IP System. Figure 2, basically seeks to highlight and explain the apparent disconnect as represented by the dotted lines in Figure 1.

Besides Heller, Barton (2001) also raises several concerns with respect to the undue global emphasis on the use of IP system as an appropriation mechanism. Some of these concerns are:

1. An unhealthy tradeoff between access and development of new technologies.
2. A skewed R&D driven by the ability to appropriate rather than by the dire needs of the populace.
3. Lack of development in the therapeutic quality of drugs for infectious diseases.
4. Inflating the cost of R&D for drug research by including opportunity cost over and above out of pocket expenses.

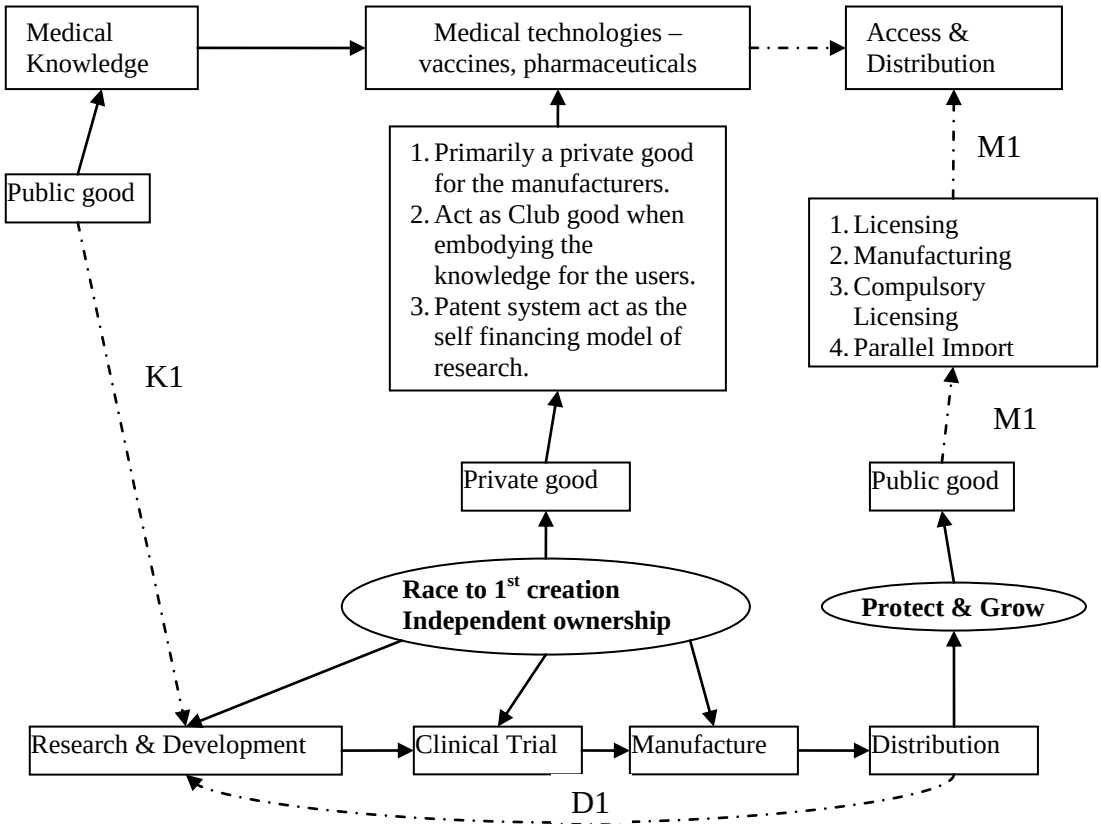

Figure 1 Changing nature of the Good, Role of IP and Business Cycle.

To overcome the above mentioned issues, researchers have argued for various appropriation models based on either jurisdictional, incentive or participatory approaches to the enabling of innovation.[15] For instance, the criticality of the above issues are visible from the 2006 WHO report on IP, Innovation and Public health, which concluded that TRIPS as an incentive (indirect market incentive) has been insufficient for the developing countries towards addressing Type II and III diseases.[16] This rises the question "Why in spite of a focus on a protective IP system, there is, an abject failure[17] in the production of drugs for neglected diseases?"

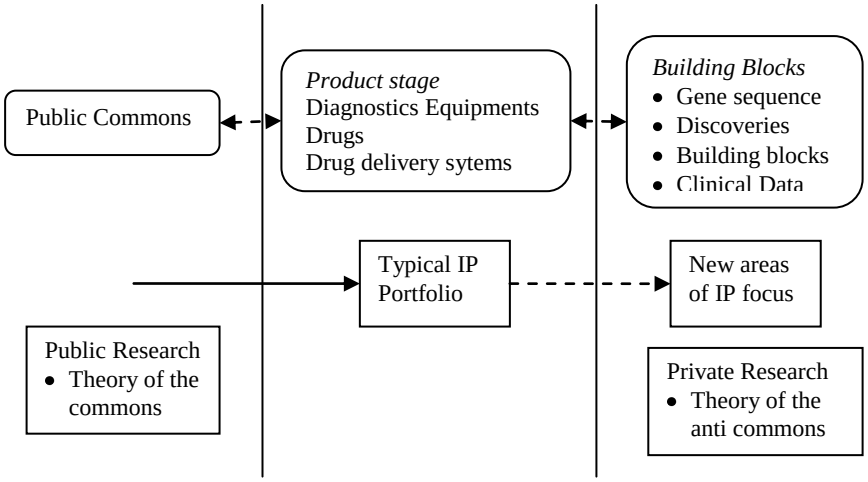

Figure 2 Inflationary behaviour of IP

From the above issues raised and discussed, it is clear, that the state can play a decisive role in enabling the access and creation of public goods. Two major strategies used by the state in such situations are to increase appropriation or extend direct government support towards such goods (Stiglitz, 1999).

Appropriation Strategies

An appropriation strategy is a framework for providing complete ownership over a tangible or an intangible entity, in our case knowledge created and its end outcome – a process or a new product. The appropriation strategy must balance the effects of monopoly control (under utilisation of the innovation) versus the public's use of the knowledge being created (free riding).

The role of the state in the appropriation strategy can be mapped in three areas – jurisdictional, incentive and participatory, as indicated in Table 1, based on Kaul et al (2003). The withdrawal of the state from providing the relevant policy directives especially weakens the case for public goods and considerably skews the essence of IP towards maximising the monopoly gains.[18,19,20] The strategising of IP towards increasing revenues through royalties or market exclusion has spread unopposed. This is quite different from the conception of IP, which stresses the role of patents in the social diffusion of knowledge (Sell 2003).

Table 1 Appropriation Strategies

Type	Example	Remark
Jurisdictional	TRIPS provisions like compulsory licensing, parallel importation	Has not really helped developing nations to enhance their domestic innovative capabilities in vital sectors such as pharmaceuticals.
Incentive	IPR – subject matter, time period, R&D Tax breaks	The focus is on firms providing break through innovations and enabling diffusion by supporting large scale production.
Participatory	Prize based, Prior bulk orders, International funding	The focus is on enabling participation of the relevant people. The motive is on creation of the missing component

More so, in the case of drugs, the dependence on IP as the sole way to recoup costs runs into rough weather due particularly to: a) process imitation, b) impact of externalities created, c) the universal right to good health [UN charter?] and d) the specific nature of the discrete product (easily copied but difficult to create) (Hollis 2005).

Innovations in Neglected Diseases: some issues & challenges

To unambiguously state the importance of neglected diseases the WHO (2000) report estimated that one third of the world's population lacked access to essential drugs, with this figure rising to 50 percent in the poorest parts of Africa and Asia. Though most of the drugs on the WHO's list of Essential Drugs (those which satisfy the core health care needs of the majority of the population), are out of patentability, the truth is that most of these drugs are so old so as to have very poor therapeutic power in treating the present generation of diseases.

The main players in the current pharmaceutical R&D are constituted by three groups – private, governments/public enterprises and non governmental organizations. The ratio of their research funding in the USA is 52%, 38% and 10% respectively. Such funding combined with market incentives has lead to the well known and yawning 10/90 gap in access to medicines, where 10% of the diseases (in the lifestyle segment) receive 90% of the R&D investment (Molyneux 2004). Anderson (2006) reflects on this asymmetry in the industry due to:

1. Negligible profitable return on investment in tropical diseases under the current global IPR regime
2. Insufficient funding from national governments, and
3. Low funding by non-profit organizations

Hence, there is no "R&D pull" for allocating resources to work on NDs. This is best captured by the real case of eflornithine[21],[22] a drug for sleeping sickness developed by Aventis. This case conspicuously reflects the low priority that neglected disease drugs attract from health companies with respect to their research strategies.

From the above set of issues described, we find that IP in its conventional formulation has its set of problems when used as the sole appropriation method for all types of goods.[23] For public goods, we need a different approach towards incentive systems that enables innovations. The major parameters that have to be related when determining the IP policy especially for health related innovations are access to the drug and the scale of the affected population (global, neglected, tropical or life style).

Health goods and incentives

Drug production is primarily impacted by two mechanisms, interventionist and compensatory (Smith 2003). The interventionist mechanism is used in situations which have set regulations on the incentive parameters. These include compulsory licensing, process patents, parallel importation or the Hutch-Waxman Act (Bolar Provision) that help facilitate the creation of robust generic markets. Correa (2001) reflects the variability across the nations with regard to conceptualising an invention. The interpretation of the patentability standards and the prior art requirements differ across nations. A typical example would be the section 3(d) of the Indian Patent Amendment Act 2005, where the efficacy of the innovation, especially in drugs is to be clearly spelt out by the innovator.

Large drug firms are typically critical of such forms of intervention as it is perceived as having political connotations and perhaps as a form of non tariff barrier. Such intervention mechanisms are seen as potentially derailing their IP centered business models. Thus countries have to tread a fine path when using such flexibilities offered under TRIPS to design their IP policies.

The compensatory mechanism uses economic models that incorporate the role of patents and other incentive mechanisms for the healthcare segment. We provide a summary of literature in this segment through Table 2. Four major families of models are identified – public incentive based, prize based, patent pooling based and public private partnership based models towards enabling innovations in the neglected diseases.

Table 2 Types of Incentives Proposed

S/No	Nature of Model	Authors	Observations / Remarks
1.	Public Incentive	Kremer and Glennstetter (2004) Center for Global Development (2005)	Advanced Market Commitments for Vaccines
		Ridley, Grabowski, and Moe (2006)	Priority Vouchers for research done on neglected diseases to be used for blockbuster drugs. Estimated to have a size with present value of sales of $3 billion (in 2004 dollars)
2.	Prize based	Shavell and van Ypersele (2001) Abramowicz (2003) Aidan Hollis (2005) Will Masters (2005)	Optional Rewards, Will Masters proposed prizes for innovation in agriculture Dependence on philanthropy and developed nations for funding to be available – hence fund tie-ins are to be analysed.
3.	Patent Pool	Gold et al. (2006)	Participation in patent pool depends on the license design.Concept was mired under antitrust issues but post 1980s' USA relaxed and approved patent pools as a method towards fair and reasonable licensing. The recent WHO plan of action (Dec 2009) on public health, innovation and IP reflects on the role of voluntary patent pools.
4.	Public Private Partnership	Moran (2005)	Auctioning fast track options and feeding the returns into neglected disease funding.
		Lanjouw, 2001	Transferable patent exclusivity rights – transfer the rights got over developing nations against developed nations.

Source: Author's representation from various literature sources

When designing incentive systems, we need to understand that in healthcare, we need funds to research on neglected diseases, which cannot be generated by the affected nations themselves. The allocation of funds in the affected nations has to take place between enabling the infrastructure for health delivery networks and the research for future benefits. Global policies towards neglected diseases can fail to kick off due to the dependence on sponsorship by the developed nations and philanthropists. Hence prize based models, PPP models find both a huge political wall of resistance and practical fund availability to be overcome.

A common thread in the above proposed mechanisms has been the targeted approach to enhance the intermediate variable's impact (patent is an intermediate variable in the research and production of a good). The methods described above do not separate out the incentive to do R&D and the final production of such R&D output. The R&D incentive has been constructed purely from the angle of rewarding the creator and assumes the affordability of the produced good by all. So, how can we enable innovation for such types of less accessible goods? Is this an issue of the nature of the good or the construct of the innovation process followed?

Given our claim of an alternate innovation process for addressing problems of provisioning global public goods, we would like to offer the following four approaches, namely: a) Cumulative Innovation (closed, internal to the firm); b) Open Innovation (closed, yet open by expanding the horizontal value chain); c) User Innovation (the end user participates to design and evolve a new application / service from the product in hand) and d) Collaborative innovation (multiple mostly unrelated teams across firms share resources towards a common goal and is different from open innovation in terms of the complete openness of the development process and its output) as the means for a firm to participate in the production of public goods. The state's role through the IP system is the thread which interconnects the various innovation processes that a firm can embrace.

We next examine and critique why the traditional innovation process, as the dominant approach, alone does not suffice as an appropriate framework. Rather, a firm requires all the four innovation processes depending on its technology development stage for an effective outcome. We first establish how the innovation process engages the issue of the "collective goods issue" of non-rivalry and non-exclusiveness. Later the case of drug development is mapped to the proposed framework of how a firm can benefit by using multiple innovation processes in its R&D activities.

Mapping Innovation process and nature of good

The earlier discussions captured what is largely required to address the problem of provisioning public goods. IP as an incentive has failed, for various reasons, to motivate the relevant innovation to occur. Precious little thought has gone into the primary reasons for such a seeming R&D debacle. The focus so far in the literature has been more on the usage of IP being generated rather than on 'how' one would generate such IP. Firms have been happy to produce the IP and wait for the state or a 'donor' to take the next step towards making it available to the public at large. We looked at the literature to find the focus of the innovation process and how IP has impacted these processes. Our analysis about the focus of different innovation processes and the role of IP are captured in Table 3.

Table 3 Innovation Processes

S.No	Innovation Process Type	Primary Focus	Potential Issues
1	Traditional	Developments done internal. Company leverages and builds on the public technical knowledge.	Worried about technology spillover. Attempts to use trade secret /use of IPR towards disclosure of innovation against temporary monopoly.
2	Open	Horizontal value chain focus. Ownership is with the single firm only. Transition from vertical to horizontal networks	Depends on a mature IPR system in place. Licensing is the key binding agent.
3	User	Early innovator / adopters are part of the fine tuning of the product. Could lead to real breakthrough innovation as not bounded by any other relationship.	Primarily driven by specific needs and not as a commercial competition. Firms to be alert enough to identify a platform technology being evolved. Leads to knowledge spillovers.
4	Collaborative	Multiple stakeholders having a common objective. Each brings their own specific focus and expertise	Held together by the common license of making developments completely open and available. Focus on knowledge spillover rather than technology spillover.

As stressed earlier, this fundamental problem needs to be approached from a different and fresh perspective. To begin with, clarity in understanding the role of IP in the current dynamic context has to be reached. The capability of technologies and how technologies themselves are being created have undergone a paradigm shift. At the heart of the issue is how does one reconsider IP from its functional role as an enabler of static equity (monopolistic power to the innovator) to an enabler of dynamic efficiency (knowledge available to the public to further research developments). We develop a new framework for firms' that enable's one to address such a question.

Figure 3 is an illustration of our basic the framework where we propose a relationship between the innovation process and the nature of the good. We propose the innovation process to be a medium to internalise the issues raised due to the public nature of the goods. The major issues that a firm faces within the innovation process are the R&D inhibitions largely due to an anticipated free riding, in turn made possible by the knowledge spillover. The spillover and free riding manifests itself in terms of a need felt for greater enforcement of IP (effecting exclusivity) and a considerable increase in pricing (effecting accessibility).

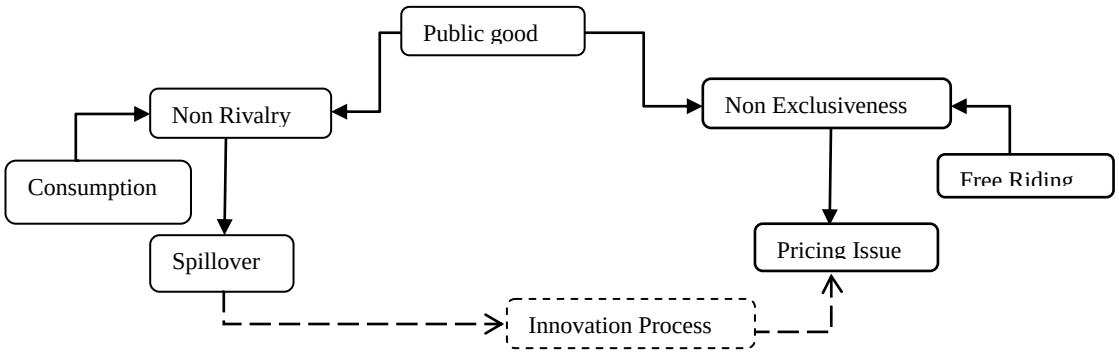

Figure 3 Linking the Innovation Process to Public Goods

We would like to examine whether it is possible for the innovation process to internalise the externalities mentioned above. Currently, the spillover and free-riding are externalised through

IP systems and state supported incentive mechanisms. Given that the innovation process is internal to the firm, it is possible to internalise the process by aligning it to the specific status of the technology development cycle.

Transitions in Technology Complexity

The technology development process is dependent on the nature of the technology. The nature of the technology being discrete or complex is dependent on the two major variables - nature of process and end product. Examples for the two are given in Table 4. Technology has enabled the horizontal growth of organisations through the evolution of specialised firms that focus on a particular component of the entire value chain. Thus, firms now have the burden/incentive to manage multiple stakeholders.

Table 4 Nature of Technology

Variable	Characteristics	Example	Nature of Technology
Nature of the process	Reproducibility of the entire process	Drug process is easy to reproduce but difficult to initiate. Telecom is difficult to process due to multi system design.	Complex - Telecommunications
Nature of the end product	Single component /collection of components	Drug is a single component while telephony encompasses an entire system.	Discrete - Drug Development

The role of complexity is present in both the technologies but its position of significant impact differs. In the case of telecommunications, it is at the end product whilst in drugs it is at the creation stage. This complexity factor is the motivator to have standardised interfaces that provides effective interaction amongst the components, leading to a creation of horizontal value chain.

As a comparative example, the telecommunications sector utilised the standards interface to address the complexity of the end product. The presence of standards leads to interoperation amongst the players. Thus, the industry tuned gradually towards a horizontal rather than vertical specialisation. They have been following the tenets of open innovation principles (courtesy standardisation) without the necessary benefit of any overt theoretical framework. This type of an interface helped the industry to face its technology development chasms by sharing responsibility between various firms leading to a win-win situation for all.[24] The firms realigned their activities around a specific technology (a standard) rather than organizing around their idiosyncratic firm specific innovation processes.

The drug industry's work flow, on the other hand, has been the exact opposite. It thrives on a vertical value chain (discovery, manufacture and distribution executed by a single coherent entity) with considerable emphasis, as an article of faith, on internal development. The industry is also worried about the technology spillover and its impact through reverse engineering of their discrete end products (i.e., new molecules). Hence the drug industry has been arguing that the high cost of R&D requires a stricter enforcement of the IP system. Firms appear to be locked into emphasizing the considerable significance of IP as their leitmotif for extracting premium commercial value. Driven by vertical integration, the incentive systems tend to reflect the control of a single entity (a large drug firm).

The five stages (S1 – S5) of drug development process are indicated in Figure 4. The vertical bars in between the stages indicate the roadblocks in the form of gaps. These gaps represent the lack of understanding of the requirements of transition from one stage to another stage (that is required for a technology/product to evolve and succeed). It is very critical for firms to understand these gaps and identify strategies to overcome the same.

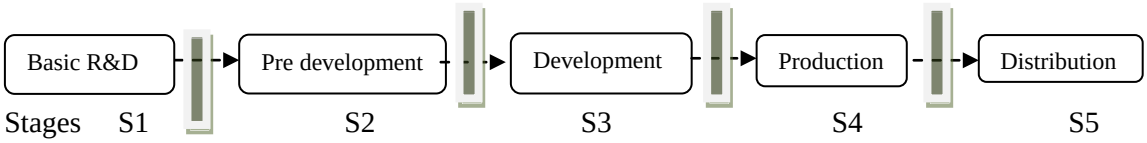

Figure 4 Technology Development Process and expected outputs

The growth of ICT in the last two decades has led to the breakup of the value chain and brought in specialisation. The ICT revolution has helped in two primary ways – increasing ability to network across the world and the availability of intense computation power. These results impact by modularising the process of the stakeholders involved.

In the case of drugs, the growth in ICT and biotechnology has forced a breakup of the existing value chain. Computational biology, Gene markers and arrays, research diagnostics have taken over the primary research activities of established firms. Coincidentally the patentable subject matter has also expanded to include biotechnological innovations into its fold. The new biotech firms are firmly entrenched and their technologies require to be licensed by the traditional firms for their regular drug discovery cycle. The emerging picture suggests that the role of the interested firm is increasingly confined towards a strategic management of the innovation process and the attendant relationship with the drug regulation.

The significance of licensing is becoming intense as it influences the interaction across multiple stakeholders and raises the transaction cost. So, firms that own the critical components (such as the gene sequences) are able to exercise greater leverage over the entire drug development process. Anticipating such a possibility certain traditional drug firms seeing their grip loosening, funded biotech projects, especially in the gene sequencing area and decided to release the entire content open to the world.[25]

Though the end product is still a single molecule, the process of manufacturing the same has undergone a sizeable change. The entire drug discovery and production chain is now woven across multiple specialised firms. We can now safely argue that defining the nature of the technology includes the number of actors that interact for a particular deliverable to occur rather than the composition of the end product alone. The addition of this characteristic reflects on the need to see manage the multiple stakeholders and their output.

What we are observing, is the transition in the locus of technology development process. Earlier it was the firm, but now, it is the technology (across stages) – be it the process or the end product. The uniqueness of the telecommunication industry structure is enveloping other sectors. Such a shift has been possible because of the innovations occurring across diverse but latently interconnected areas. The innovation process of a firm is supposed to identify these latent links and create the synergies required for its success. This transition brings its own issues of incentivising such actions. Concurrently, the innovation process also has experienced a sea change due to the various ways in which the intangible good (basic building blocks) are being created. These transitions in the innovation process enable us to differentiate the incentive systems for R&D and the production of the final good.

Development of framework for Multiple Innovation Process within a firm

The proposed framework is structured on the issues presented earlier and is inherently designed to incentivise innovations for public goods. The proposed framework advances the need to blend multiple actors towards creation, generation and provisioning of low 'commercial' value public goods (drugs).

The firm is the focal point of the proposed framework. Firms have the onus to interface and integrate the results from its horizontal value chain. The innovation strategy proposed covers the entire spectrum of open to closed processes, enabling firms to manage their manufacturing costs. Table 5 lists type of innovation processes that a single firm can follow, the interface required for each such process and the expected outcomes of following this framework.

Table 5 Type of Innovation Processes in a Firm

Type of Innovation	Inputs / Interface	Expected Outcomes
Collaborative	Dedicated Research centres / Public driven labs ("open source equivalents")	Real breakthrough innovations, fundamental identified choices. Works under the premise of right to distribute the source (aligns with public good characteristics)
Open / Collaborative	Universities	Knowledge spillovers, Prototyping support.
Open	Third Parties Specialised firms, IPR systems	Knowledge Spillovers, Licensing strength and related infrastructure growth in the nation
Traditional / Open	Generic Industries	Production of accessible goods, Technology Spillovers, cumulative development (Scotchmer 1991)
Traditional	IPR system & Policies, State interface	Horizontal networks by industries

The framework for multiple innovation processes within a single firm is shown in Figure 5.

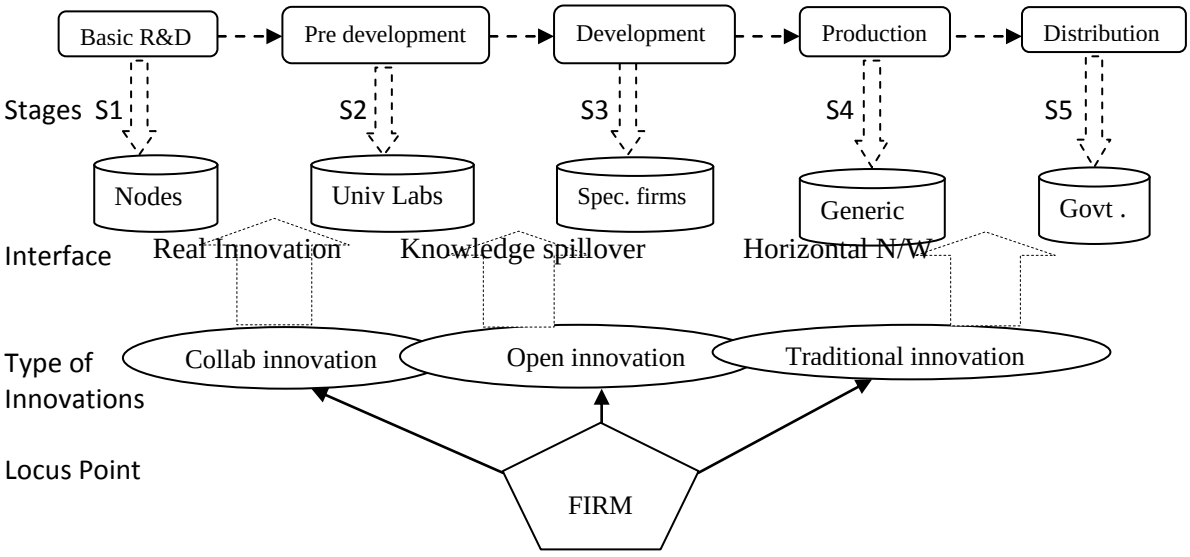

Figure 5 Technology Development Process and expected outputs

The novel aspect of the framework is the straightforward aggregation of multiple innovation processes by the firm to achieve the end objective. The following four major transitions that have occurred gives credence to our proposal: biotech focus, growth of specialised IPR based firms, wide acceptance of open source and finally the embracing of open innovation.

The state also leans more towards the design of support systems and policies such as the acceptance of a patent pool, enabling funding towards basic R&D research along with industrial partners, creating an ecosystem for licensing to pickup so that open innovation by firms can be practiced.

These transitions bring a host of new firms into the new product (public good) development market and the traditional mode of new product development is recast. In essence, a vertically integrated structure is on the throes of becoming more horizontal. Examples include specialised firms like Amgen, Genentech, university research centers (Univ of Wisonsin Madison) working in tandem with traditional firms like Merck, Novartis, Bristol Squib, Glaxo and others.

Applying the framework to Neglected Diseases

Earlier, we discussed how the public nature of the drug requires a patent free approach to the drug discovery process and the open source movement for the drug discovery process for neglected diseases. Patents in spite of their monopoly power have so far failed in their action of incentivising R&D in certain identified segments of the drugs field. This entire transition brings a fresh concept to the role of collaborative innovation process.

Unconnected people and the open availability of the source code are linked through the internet and submit their debug and enhancements towards the building up of a repository of open source software. With the increase in the dependence on computational techniques towards new molecule discovery and other various computational biology actions, open source equivalent license and participation towards molecule modeling has gathered steam. Table 6 proposed the type of innovation process that suits the drug discovery stages and the type of organizations through which the interface can be enabled. The table 6 also lists the application and outcomes from each stage based on the type of innovation process followed.

Table 6 Stages of Innovation Process in a Firm

Stage No:	Type of Innovation	Inputs / Interface	Application	Outcome
S1	Collaborative	Dedicated Research Centres	Basic R&D generation of foundation blocks that is modular in nature.	Real breakthrough innovations, fundamental identified choices. Works under the premise of right to distribute.
S2	Open / Collaborative	Universities	Trials	Knowledge spillovers, Prototyping support
S3	Open	Third Parties	Conformal testing	Knowledge spillovers, Licensing strength and growth in the nation
S4	Traditional / Open	Generic Industries	Manufacturing	Production of accessible drugs, Technology spillovers
S5	Traditional	IP system & policies and State interface	Policy level, access to goods	Horizontal networks by industries

Figure 6 maps the generic framework to the five stage drug development process. Real examples of relevant interfaces that enable the success of the relevant innovation processes are identified. Next we discuss each stage of drug development process and the role of the identified interface.

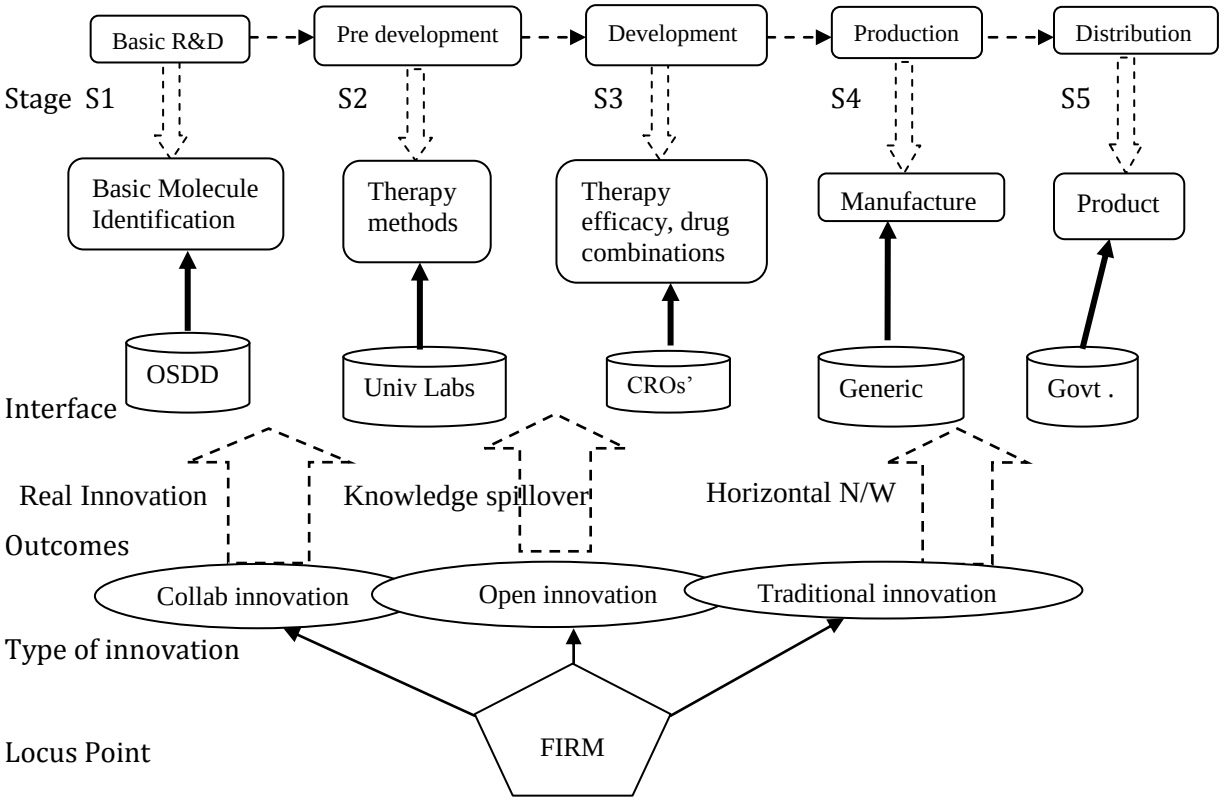

Figure 6 Mapping the framework for Neglected Disease

Stage S1
The contemporary example is that of the open source drug discovery (OSDD) project by the Council for Scientific Research in India (CSIR). The OSDD is targeted towards identification of new molecules and drug development towards neglected diseases – TB as the starting point. Researchers, government labs, institutes, universities and likeminded industrial researchers have joined hands towards this quest.

This is an example of how collaborative innovation occurs with non tangible products like drug molecule design. The OSDD owns the IP that is generated by the project and is released to the industry as required under license. The major difference is the submissions that make the OSDD collaboratively rich – all the OSDD submissions are under attribution based open licenses. This enables interested people to expand their related work. The OSDD equivalent relationship will best serve for computational support in the molecule identification stage.

Stage S2
Post the OSDD developments of identifying the base molecule; an interested firm now has an opportunity to leverage the research capabilities of the research centres/ universities. The universities with their laboratory setup can help in this next stage post the identification of base molecules. This stage links collaborative and open innovation policies.

Stage S3
Here, the firm uses the open innovation principles to outsource specific functionalities to specialised firms. The major challenge for this stage is to develop an appropriate IP licensing system as it is a very significant variable for facilitating the success of stage 3 and beyond. This stage uses the open innovation policies.

Stage S4
This stage links the cumulative and open innovation segments of the firm. The firm can here use the role of generics through technology transfer/spillovers towards better production of the engineered drug.

Stage 3, 4 requires the firm to use the open innovation principles optimally. The firm's main role is to identify its core research work and the rest of the development that can happen in parallel through external entities. These two stages also enable the horizontal networks to evolve in the drug industry.

Stage S5
In this stage, the firm relates the innovation process to the availability of the goods produced and the interface with the state. The interface with the state provides the ground work for a firm to take forward the horizontal network based open innovation policies. The state plays its part by framing the right IP policies.

The firm comes under the traditional innovation process when integration with the various efforts has to take place and see a targeted output being achieved. Each innovation process that a firm follows has knowledge and technology spillovers as indicated in the figure 6.

By mapping the types of innovation process to the life cycle of the product / technology, we can relate the bottlenecks that are faced in the production of a public good and its resolution. Drug firms by joining hands with such endeavors see a potential reduction in their individual contribution towards drug discovery, thus reducing a major cost portion of the end product. By taking care of the basic research, the role of the firm is now extended to coordinate with a host of other license or co-developers. The concept of open innovation values the IP generated by the firms that take part in the new horizontal chain. The large drug firms can use the specialised firms towards completing the various stages of drug discovery – all within the boundaries of accepted open innovation licenses. In this way, the firm is also ensured of the quality of the access to the drug development process.

Conclusions

Firms are interested in maximising their returns (recoup the R&D costs) from the legal monopoly position (IP design) they receive while the government looks towards social innovation benefits. Coupled with the expansion of the patentable subject matter as a prelude to the TRIPS, has only reiterated the firm's compulsion towards supporting a strong IP system. This is the primary reason for drug production to fail, causing the 'access gap' in the drug industry and the world. To comprehend the role of IP effectively, we have discussed how innovation is occurring in a firm and whether a firm can benefit by the paradigms of change occurring in the innovation process.

The need for horizontal value chain is stressed and a new characteristic (number of stakeholders) that determines the nature of the technology is identified. This new characteristic when mapped to the principle question raised in this work leads us to the formation of a generic framework that enables multiple innovation process to be followed within a frim. Licensing designs together with IP subject matter, act towards enhancing dynamic efficiencies rather than static ones and remains a pivotal concern across the innovation processes.

The drug industry, which is rather belatedly recognising the significance of open collaborative innovation, is mapped to the proposed framework. The proposed framework reinforces that

public goods are a multi actor variable requiring judicious, reinforcing relationship amongst the private and public domain.

The type of the innovation process is now a policy lever towards enabling production of public goods. The proposed framework also identifies the appropriate examples for each type of innovation process that can help in the drug discovery process. Further research is intended to understand how to design the appropriate handoffs between the various innovation processes and increase the benefits from each such process.

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Endnote

[1] Less than 1% of the 1393 new drugs registered between 1975 -1999 were for tropical diseases.

[2] One must understand that health insurance is not available in many countries for the majority of populace suffering from communicable diseases.

[3] In the late 1990s', the traditional role of IPR acutely impacted the HIV/AIDS drug combination by pricing at US $10,000 but later available for US $176 after the introduction of generics (Molyneux 2005). A policy lever like Compulsory License [CL] seeks to primarily address, among other things, the lack of access to cures for life-threatening diseases.

[4] Low income of target customers for drugs for infectious diseases, among others, appears to be a significant reason for firms to not invest in R&D for such drugs.

[5] A public good is one that can be produced at a very minimal marginal or no cost (non rivalry) and consumed undifferentiated without restricting consumers irrespective of their ability to make payment (non excludability) (Holocombe, 1997).

[6]Global public good is defined as a good which is rational, from the perspective of a group of nations collectively, to produce for universal consumption and for which it is rational to exclude an individual nation for its consumption, irrespective of whether the nation contributes to its financing (Smith et al 2003).

[7] Thomas Jefferson once said that knowledge was like a candle: when one candle lights another it does not diminish the light of the first candle. There is no marginal cost associated with the use of knowledge. It is more efficient to distribute knowledge freely to everybody than to restrict its use by charging for it. See Economic foundations of Intellectual Property Rights by Joseph E. Stiglitz in Duke Law Journal, Vol. 57: 1693.

[8] For any efficient output, resources are required to be expended, and if after incurring such expenses, the good can subsequently be reproduced at zero marginal cost there is little incentive to share/produce the good.

[9] Due to these mentioned issues, knowledge is treated as an impure public good.

[10] The potential impact of communicable disease like Tuberculosis on other countries is increasingly being recognized as an important aspect of its public good nature.

[11] Health of an individual impacts the economic output of a society. Hence, though health could be a private good, the well being extends a positive signal to the society. The three largest disease types are lower respiratory infections, HIV/AIDS and diarrheal diseases. Communicable disease accounted for 26% of deaths in 2000 and 30% of global DALY11 (WHO 2001b)

[12] A total of 14 NTDs are present at the moment: Buruli ulcer, Chagas disease, cholera/epidemic diarrhoeal diseases, dengue/dengue haemorrhagic fever, dracunculiasis (guinea-worm), endemic treponematoses (yaws, pinta, endemic syphilis), human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, onchocerciais, schistosomiasis, soil-transmitted helminthiasis, and trachoma (Molyneux 2005).

[13] The cost of engaging in trials for new molecules for neglected diseases typically running into hundreds of millions of dollars, with buying power largely absent, allegedly prevents private players from entering the fray

[14] Data exclusivity is one example of how a public good (knowledge) becomes private.

[15] The Global Alliance for Vaccines and Immunization (GAVI) in 2005 received $750 million from the Bill and Melinda Gates Foundation and $290 million from the Norwegian government to increase access to existing vaccines and accelerate R&D efforts for treatments for neglected diseases Ridley (2006).

[16] Type I, II, III are WHO classifications of the diseases types based on its incidence. Type I/Global diseases know no geographic boundaries while Type II–III/Neglected-Most Neglected are predominantly or exclusively prevalent among populations of developing countries.

[17] Only five of the nearly twenty one drugs developed in the period 1965–1992 were from private research labs (Cockburn & Henderson 1997). Between 1975 and 2004, of the 1,556 new chemical entities marketed globally, only 20 new drugs - a mere 1.3% - were for tropical diseases and tuberculosis, which accounts for 12% of global disease burden. 68% of the 3,096 new products approved in France between 1981 and 2004 offered 'nothing new' over previously available, 5% of all newly-patented drugs in Canada as 'breakthroughs' and over one thousand new drugs approved by the US FDA between 1989 and 2000 revealed that over three quarters had no therapeutic benefit over existing products.

[18] There were several critics of the interventionist role of the state with respect to IPR. MacTaggart of Pfizer, alleged in a 1982 New York Times article, that the World Intellectual Property Organization (WIPO) helped in "trying to grab high-technology inventions for underdeveloped countries" and for contemplating treaty provisions that would "confer international legitimacy on the abrogation of patents" (Drahos & Braithwaite 2002).

[19] Two significant events in the USA in the 1980s'made a significant difference: on the jurisdictional front, the setting up of a separate court system for IP related issues (CAFC) in the USA and on the incentive front, the acceptance of patent pooling as a remedy towards antitrust issues raised due to patent monopoly.

[20] Between 1982 and 1990, the CAFC upheld on appeal 90 percent of patents held to be valid and infringed, compared with 62 percent in the various relevant courts between 1953 and 1978. It reversed on appeal only 28 percent of patents held invalid and lacking infringement, compared with twelve percent previously (Jaffe 2000).

[21] Melarsoprol, the earlier known drug for sleeping sickness had a huge side effect (10% of the patients died due to its side effects). A later drug, eflornithine, which had fewer side effects, was developed by Aventis and discontinued in 1995. Aventis gave the license to WHO, which tried unsuccessfully to identify a manufacturer. Five years later, Aventis identified a newer use as a depilating agent and started to manufacture again. Case available at www.essentialmedicine.org/uploads/HilaryMarstonResearchGap.ppt

[22] With the support of two pharmaceutical companies, a new combination of eflornithine and nifurtimox was launched in September 2009 to treat human African trypanosomiasis. Status from the online document http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_6-en.pdf

[23] There are several types of public goods such as a) Common Pool Goods which are basically non excludable but rivalrous in consumption (food, water and forests); b) Club goods which are excludable but non-rival (such as private goods required to access a public good, network access point to connect to the Internet) and c) Access goods, which are private goods which help in reaching the public goods (television) These goods increase the cost of public goods.

[24] Leveraging economies of scale and scope through the presence and usage of commercial off the shelf components

[25] Furthering it, the approach of Eli Lily towards innovation in the drug sector was a refreshing change. The birth of the Innocentive.com as a spinoff and it later as a separate entity clearly recognises the success of open innovation in a discrete as drugs industry.