Reconfiguration of competencies from emerging country firms as a response to the emergence of disruptive new market: Evidence from the Indian pharmaceutical industry

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Abstract

This paper examines the response of Indian firms to the emergence of a new disruptive market segment resulting from evolving biosimilar regulation and saturation of existing generics markets. Using novel analytical tools such as a technology–market capability matrix and a capability creation model, we show technological trajectories and heterogeneity in firm strategies employed by incumbent firms to compete in the biosimilars market. Analysis reveals that entry into emerging country markets and R&D collaborations formed core elements of experimentation with strategy.

1.0 Introduction

Transitions to new technology, science, a new market sector or changed regulatory regimes are difficult to manage for any organisation, public or private. The emergence of a new market or technology can catch off-guard incumbent firms that are locked into existing markets. This may affect their survival in a new era (Christensen, 1997). In the last two decades firm response to changes in the external environment has emerged as a major concern of the dynamic capability and industry evolution literature.

In the healthcare sector, the emergence of a new technology or market presents challenges for policy makers and regulators who must create policies and regulations to ensure a competitive market and safe products. Incumbent firms need also to respond to the challenges posed by new technology, evolving policy and transitioning regulatory frameworks. In this scenario, firms have to reconfigure existing capabilities and business models as a response to emerging disruptive markets. To a large extent, the dynamic capability literature has been focused on firms in advanced countries. However, for firms in developing countries, the challenge is harder as technological, political and economic complexities make transformation of capabilities a difficult process. This paper fills a gap by investigating how incumbent Indian pharmaceutical firms are reconfiguring their existing capabilities as a response to the emergence of a market for biosimilars.

Biosimilars (also known as biogenerics or follow-on-biologics) are generic versions of biologics - a therapeutic drug category comprising large complex molecules. The market for biosimilars has been created by three drivers; evolving regulatory frameworks, increased demand for affordable therapies and saturation of small molecule generics markets. The complexity of biological drugs and evolving regulation creates new challenges and opportunities for developing country firms. In this context the Indian pharmaceutical industry provides us with informative case studies to study the development of dynamic capabilities of resource-constrained firms operating in emerging countries.

In the past, the challenge facing the Indian pharmaceutical industry was to make a successful transition from the era of protected markets to an era of global competition. This they did and much scholarship in recent years has focussed on what the industry did to achieve this feat (Athreye et al., 2009; Gehl Sampath, 2006, Kale, 2010). Post 1990, the Indian pharmaceutical industry emerged as a cheap global supplier of generic drugs. Indian firms accomplished this by targeting generic markets in advanced countries, enabling growth and development. However ‘small molecule’ generic markets in advanced countries are

witnessing a significant drop in value (Kamath, 2011). For Indian firms reduced opportunity in advanced countries raises important questions for long-term growth and survival. Thus the emergence of biosimilar markets along with the decline in traditional generic markets has created significant hurdles for the Indian pharmaceutical industry. This gives rise to the key research question; how are firms reconfiguring strategies for development of capabilities as a response to the emergence of biosimilar market opportunities? To answer this question we investigate heterogeneity in firms' reconfiguration strategies and explore the origin of heterogeneity when different firms operate in the same environment with the same resource base.

Using case studies of six Indian pharmaceutical firms we demonstrate the processes involved in development of dynamic capability. We employ two novel analytical tools; a 'technology - market' capabilities matrix and a capability creation model, to investigate heterogeneity in strategy reconfiguration and technological trajectories. Our paper makes three critical contributions to dynamic capabilities and industry evolution literatures. First, this research demonstrates how a change in market re-orientates technological capabilities even in the absence of a radical technological discontinuity. The saturation of existing global generic markets, emergence of a disruptive biosimilar market and the evolution of new regulation for biosimilars, significantly alters Indian firms R&D and market priorities. Reduced value of the traditional generic market has created a need for alternative strategies. The emergence of the biosimilar market is shaping the evolution of new capabilities and strategies all along the value chain of biosimilars and biological commercialisation.

Second, the paper points out the kinds of dynamic capabilities that can be developed as a response to emergence of a new disruptive market. They are of three kinds and are significantly inter-related: diversification of knowledge and technological capabilities; partnering with overseas firms related to a new technology (biosimilars) and development of biosimilar capabilities. Based on the capability creation model, we show that reconfiguration strategies are a function of past firm specific technological trajectories, firm-specific managerial vision and inter-organisational learning through observation of strategies of other firms. The novel matrix further explicates how heterogeneity is rooted in technological path dependencies and firm specific managerial vision.

Third, this paper shows that unlike small molecule generic markets, Indian firms are focusing on biosimilar markets in other emerging countries and not targeting advanced country markets. This focus has origin in two factors: first, the high cost associated with regulatory

requirements in advanced countries and second, the possibility of de-risking investment by catering to the unmet needs of emerging country markets for affordable biosimilars.

We argue that these findings together highlight the clear impact of regulation on firm level strategies in the healthcare sector and hints towards subtle shift in firm focus from advanced country markets towards emerging country markets. This research has implications not only for pharmaceutical firms in other emerging countries facing similar challenges but also for ensuring affordable healthcare for poor people all over the world.

This paper is structured as follows: Section 2 discusses size and growth of the biosimilar market, and subsequent opportunities for emerging suppliers. Section 3 explains the salient features of the Indian pharmaceutical industry and tracks challenges and opportunities of the biosimilar sector. Section 4 briefly reviews the literature focused on heterogeneity and the dynamic capabilities approach. Section 5 details our data collection methods and the six Indian pharmaceutical firm case studies that are used to illustrate evolution of firm strategy and biosimilar R&D capability. In section 6 we present our results on different strategies and reconfiguration of capabilities of Indian pharmaceutical firms in response to market opportunities. Section 7 concludes.

2.0 Emergence of a disruptive new market: Biosimilars

A biologic or biological drug is a large complex molecule that has been sourced from a living cell, for example, insulin. They are too complex to manufacture in the same way as simple small molecule drugs (e.g. aspirin). Biosimilars are generic versions of biologicals. They have been produced for growth factors, cytokines, hormones, monoclonal antibodies and vaccines. They are similar in terms of quality, safety and efficacy to an already licensed reference biological product, but due to the complexity of the manufacturing process, possibility for variance is very high. Unlike the production of small molecule generics, creating a generic version of a biologic that is identical to its reference product is close to impossible. Slight variability in process or input can lead to slightly different large complex molecules, which in turn can have significant effects on safety, quality and efficacy. Thus there is a need for an expanded regulatory framework, which is different to that guiding the approval of simple generics.

While the production of generic versions of biologics are not an obvious disruptive technology as defined by Bower and Christensen (1995), the challenges facing leading Indian manufacturing firms are somewhat akin to firms that have faced the innovators

dilemma (Christensen, 1997). The emergence of a new market and new process innovations that have accompanied the emergence of biosimilars, can catch incumbent firms off guard, since most are locked into existing markets of small molecule generic markets in advanced countries. As a result, to survive and grow, incumbent Indian firms with interests largely in generic markets in advanced countries must consider alternative business models and investment in capability building for biosimilar production. As mentioned above, in this new environment incumbent firms must respond to the twin challenges of new process technologies and also new and emerging regulatory frameworks. In this scenario winners and losers are selected in function of the dynamic firm capabilities most appropriate for the emerging market environment.

There are two main drivers behind the emergence of the biosimilar sector and subsequent disruption to the market and current players;

- Growth in demand due to original biologics coming off patent and pressure on government to reduce healthcare costs.
- The development and harmonisation of regulatory guidance for biosimilar approval.

2.1 Growth in demand for biosimilars

By some accounts, the growth of biologics is outstripping that of conventional pharmaceuticals (Mahler and Gray, 2011). Therapeutic biologics such as genetically engineered recombinant proteins and monoclonal antibodies represent an increasingly large portion of newly approved therapies for conditions such as chronic inflammatory diseases and cancer (Kozlowski et al, 2011). It has been estimated that sales worldwide of biologics in 2009 reached US$130 billion and is expected to reach US$210 million by 2016 (Manufacturing Chemist, 2010). With patents for top selling biologics expiring between 2012 and 2019, biosimilars are poised to acquire a significant share of the generics pharmaceutical market (Wechsler, 2011). IMS health estimates that by 2015, the biosimilar market will be worth US$64 billion (Greer, 2012). Table 1 shows key biological products that have already expired or will go off patent in the near future.

(Table 1 here)

One of the key driving factors for the increasing demand for biosimilars is the universal need for more affordable drugs. The cost of biologicals in any country represents a large fraction of the drug bill. For example, there is particular need to reduce the cost of drugs in cancer care, which is a growing burden in many countries, and biological products dominate this field

(Cornes, 2011). There is increasing evidence that biosimilars offer reductions of up to 30% compared to an original biologic (Krull and Rathore, 2010). For example, in Europe, a biosimilar made by Novartis, which helps cancer patients grow white blood cells, costs about 26% less than Amgen's original Neupogen. In 2011 the European Commission report on biosimilars found that the price of biosimilars is on average between 10% and 35% lower than their respective reference products.

2.2 Evolution of the biosimilar regulatory guidance

The comprehensive set of guidelines for biosimilars adopted by the EU in 2006 and the WHO guideline on Evaluation of Similar Biotherapeutic Products finalised in 2009, demonstrate important steps towards harmonisation and consistency (Schiestl, 2011). The passing of the Biologics Price Control and Innovation (BPCI) Act of 2009 in the US is credited with creating a regulatory pathway for biosimilars. A significant number of emerging countries have produced draft or final guidelines on biosimilars, based largely on the WHO and EU frameworks (Ellis, 2010). As national regulatory agencies in emerging countries now begin to draw their own guidelines for biosimilars, we are observing convergence around regulatory requirements and a new market opportunity. Fig 1 charts evolution of regulatory guidelines against market potential of different pharmaceutical markets.

(Fig 1 here)

For resource constrained firms based in emerging countries this gradual but significant shift in global generic markets will demand a new set of R&D, regulatory and distribution infrastructure and capabilities. For example, these firms will need expertise to reverse-engineer the biologics and develop stable, therapeutically active cell lines. They also will need to develop manufacturing processes to meet specifications and to invest in new infrastructures for controlling living cells, purification, and producing biologic products consistently at commercial scale (Lee et al., 2011).

Evolving regulation implies a need for a regular investment in developing regulatory capabilities. As a result these emerging country firms will have to develop dynamic capabilities to protect their long-term future. In this context our investigation focuses on how Indian pharmaceutical firms are reconfiguring strategies and business models in response to emergence of this disruptive new market.

3.0 The Indian pharma-biotech industry

The Indian pharmaceutical industry ranks 12th in the world in terms of value and by volume it is the second largest market in the world. Taking advantage of weak patent law introduced in the 1970s by the Indian government, local firms used reverse engineering to develop cheap generic drugs, and as a consequence, extensive process R&D capabilities. The industry grew rapidly in the 1990s, with an average industry growth rate of about 15% for bulk drugs and 20% for formulations (OPPI, 2001). In the post TRIPS agreement era, Indian firms targeted small molecule generic markets in advanced countries and built their businesses using their superior process R&D skills, cheap production processes and deep distribution and marketing capabilities (Kale and Little, 2007).

3.1 Saturation of the 'small' molecule generics market in advanced countries

Business models based on generating revenue from small molecule generics markets in advanced countries are now under threat. Kamath (2011) suggests that the value of drugs going off-patent between 2016 and 2020 will fall 62% from the value in the preceding five-year period (2011-15). Price erosion is not the only factor. Until 2003, Indian firms tried to gain first to file status in the US generic industry. 180 days exclusivity granted to generic manufacturers was a significant opportunity until 2003 when the provision was diluted allowing more than one generic drug company to enjoy 180-day exclusivity, provided they filed their ANDAs[1] on the same day.

Finally, the entry of large pharmaceutical firms into generic markets has blurred conventional pharma business models. It has led to a number of mergers, acquisitions and alliances that are narrowing the distance between these conventionally separate business models. For Indian companies, this means a smaller opportunity in their main business (off-patent drug exports) and they will need other drivers to grow. Biosimilars represent one such key opportunity for Indian firms. A senior scientist from leading Indian firm comments,

> You know how generic industry is shaping up on the small molecule side, so focus is on more complex generics that will help to build that distinctiveness in terms of competitive models. Biosimilars and proprietary products are expected to provide us with our next phase of growth from business standpoint. If not in terms of revenues then in terms of profitability these businesses are expected to contribute in the future.

[1] Abbreviated new drug application

(author's interview,2013)

3.2 Challenges for biosimilar development

Switching to biosimilars is not an easy, minimum risk strategy, but a decision that requires considerable financial and organisational investment in developing regulatory, technical and scientific capabilities (Barei et al, 2012). A significant challenge for Indian firms is accessing biosimilar markets in advanced countries as regulatory frameworks present significant requirements in terms of clinical trials and data. G.V. Prasad, vice chairman and CEO of Dr Reddy Labs (DRL) explains;

> "It is a big game. It will cost at least $20 million to take a biosimilar drug to the European market. It takes only a small fraction of that amount for a conventional generics pharma product"
>
> (Suresh, 2008)

The technical competencies and capabilities that are required include pharmacovigilance and verification of similarity or comparability with an innovator product. As biosimilars can compete not just on price, but with improved formulations[2] and different methods of drug delivery, some innovative capability will also be needed (Barei et al, 2012).

3.2.1 Knowledge base: Moving from simple chemistry based generics to biosimilars

Over the years Indian pharma firms have developed a knowledge base firmly embedded in organic and synthetic chemistry. In the case of biosimilars, manufacturing firms have to develop absorptive capacity and more advanced biotechnology capabilities. The main constraint in innovative R&D for Indian firms is the lack of scientists with expertise in particular areas of medicinal chemistry and biology pertinent to biosimilars.

A senior scientist in Serum Institute of India points out that there is a serious lack of knowledge among Indian firms regarding issues of quality, safety and efficacy. He highlighted that in biosimilar production even small variations in the manufacturing process might trigger change in quality, safety and efficacy,

[2]Differentiated biosimilars and biobetters can result in lower dosage, reduced side effects, reduced rate of degradation in the blood stream and reduced risk of immunogenicity (Barei et al, 2012).

> "In biosimilar development it is quite hard to spot small differences in production processes. These can lead to significant changes to drug safety and efficacy. But in India there are very few people who have this knowledge"
>
> (author's interview, 2013)

3.2.2 Evolving regulation

Indian firms are also facing severe challenges in relation to the creation of appropriate institutions and infrastructure related to regulatory demand and regulatory capabilities. Regulatory policy in some advanced markets are yet to take final shape while in developing countries it is still at a nascent stage. The delay in confirming regulatory requirements and in some cases, the evolving nature of regulation, is creating investment challenges for Indian R&D firms. The head of Biosimilars at Serum Institutes laboratories phrased this situation as 'changing goal posts'. He elaborated this with the example of immunogenicity. Immunogenicity is defined as an immune reaction to the introduction of a foreign protein and is the most important safety issue in biosimilar development. In the case of small molecules, drugs rarely elicit immune responses but large molecules such as biologicals are capable of triggering immune responses of varying consequences. To understand and monitor immunogenicity, firms have to conduct extensive clinical trials and develop pharmacovigilance data. To collect this data firms must invest extensively and over a longer period of time including during the post market phase. This is riskier where regulation is uncertain.

Referring to some of these challenges, a senior pharmaceutical scientist based at Utrecht University in the Netherlands argues:

> "[US and European] markets will be dominated by big pharma. It takes between 50 and 100 million euros to develop a biosimilar that meets the regulations in Europe, the US and Japan…. that's in addition to post-marketing costs and pharmacovigilance demands. I do not see how a small company, especially from India and China, even if they have the technical skills and money to develop a high quality biosimilar could be able to compete with Teva, Sandoz or Hospira"
>
> (Jayaraman, 2010)

The above discussion confirms that the saturation of existing global generic markets, the emergence of a growing biosimilar market and the evolution of new regulation are creating a new set of challenges and opportunities for Indian firms. Furthermore, the growth of Indian

firms in the biosimilar sector depends on their capacity to identify and develop dynamic capabilities to exploit opportunities. In sections 5 and 6 we provide extensive evidence of transformation of capabilities and firm strategies as a response to the emergence of a disruptive biosimilar market.

4.0 Firm strategies and dynamic capabilities

Our investigation of Indian pharmaceutical firm response to significant change in the market, depends importantly on building an understanding of both heterogeneous strategies of firms and also firm capabilities. We need also to understand how these two characteristics of the firm are related and how they are impacted on by dynamic markets. Both capabilities and strategies are particularly important in dynamic markets, where firm-specific deployment of capabilities, entrepreneurship and ad hoc problem solving skills determine the winners of the race for market shares as new or untapped economic opportunities emerge (Athreye et al., 2009).

Firm capabilities were explored as early as 1959 in the works of Penrose who suggested that the growth of firms is conditioned by their resources and the desire to fully exploit them. Such resource based views of the firm place special emphasis on the roles of heterogeneous capabilities of firms in driving variety in strategy.

Taking an evolutionary view, Nelson and Winter (1982) posited that each firms access to technological and organisational knowledge differs and is conditioned upon past learning. This implies not only heterogeneity of firm capability, but 'stickiness' as firms find that favoured strategies may be limited by firm specific resources and capabilities (Suzulanski, 1996). Highlighting the influence of path dependency and mechanisms of knowledge transfer, Cohen and Levinthal (1990) point out that a stock of past capabilities and mechanisms of knowledge transfer provides the base upon which firms develop the capabilities to cope with new technological change. Change then, is possible, but is conditioned by the past.

Firm capabilities are known to evolve over time as firms encounter endogenous market changes and exogenous shocks (Athreye et al., 2009). In markets where the competitive landscape is continuously shifting, dynamic capabilities become the source of competitive advantage (Teece et al., 1997). Here 'dynamic capabilities' refer to the 'firm's ability to integrate, build and reconfigure internal and external competencies to address rapidly changing environments'. These capabilities are rooted in high performance routines operating inside in the firm, embedded in firm's processes, and are conditioned by its history.

Building upon the resource based approach, this perspective stressed both the dynamic dimension of the capability building process and the role of organisational capabilities in that process.
Eisenhardt and Martin (2000) add that dynamic capabilities are a set of identifiable processes such as product development, strategic decision-making and alliancing, which are path dependent in their emergence. The dynamic focus of this perspective is based on stressing the importance of continually developing new capabilities as well as exploiting old ones in the context of a shifting environment. Dynamic capabilities refer then, to a higher order of capabilities that have the capacity to produce lasting new competitive advantage as a consequence of changing market opportunities (Athreye et al., 2009).

Firms develop strategies in order to balance the use of resources (March, 1991), in particular the resources allocated to exploration and exploitation, both of which are essential. Strategies are key because learning can involve discarding competencies, which might have been useful in a previous era but are no longer relevant in new environments (Kale, 2010) and because technological learning is not linear or automatic, but depends on the decisions that firms make (Forbes and Wield, 2002). Srhrolec and Verspagen's (2012) evolutionary interpretation of the resource based theory of the firm, holds that firms adopt different strategies, even in the same sector, because they start from different resource bases, interpret the environment differently and use different models for reaching decisions.

In contrast to resource based views of the firm in determining heterogeneity, stand sectoral views. Malerba (2004: 387) suggested that differences in innovative behaviour of firms are explained by sectors; "heterogeneous firms … undertaking similar production activities and embedded in the same institutional setting, share some common behavioural traits and develop a similar range of learning patterns, behaviour and organizational form". Pavitt's influential work in 1984 is read as affirming the sector as the unit of analysis - that technological trajectories are explained by sectoral differences in sources of technology, users' needs and means of appropriating benefits. Patel and Pavitt (1997, cited by Srholec and Verspagen, 2012) also argue that the external environment severely limits technological heterogeneity. Extrapolating a global view however, presents the possibility that globalisation of innovation systems and markets, create a far less limited external environment.

For firms in developing countries, external policy uncertainties and internal resource constraints create additional hurdles. Athreye et al., (2009) found that in response to radical regulatory change, Indian firms have developed three kinds of dynamic capability:

diversification of knowledge and technological capabilities; internationalisation of production and distribution units; integration in the innovation creation process of Western country firms through providing services related to innovation creation. This paper builds and adds to the research focused on analysing heterogeneity and evolution of dynamic capabilities in the Indian pharmaceutical industry by investigating the capability development required for the emergence of a biosimilar sector in India.

5.0 Strategy and dynamic capabilities: Case studies of six firms

The Indian biosimilar market is worth around $200 million and there are 7-9 companies with capabilities in the manufacture of recombinant products (Ariyanchitra, 2010). Some Indian firms have introduced biosimilar products to the Indian domestic market and other emerging countries. Desai (2009) points out that more than 40 biologics are marketed in India, of which 25 are biosimilars and are manufactured locally while another 25 biosimilars are in the final stages of development. Products manufactured by Indian firms include insulin, filgrastim, streptokinase, hepatitis B vaccine and rituximab. Table 2 provides details of leading Indian firms involved in biosimilar development.

(Table 2 here)

Some of these firms have evolved capabilities for the development and manufacture of biosimilars at rates that are in some cases, 40 percent cheaper, and are now trying to enter world markets (Frost and Sullivan, 2011). To explore Indian firms' strategies, we will present brief case studies of six Indian pharmaceutical firms involved in development, production and marketing of biosimilars (Table 3).

(Table 3 here)

Primary data for the case studies was collected through interviews with R&D presidents, senior scientists and heads of biotech R&D in the six firms. In parallel we conducted interviews with a key member of the Indian pharmaceuticals industry association and with a senior sector specialist journalist. This data was triangulated by using information in annual reports, analysts' presentations and articles in the business press. Comparative data for the six firms are given in table 3.

A semi-structured questionnaire was used with questions focused on the response of Indian firms to the emergence of biosimilar market opportunities and evolving regulations. Interviews focused on firm strategy, challenges and organisational learning activities involved in acquisition of new knowledge required for biosimilar capability development. It also covered questions regarding the relevance of existing pharmaceutical R&D and manufacturing in the development of biosimilar capabilities.

Our reasons for focussing on these firms are threefold. One, the firms selected for study are in different stages of developing biosimilar product portfolios and thus provide ideal cases to study the reconfiguration of firm level capabilities (Table 3). Firms such as Wockhardt, Biocon and DRL are early entrants while firms such as Cipla, Lupin and Serum are late entrants. Second, these cases provide a mix of different types of Indian firms with biosimilar capabilities; pharma firms, biotechnology dedicated firms and pharma-biotech firms. For example, Serum and Biocon are dedicated biotech firms while DRL, Lupin and Cipla represent pharmaceutical firms moving into the biosimilar area. Wockhardt represents a biopharmaceutical firm, which has presence in both pharmaceutical, and biotechnology markets. This allows us to examine the significance of path dependency, differences in strategies and the role of established routines in reconfiguration of capabilities. Third, there is a very strong correlation between size and R&D intensity in the Indian pharmaceutical sector (Pradhan, 2007). Therefore, any investment in the biosimilar market is likely to emerge only from the top 30 firms. Five of the six case study firms are among the top 30 Indian pharmaceutical firms.

5.1 Case study firms

5.1.1 Biocon: Dedicated biotech firm (Group 1)

Biocon, established in 1978, is a fully integrated biotechnology company focused on biopharmaceuticals, custom and clinical research. Biocon was the first Indian company to manufacture and export enzymes to the US and Europe in 1979.

In the mid-1990s, Biocon decided to focus on biopharmaceuticals rather than enzymes and in 2001 Biocon started manufacturing insulin. After the 2001 patent expiration on Lovastatin, one of the earliest cholesterol blockers, Biocon obtained permission from US Food & Drug Administration (FDA) to sell the generic in the US. In 2001 Biocon became the first Indian company to sell Lovastatin in the US. Currently Biocon has 8 biosimilars in the market and a further 7 at different stages of development.

5.1.2 Serum Institute of India: Dedicated Biotech firms (Group 1)

The Serum Institute of India Ltd. was founded in 1966 with the aim of manufacturing life-saving immuno-biologicals, which were in short supply. It currently produces bacterial vaccines, viral vaccines, recombinant and combination vaccines, anticancer products, antisera, plasma and hormonal products. It is the world's largest producer of measles and DTP (diphtheria, pertussis and tetanus) vaccines. Currently Serum has erythroprotein in the market and two more under different stages of development. According to a senior scientist working in Serum, the company sees biosimilars as a future area of growth and is establishing collaborations to strengthen biosimilar R&D capabilities.

5.1.3 Cipla: Pharmaceutical firm (Group 2)

Cipla or 'Chemical, Industrial and Pharmaceutical Laboratories Ltd' was established in 1935. Over the last five decades Cipla has developed extensive capabilities in reverse engineering small molecules and is well recognised as a cheap supplier of generic products. Post-2000 Cipla has been targeting global biosimilar markets and has started to enter into collaborations for biotechnology capability development. Currently Cipla has entanercept in the market.

5.1.4 Lupin Laboratories limited: Pharmaceutical firm (Group 2)

Lupin pharmaceuticals Ltd was established in in 1968. In 2008 Lupin entered the biosimilar sector by setting up the Lupin Biotechnology Research Group to develop affordable, high quality biosimilars for India and other emerging countries. Lupin currently has two biosmilars in the market and eight in its development pipeline.

5.1.5 Dr Reddy's Laboratories (DRL): Pharmaceutical firm (Group 2)

DRL was founded in 1984 and by 2000 it emerged as a global generics player with superior process technologies. For DRL, biosimilars are a major investment for the future. The company acknowledges that to survive and grow in the future, DRL will need strong biologics development, manufacturing and commercialisation capabilities. Currently DRL has four biosimilars in the market and a further five at different stages of development.

5.1.6 Wockhardt: Bio-pharmaceutical firm (Group 3)

Wockhardt Ltd was established in 1959. The company went public in 1992 and in the same year began building biotechnology capability by hiring scientists from local R&D institutes and collaborating with overseas biotech firms. Since the early 1990s Wockhard has put biotechnology at the heart of its strategy, making it core to the development path of the

company. Since this time the company has spent 20 -30% of its total R&D budget on biotechnology.

5.2 Analytical framework

To analyse similarities and differences in firm level reconfiguration strategies we employed a novel technology-market capability matrix (Fig 2). This matrix provides an analytical tool to investigate firm level heterogeneity in business models and its linkage with capabilities.

(Fig 2 here)

In this matrix technological capabilities are classified on the basis of three component capabilities comprising of R&D capabilities, manufacturing, and regulatory handling capabilities while market capabilities are classified on the basis of diversity of a company's markets and marketing capabilities. R&D capabilities include capacities for clinical trials, PK/PD studies, preclinical research, biological characterisation, physiochemical characterisation and development of processes to improve manufacturing efficiency. R&D capabilities also include regulatory handling capabilities, which are concerned with completion of regulatory requirements. For example, to introduce a biosimilar in European market, firms have to provide extensive data demonstrating that biosimilar has the same effect on the body as an original biological. It will involve preparing clinical trial data, specifically efficacy studies and pharmacodynamics data in a format required by regulatory authorities. It further involves demonstrating their manufacturing methods are satisfying prescribed guidelines. Marketing capabilities include the development of a portfolio of products, a sales force in overseas markets and partnerships overseas.

Market capabilities are closely linked with regulatory, marketing and technical capabilities in that advanced country markets have more stringent regulatory requirements relative to emerging and developing countries. Firms operating in advanced country markets or a significant number of other emerging markets, show superior technological and regulatory capabilities**.** The risk and investment associated with these decisions, guides technology strategies of the firm in biosimilar markets.

6.0 Analysis and discussion

Findings from the case studies demonstrates that emergence of a biosimilar market has significantly altered Indian firms R&D and market priorities and led to reconfiguration of existing strategies. The case study evidence is summarised in Table 4. Table 4 lists the

main indicators of rising technological ability in the biosimilar area and strategies employed to gain these capabilities.

(Table 4 here)

This supports our assertion made in section 4, that the growth of Indian firms in the biosimilar sector depends on their capacity to identify and develop dynamic capabilities to exploit opportunities associated with the process of bringing a biosimilar to the market. In addition, the findings add further detail by identifying the kinds of dynamic capabilities required to exploit the opportunities thrown up by the change in market viz. (i) entry into other emerging country markets, (ii) collaboration with overseas firms and (iii) acquisition of skills for development of biosimilar capabilities. The findings also reveal the various technological trajectories followed by Indian firms as they develop biosimilars and evidence the heterogeneity in firm strategies in terms of technology and market.

6.1 Capability creation model

The emergence of the biosimilar market is shaping the evolution of new capabilities and strategies involved in biosimilar commercialisation. We have developed a capability creation model to plot the technological trajectory of the Indian pharmaceutical firms in the biosimilar sector. In the capability creation model (fig 4) a basic level of capability is taken as the ability to make minor adaptations to production and assimilate technology into a firm's environment. Intermediate innovative capability is the ability to generate incremental technical change in product design, quality and production processes, it also includes ability to search and evaluate external sources of technology. Advanced innovative capabilities refer to the ability to generate new products and process innovations. A knowledge base is categorised as simple or complex, based on the technological challenges involved in developing particular products and underlying capabilities. This classification of capabilities is based on the work by Bell and Pavitt (1993) and Lall (1992).

Based on the classification of capabilities in the biosimilar industry, biosimilar R&D capability (ability to develop biosimilar products by copying the process), is categorised as basic capability. 'Biobetter'[3] and differentiated biosimilar R&D involves incremental change

[3] Understood to be generic biological products that have been shown to be similar to a reference product, but offer advantages or improvements over the original biologic. Regulatory authorities have not as yet allocated a strict definition to biobetters.

representing intermediate capability, while advanced capabilities involves creating a novel biological.

(Fig 4 here)

In the case of progression towards novel biologics, Indian firms are following a stepwise approach. Fig 4 illustrates the capability creation approach adopted by Indian pharmaceutical firms under study. Indian firms are adopting a stepwise approach towards development of advanced capabilities in biological R&D. It involves progressing from basic capability (developing biosimilars) to intermediate capability (developing improved biosimilars in the form of bio-betters or differentiated biosimilars) to advanced capability (creating novel biologics). Table 4 reveals that Biocon have launched two novel biologicals in the Indian domestic market while these products are still undergoing further clinical trials to get approval for marketing in advanced country markets. It reveals that Biocon is using biosimilars as a stepping-stone to gain capabilities required to create novel biologics (Table 4).

The capability creation model illustrates that a duplicative imitation process is being followed that will eventually allow firms to accumulate capabilities to enable them to produce novel biologics. However it is not a linear process and each stage requires resource investment and technological strategies to progress towards an advanced level of capabilities. As they are non linear, the capabilities do not map neatly onto Levies (1996) conceptualisation of capability substitution, evolution and substitution. Basic, intermediate and advanced capabilities do however, require to different degrees, the strategies for reconfiguration that Levie describes.

6.2 Firm level reconfiguration strategies

Our data demonstrates some similarities in firm level reconfiguration strategies but significant differences in business models.

6.2.1 Firm level reconfiguration strategies: Similarities in knowledge acquisition mechanisms

Significantly analysis reveals some similarities in Indian pharmaceutical firms' knowledge acquisition mechanisms for target markets. Table 4 shows that all firms have invested in development of biosimilar capabilities by setting up dedicated biosimilar R&D, manufacturing and marketing facilities. It suggests that strategies to improve biosimilar capabilities have included increasing the level of own R&D spending, setting up dedicated manufacturing facilities and facilitating interdisciplinary communication.

It further highlights all firms are marketing some biosimilars in the Indian domestic market and have biosimilars at different stages of development. It is observed that all these firms are employing three reconfiguration strategies viz. (i) entry into other emerging country markets, (ii) collaboration with overseas firms (big pharma, MNC generic firms, biotechnology firms) and (iii) acquisition of skills for development of biosimilar capabilities by hiring scientists experienced in biological development working overseas with big pharma or biotechnology companies. Table 5-7 indicates the extent to which each mode was employed by the six case study companies, pointing out learning through observation of other companies and revealing diversification of technological capabilities.

Entry into other emerging countries

In the case of generic markets Indian firms have extensive presence in advanced country markets whether measured through their exporting activity or through their foreign investment activity (Table 5). This has created significant complimentary capabilities (Teece, 1986) and in-depth understanding of overseas market facilitating entry of Indian firms into overseas biosimilar markets.

(Table 5 here)

Unlike the generic pharma sector, in the case of biosimilars, Indian firms are focusing on the Indian domestic and other emerging country biosimilar markets, and currently not targeting advanced country markets such as the USA and EU (Table 4). Evidence points to Indian firms reverting to strategies prevalent amongst pharma firms in the pre -1990 era; targeting the rest of the world (excluding advanced country markets) and domestic markets for growth. This strategy is based on the need for short-term revenue to balance R&D investments, unmet needs for affordable biosimilars in emerging countries and the significant cost associated with data requirements demanded by regulatory systems in advanced countries. The Head of Strategy of a leading Indian firm points out:

> Taking the emerging country market route helps us do two things: one, stay close to our purpose of accelerating access to affordable biosimilars in emerging countries and second, to access short term revenue that de-risks our business journey and makes business more sustainable.
>
> (author interview, 2013)

It is also suggested that regulators in emerging countries are inclined to treat biosimilars with urgency, resulting in less time consuming approval processes. A senior scientist explains,

> A regulator in the emerging country market has to balance the burden of unmet needs in their market along with safety and efficacy of drug products they are approving. While they are in interested in
>
> maintaining patient safety and efficacy of the product, they are also cognizant of the fact that we don't have access to this life saving drug, so it is in their interest to approve a product quickly.
>
> (author interview, 2013)

This reaffirms that to be sustainable in biosimilar markets, Indian firms are reverting to those pre-1990 strategies; targeting the domestic market and the rest of the world (excluding advanced countries). Part of this strategy evidences capability evolution (Levie 1996) where firms incrementally modify and adjust existing capabilities through the modification and adjustment of constituting routines to suit a not dissimilar external market.

Collaboration with overseas firms (big pharma, emerging country firms, generic firms) and research institutes

Firms in our study set up collaborations with overseas firms and research institutes to access markets and acquire R&D knowledge. These firms lack some R&D resources in-house to carry out certain functions and activities such as bioprocess development and cell-line development. Thus they collaborate and interact with overseas research institutes and firms in advanced countries to get their work done. A typical strategy involves Indian firms handling early product development and early stage clinical trials, while overseas firms produce the compound and handle late-stage clinical trials. An R&D head at a leading firm commented,

> Now we are focusing on more global development efforts so we are investing in technologies, investing in partnerships that can give us some late stage capabilities and that can help us access markets like the US and Europe.
>
> (author interview, 2013)

Table 6 below, illustrates some of these key R&D collaborations.

(Table 6 here)

Some early starters such as DRL, Wockhardt and Biocon developed collaborations with international research institutes and companies in order to develop basic capabilities in biological R&D. For example, in 2009 Biocon and Amylin Pharmaceuticals entered into a collaborative development agreement for potential treatment of diabetes. In the same year Biocon entered into an agreement with US-based Mylan for the global development and commercialisation of three biosimilar insulin analogue products and cancer treatments.

It is quite evident that Indian firms collaborating with other emerging country firms are focused on gaining market access in contrast to linkages with MNCs in advanced markets which are aimed at capability building. Table 4 lists key market focused partnerships of Indian firms. For example, in 2013 Intas pharmaceuticals entered into a partnership with Besins Healthcare, which has strong marketing and distribution presence in emerging markets, particularly for the markets of China, Russia, Thailand, South Africa and some others. A head of biologicals from an Indian firm suggests,

> We basically have a business-to-business model in biosimilar markets; we access various regions of the world through commercial partners. For example, to pick up the Latin American region we work with the local pharma company to get access to that market. We still haven't built up the strength ourselves in understanding nuances of the domestic biosimilar market. For example, going to the Latin American market and understanding how the regulators work, understanding how the prescriber players behave there, setting up the distribution network, these kind of nuances. Instead of investing in those ourselves it is easier for us to find a like-minded partner to take us to market quickly and bring us those capabilities right away.
>
> (author interview, 2013)

Collaboration allows capability transformation (Levie 1996) through the incorporation of both existing and new know-how. Capability transformation involves learning from a combination of internal sources of knowledge and external sources, provided by the collaborating partner.

Acquisition of biosimilar capabilities: Diaspora connection

Indian firms are trying to acquire specific knowledge (in biosimilar production, development and regulation) by targeting Indian diaspora and hiring senior Indian scientists working with MNCs in the USA. All case study firms show evidence of development of biosimilar R&D capability through hiring of scientists. These firms attract these scientists by offering leadership positions and provide scope to develop their biological business. For example, before joining DRL, Dr Cartikeya Reddy was working with Genentech as a Group Leader in

the area of Cell Culture Process Development. However in a chance encounter, Anji Reddy offered him an opportunity to lead DRL biological R&D as an independent integrated business unit. To further boost its biosimilar capabilities in 2010 Biocon hired in expertise from a US based biotech firm to head one of its subsidiaries and preside over R&D.
Other Indian firms followed similar strategies to develop biological capabilities and table 5 below, shows some of these connections. Hiring new personnel represents capability substitution (Levie 1996). New knowledge replaces capabilities that have been rendered obsolete. In this case the need to acquire new knowledge is necessitated by the need to fill a specific gap in technical ability in the production and marketing of biosimilars.

(Table 7 here)

6.2.2 Firm level reconfiguration strategies: Heterogeneity in business models

This analysis highlights differences in competencies and the heterogeneity in business models adopted by Indian firms in the biosimilar product market. Table 8 presents the differences in the Indian firms R&D, manufacturing and market competencies.

(Table 8 here)

This table distinguishes Indian firms competencies using criteria of strong competence, building capacity and no competence. It reveals that some firms such as Biocon have developed superior competencies compared to some late entrants such as Lupin and Serum while some firms such as Cipla have chosen an acquisitions route to developing new capabilities requiring high investment. Fig 5 tracks the heterogeneity in business models adopted by Indian firms.

(Fig 5 here)

High technology capabilities - Advanced markets (first mover): High investment, high risk but high profit model.

In this category we use the example of Biocon to illustrate a high investment, high risk but high profit strategy. Biocon was the first company to identify the opportunity offered by the emerging biosimilar market. The company was a biotechnology company from the beginning, a factor that created path dependency and complementary competencies. The big breakthrough for the company came with the development of human insulin in 2003. Biocon became the second Indian company to launch human insulin in the Indian domestic market

causing an almost 40 per cent drop in the price of insulin products and a 20 percent increase in usage of insulin by diabetic patients in India. By 2006 Biocon had identified diabetes and oncology as areas of growth and started focusing on biosimilars in those therapeutic areas. In the same year Biocon entered a joint venture with the Cuban Institute of Monoclonal Antibodoes (CIMAB) to develop antibodies and cancer vaccines. Biocon set up two clinical research organisation companies (Syngene and Clinigene) and has collaborations with MNCs specifically for biosimilar development. Its broad product portfolio consists of vaccines, MABs, insulin and EPO.

Biocon adopted an aggressive strategy of targeting emerging as well as advanced country markets and to achieve that, entered into a range of collaborations and acquisitions (Tables 4-6). Through these collaborations and acquisitions Biocon has augmented its biosimilar capabilities and gained access to new markets. For example, Biocons collaboration with Mylan, an MNC generic firm, led to the joint development of the world's first biosimilar version of Transtuzumab, a drug used in treatment of metastatic breast cancer. In 2009 Biocon acquired a majority stake in German pharmaceutical company AxiCorp GmbH (70%) in 2008, for €30 million, to market and distribute its biosimilar insulin and analogues in the German market. But a big moment for Biocon came with its collaboration with Pfizer. In 2010 Biocon entered a landmark $350mn deal with Pfizer to globally commercialise several of Biocon's insulin products - Recombinant Human Insulin, Glargine, and Lispro. It was expected that this deal would pave the entry of Pfizer into the biosimilar market and gain Biocon an international reputation for biosimilar capability. This deal signalled the coming together of Pfizer's strong marketing and commercialization capabilities, especially in the highly regulated developed markets of the world, and Biocon's expertise in biotech R&D. The insulin products started to roll out in emerging markets by 2011, followed by Europe in 2012 and the US planned for 2015. Shortly after completing its highly profitable US $350 mn deal with Pfizer, Biocon started setting up a manufacturing plant in Malaysia to supply products to advanced markets. The high risk in Biocon’s strategy is reflected in the eventual breakdown of the deal with Pfizer. Pfizer decided to pull out of the deal in 2012 leaving Biocon struggling with its expansion plans (Banerjee, 2012).

High technology capabilities - Emerging markets (early entrants): high investment, low risk but moderate profit model.

In this category, we draw upon the examples of DRL, Wockhardt and Intas to illustrate a high investment, low risk but moderate profit strategy. In 2004 DRL hired Dr Cartikeya Reddy from

Genentech Corporation as head of biotechnology R&D to lead biosimilar business and by 2013 DRL had successfully launched four biosimilars. Kamath (2011) points out that DRL's rituximab was the first biosimilar referencing Roche's original $6 billion cancer drug Rituxan, anywhere in the world. By 2010 DRL had begun selling its generic version of rituximab in emerging markets at a 30-50% discount compared to the innovator brand and has started trials for regulatory approval in Europe. Similarly, its darbepoetin, a drug for severe anaemia, was the first biosimilar of Amgen's $2 billion originator drug, Aranesp.

To further strengthen biosimilars, DRL entered into an alliance with Merck Serono, a division of Merck KGaA, Darmstadt, Germany in June 2012 (table 4). Merck KGaA is a global pharmaceutical company with proven expertise in developing, manufacturing, and commercialising biopharmaceuticals and chemical compounds. The partnership is to co-develop and globally commercialise a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (mAbs). Such an alliance allows DRL to mitigate the risks involved in developing a biosimilar — the cost is pegged at $100-200 million, with 70% going towards clinical development.

In 1995 Wockhardt formed a joint venture with the German firm Rhein Biotech for manufacturing hepatitis B vaccine and in 2000 the company launched its first biotech product, the hepatitis B vaccine, Biovac-B. This joint venture helped the company to develop expertise in biotechnology R&D and biologics production, and provided access to crucial know-how. In 2001 Wockhardt emerged as the first Indian company to indigenously produce erythroprotein (EPO) using genetic engineering. For Wockhardt a significant milestone in the production of biologics came with development of human insulin. In 2003, Wockhardt emerged as the first Indian company and only the fourth company in the world (the first outside the US and Europe) to develop, manufacture and market human insulin.

Wockhardt is currently involved in development of a version of the Interferon alfa 2b antiviral, used for treatment of cancer. M.K.Sahib, head of biotech operations in 2004 explains the seeds of biotechnology capability development in Wockhardt;

> "…. we started here the recombinant area in collaboration with Rhein-biotech and we have today all the expression systems that are approved for the manufacture of recombinant products, E-Coli, yeast and mammalian cells. We are the only Indian company that is manufacturing in India while others are importing. [For other] products like Hepatitis vaccine we have the largest brand and third is

recombinant insulin. We will also have a very strong pipeline for different recombinant products. Bio-generics will be the first and then there will be second generation products and also monoclonal antibodies".

(author interview, 2013)

In 2004 Wockhardt commissioned a state of the art production facility dedicated to manufacturing biotechnology products. In 2010 Wockhardt entered into a strategic alliance with Sheffield Bio-Science of the US, for exclusive distribution of Wockhardt's recombinant insulin in the US.

Each of these firms has shown strong technological capabilities in biotechnology R&D evidenced by their product portfolio and their record of being the first company in India to develop those products (rituxan in case of DRL and human insulin in case of Wockhardt). These firms are yet to develop a comprehensive portfolio of biosimilar products and they focus on emerging country markets. This helps to de-risk investments and generate revenue to sustain their biosimilar investments.

Following in the footsteps of Biocon these firms are also entering into partnership deals with MNCs or Europe based biotech firms as evidenced by DRL's partnership with Merck Serono and Intas's deal with Apotex. Both of these deals involved co-development and marketing of biosimilar products all over the world.

Low technological capabilities – Emerging markets (India) (Late entrants): low investment, low risk and low profit model.

This category exemplifies Serum and Lupin as firms that utilise a low investment, low risk and low profit margin pathway. Currently biosimilars are not a priority area of focus but these firms are building R&D infrastructure and creating path dependency for future expansion. Serum for example, is a world leading vaccine manufacturer and is developing biosimilar capabilities on the basis of their current skills in biologics, vaccine development and production. According to a senior R&D scientist working in the Serum Institute, biosimilar production would be a natural progression and mainstay for business for this firm in the future. In 2011 Serum Institute and Merck entered a collaboration to develop and commercialise a pneumococcal conjugate vaccine (PCV) for use in the emerging and developing world. In 2012 Serum Institute of India Ltd. acquired Bilthoven Biologicals of the Netherlands to gain access to technology and expertise for making the injectable polio vaccine (Salk).

Lupin is building complementary capabilities by setting up a research centre to conduct clinical and bioequivalence studies for biosimilar products. In 2011 Lupin established the Lupin Bioresearch Center (LBC) to conduct clinical and bioequivalence studies for Lupin's generic products and branded formulations.

In 2010 Lupin hired in expertise from a US based biotech firm as president of Biological R&D to lead its efforts in biosmilars. In 2012 Lupin entered into a licensing agreement with Sydney-based NeuClone for proprietary cell-line technology to be developed into biosimilar drugs targeting the oncology segment (Mahalakshmi, 2012). Currently these firms are targeting the low risk and low profit Indian domestic market for growth (Table 4).

Low technological capabilities – Advanced market (Maverick): high investment, low development risk and high profit model.

In our final category are firms demonstrating high investment, low development risk and high profit margins. Here we see firms such as Cipla and Reliance, which have no previous experience of reverse engineering large and complex molecules but are driven by strong cash flow and ambitious leadership. Companies aim to use complimentary assets and a partnership or acquisition model to build their biosimilar business.

Cipla aims for biosimilars to be an integral part of future business. With no expertise in reverse engineering of large molecules or proteins, Cipla started hiring key people from competitors and has entered into strategic alliances to build biologic capabilities.
In 2004, Cipla entered into a 50:50 partnership with Meditlab + Avesthagen. It acquired a 40% stake in Mab Pharm and a 25% stake in Bio Mabs, a Shanghai based firm. Further in 2013, Cipla launched its first biosimilar product in collaboration with another Chinese firm, CP Guojian Pharmaceutical Co. In this Cipla has already bought a business with a biosimilar portfolio reducing its risk but needing high investments. However it is still not clear whether Cipla will achieve the high profits it expects from advanced country markets due to lack of commercialisation infrastructure.

In 2010 Cipla made a $65 million investment to develop biosimilar capabilities by acquiring a 40% stake in Goa-based Mab Pharm and a 25% stake in Bio Mabs, Shanghai to gain the rights to sell biosimilars in India and other emerging countries. Under this collaboration a new biosimilar facility is being set up in Shanghai and these capabilities will be also used by Mab Pharm in Goa. Cipla's China collaboration is aimed at developing ten monoclonal

antibody (mAb) drugs and fusion proteins against rheumatoid arthritis, cancers and asthma for marketing in India and China. Yosuf Hamied, Chairman of Cipla commenting on the deal reveals the significance of the biosmilar market for the future survival of the company:

> "This is major decision. A time will come when the world will be selling only biotech drugs. When the day arrives Cipla will be prepared"
>
> (Jayaraman, 2010)

Cipla is targeting three of Roche's top biologics: Avastin, Herceptin and Enbrel. These account for $19 billion in annual revenue. In April 2013 Cipla launched its first biosimilar, Etacept in India for the treatment of rheumatic disorders (competing against Enbrel). Etacept was formed from a partnership and will be manufactured by China-based Shanghai CP Guojian Pharmaceutical Co and marketed by Cipla in India.

Following similar footsteps Reliance Life sciences acquired GeneMedix, a UK based biotech firm in 2007 and gave impetus to its biosimilar programme. Within two years of this acquisition, Reliance launched seven biosimilar products in the Indian market. Further, Reliance Life Sciences is part of a refining and petrochemical conglomerate, which is known for building large scale manufacturing operations to drive big volumes at lower prices. Applying the same philosophy in biosimilar business Reliance Life Sciences have built the largest mammalian cell culture facility (10000 litres) in Mumbai giving them cost advantage.

6.3 Strategy, disruptive market and dynamic capabilities

The preceding section shows that there are clear relationships between existing capabilities and the changed capabilities built in response to new opportunities. There are capabilities targeted by firms, that is, which are identified as being likely to capture competitive advantages in biosimilars. While existing technological competence played an important role as did the firms historical trajectory, two other factors also have important roles to play in defining the strategy-mixes adopted by Indian biosimilar producers: namely, 'firm specific managerial vision', and 'inter-organisational learning through observation of compatriot leader firms'.

In transitioning to a biosimilar era, we find that firms choose different paths and business models to create a market- technological capabilities mix. Yet the strategies firms have used to achieve these transitions have also been borrowed from each other. Biocon, an early entrant in the biosimilar segment for example, has built complementary capabilities in clinical R&D. Late entrants such as Lupin and DRL following Biocon's example have invested in

development of complimentary capabilities by setting up clinical research organisations (CRO's). De-risking biosimilar investment through targeting emerging country markets was initiated by Biocon but is now followed by other Indian firms. Similar to the findings of Athreye et al. (2009) on innovative R&D capability development in Indian pharma, it seems that in the biosimilar area, inter-organisational learning through observation of other firms' successful strategies has significantly influenced the strategies pursued by firms and may be as important as own firm learning. In this sense the heterogeneity in business models and inter-organisational learning initiated by firms constitute a natural experiment for the whole industry.

It is also quite evident that firm specific managerial vision are driving reconfiguration strategies and shaping firm level technological learning in Indian firms. The vision of Yosuf Hamied, that Cipla could be a significant global player in biosimilars led to change in the management team and drove the company's ambitious acquisition strategy. In a similar vein, Biocon is guided by the ambition of Kiran Muzumdar Shaw to draw global recognition for Indian firms in the biotechnology sector. Her unique vision has guided Biocon's transition from an industrial enzymes company to an integrated biopharmaceutical company on the cusp of entering biosimilar markets in advanced countries.

Our study examines firms that are entering the biosimilar sector in the same country. We demonstrate that significant differences exist in their strategies and approaches to product development. Notably our work shows the contribution of global partnerships to heterogeneity. Using the same criteria laid down by Pavitt (1984) to explain different technological trajectories, we might extend his reasoning to show how patterns of global acquisition and targeting of markets abroad, widen sources of technology, present an increased array of user needs and means of appropriating benefits, thus allowing for heterogeneity in a single sector. In the biosimilars sector, we find that big pharma and emerging suppliers form partnerships in order to access capabilities, technologies and markets, leading to significant heterogeneity of strategy. Differences in strategy both give rise to, and result from capabilities acquired through different means.

7.0 Conclusion

This paper highlighted the reconfiguration of capabilities and transformation of Indian pharmaceutical firms in order to compete in the biosimilars market. It demonstrated that dynamic capabilities can co-evolve with firm strategies as a response to the emergence of a disruptive market through three main findings.

First, saturation and reduction of value in small molecule generic markets in advanced countries has forced Indian firms to look at complex biosimilars and alternative strategies. Indian firms are targeting biosimilar markets in India and other emerging countries to avoid the high cost of regulatory requirements in advanced countries and de-risk their investments. This clearly indicates impact of regulation in influencing firm level strategies in the healthcare sector. It also points to a subtle shift for firms, in focusing not primarily on advanced country healthcare markets, but towards emerging country markets.

Second, the capability creation model highlights Indian firms technological trajectories in biological R&D. It is quite evident that a majority of Indian firms are operating at the basic technological capabilities stage but have plans to develop advanced capabilities. Indian firms are reconfiguring existing srategies by entering into collaborations and partnerships with overseas firms and research institutes to augment their own capabilities and targetting emerging country markets to de-risk their investments. Further these firms are learning through observation of other firms strategies as evident in the hiring of Indian scientists working in advanced countries to fill their knowledge gaps in biological R&D .

Third, four kinds of reconfiguration strategy variations have been identified using a technological capability and market matrix. These include the 'high investment, high risk but high profitability model' of Biocon, 'high investment, less risk but moderate profit model' of DRL, 'less investment, less risk and lowprofit model' of Lupin and 'high investment, low risk and high profit' untested maverick model of Cipla. Most probably the winning combination will include certain elements of the different models and will prove to be a robust way in which to overcome the key challenges of talent unavailability and resource constraints. Analysis of heterogenity in strategies to exploit biosimilar opportunity point towards an evolution of Indian firms capabilities throughout the production process, starting from upstream expansion of the knowledge base and re-orientation of R&D to downstream enhancement of partnership and marketing capabilities in emerging markets. It is also evident that evolution in firm capabilities is determined by two main factors: path dependency and firm-specific managerial vision.

This research also indicates that the Indian pharmaceutical sector, in the attempt to pursue biosimilars is likely to face the challenges of developing process R&D expertise in biotechnology, availability of skilled human resource in biochemistry and medicinal biology

and developing financially robust strategies to operate in evolving regulatory environments in advanced countries.

It is quite clear that Indian firms are entering the next phase of industry evolution by targeting the biosimilar market but still remain uncertain about the payoffs due to evolving regulations, high financial cost associated with biosimilar development and a restricted talent pool. These firms are currently testing the water by experimenting with strategy.

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Table and figures

Table 1 Emerging biosmilar market (ABLE-PWC, 2010)

Generic name	Company	Therapeutic sub category	2009 (US$ sales bn)	Patent expiry
Eptacog alfa	Novo Nordisk	Anti-fribrinolytics	1.32	2010
Nonacog alfa	Pfizer	Anti-fribrinolytics	0.98	2011
Etanercept	Amgen	anti-rheumatics	3.49	2012
Filgrastim	Amgen	Immunostimulants	1.28	2013
Insulin Lispro	Eli Lily	Anti-Diabetics	1.95	2013
Interferon beta-1a	Biogen Idec	MS Therapies	2.32	2013
Epoetin alfa	Amgen	Anti-anaemics	2.66	2013
Imiglucerase	Genzyme	Other therapeutic products	0.79	2013
Insulin Insulin aspart	Novo Nordisk	Anti-diabetics	1.21	2014
Rituximan	Roche	Anti-neoplastic Mabs	5.62	2014
Octocog alfa	Bayer	Anti-fribrinolytics	1.23	2014
Pneumococcal vaccine	Pfizer	Vaccines	0.287	2015
Insulin glargine	Sanofi-Aventis	Anti-diabetics	4.29	2015
Tocilizumab	Roche	Anti-rheumatics	0.44	2015
Follitropin alfa	Merck KGaA	Fertility agents	0.67	2015
Pegfilgrastim	Amgen	Immunosimulants	3.35	2015
Nimotuzumab	YM Biosciences	Anti-neoplastic Mabs		2015
Somatropin	Novo Nordisk	Growth hormones	0.82	2015
Adalimubab	Abott	anti-rheumatics	5.48	2016
Herpes Zoster vaccine	Merck	Vaccines	0.27	2016
Natalizumab	Elan	MS Therapies	0.59	2017
Sipuleucel-T	Biogen Idec	MS Therapies		2017
Liraglutide	Novo Nordisk	Anti-diabetics	0.13	2017

Human papillomavirus vaccine	GSK	Vaccines	2.93	2017
Bevacizumab	Roche	Anti-neoplastic Mabs	5.74	2018
Insulin glulisine	Sanofi-Aventis	Anti-diabetics	0.19	2018
Infliximab	Johnson & Johnson	anti-rheumatics	3.08	2018
Rotavirus vaccine	Merck & co	Vaccines	0.52	2019
Cetuximab	Merck	Anti-neoplastic Mabs	1.6	2019
Insulin determir	Novo Nordisk	Anti-diabetic	1.1	2019
Trastuzumab	Roche	Anti-neoplastic Mabs	4.86	2019
Peginterferon alfa 2a	Merck	Interferons	1.52	2019
Ranibizumab	Novartis	Eye – preparations	2.32	2020

Table 2: Indian companies marketing biosimilars in India (Jayaraman, 2010; CDSCO, 2013)

Company	Active substance	Therapeutic area	Year of launch
Dr Reddy's Laboratories	Filgrastim (G-CSF)	Neutropenia, cancer	2001
	rituximab	Lymphoma, Leukaemia, rheumatoid arthritis	2007
	darbepoetin alpha	Anaemia, cancer, chronic kidney failure	2010
	Pegfilgrastim	Cancer, Neutropenia	2011
Biocon	erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2006
	nimotuzumab		2006
	Filgrastim (G-CSF)	Neutropenia, cancer	2007
	streptokinase	Acute myocardial infarction	
	Itolizumab	Psoriasis	2012
	Human insulin	Diabetes	2003
	Insulin Glargine	Diabetes	2013
	Transtuzumab	Breast cancer	2013
Reliance Life sciences	erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2008
	Filgrastim, (G-CSF)	Neutropenia, cancer	2008
	interferon alpha-2b	Chronic hepatitis B, Chronic hepatitis C, cancer	2008
	Epoetin alpha	Anaemia,	2008
	Tissue plasminogen activator	Myocardial infarction	2009
	Follitropin alfa	Female infertility	2010
	Chorionic gonadotrophin hormone r-hcg	Fertile infertility	2011

	Interferon beta -1a	Multiple sclerosis	2011
	Abciximab	Angina Cardiac ischemia	2013
Intas	Filgrastim (G-CSF)	Neutropenia, cancer	2004
	Pegfilgrastim (G-CSF)	Neutropenia, cancer	2007
	interferon alpha-2b	Chronic hepatitis B, Chronic hepatitis C, Cancer	2007
	Erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2005
	Epoetin alpha	Anaemia, cancer, Chronic kidney failure	2005
	Follitropin alpha	Female infertility	2013
	Rituximab	Lymphoma	2013
Wockhardt	Erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2001
	Epoetin alpha	Anaemia, cancer, Chronic kidney failure	2001
	human insulin	Diabetes	2003
	Insulin glargine	Diabetes	2009
Cipla	Etanercept	rheumatoid arthritis, psoriatic arthritis	2013
Shantha Biotech	interferon alpha-2b	Chronic hepatitis B, Chronic hepatitis C, Cancer	2002
	streptokinase	Acute myocardial infarction	2004
	erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2005
Serum	erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2011
Ranbaxy	Epoetin alpha	Anaemia, cancer, Chronic kidney failure	2001

	erythropoietin (EPO)	Anaemia, cancer, Chronic kidney failure	2013
Cadila	erythropoietin (EPO)	Anaemia, Chronic kidney failure	2010
	interferon alpha-2b	Chronic hepatitis B, Chronic hepatitis C Cancer	2011
	Filgrastim (G-CSF)	Neutropenia, cancer	2013
Lupin	Peg filgrastim (G-CSF)	Neutropenia, cancer	2013
	Filgrastim (G-CSF)	Neutropenia, cancer	2013

Table 3 Firms under study (Annual Reports, 2013)

Firms	**Nature of firm**	**No of employed**	**Turnover 2012-13** US $ million	**R&D intensity (2013)**	**Biosimilar Products**	**Supply of Biosmilar in overseas market**
Biocon (Group 1)	Biotech	7100 (4% doctorates & post doctorates)	364.16	10% ((US $ 36.4 million)	Human insulin, Insulin Glargine, Erythropoietin, Filgrastim, Streptokinase, Itolizumab, Transtuzumab	27 countries
Serum (Group 1)	Biotech		444.40		Erythroprotein	ROW, WHO
Cipla (Group 2)	Pharma	20000 (5% scientists)	1545.00	4.9% (US $ 79.5 million)	Etanercept	India
Lupin (Group 2)	Pharma	13000 (10.7% scientists)	1309.63	7.5% (US $ 132.8 million)	Peg Filgrastim, Filgrastim	India

DRL (Group 2)	Pharma	16500	1560.00	6.6% (US $ 143.6 million)	Filigrastim, Rituximab, pegfilgrastim,darbepoetin alpha	12 countries
Wockhardt (Group 3)	Bio-pharma	8600 (7% scientists)	2515.52	6.7% (US $ 70.3 million)	Human insulin, erythroprotein, Insulin glaring, Epoetin alpha	31 countries

Table 4 Biosimilar R&D capabilities

	Biocon	**Serum**	**Cipla**	**Lupin**	**DRL**	**Wockhardt**
Year of starting biotechnology R&D	1999	1996	2010	2009	2004	1994
Dedicated Biological R&D facilities	Bangalore, India	Pune, India	In process of setting up a new R&D facility in Goa, India	Pune, India	Hyderabad, India	Aurangabad, India
Multidisciplinary teams in India/understanding of biosmilar research approaches	Yes, in Bangalore R&D facility	Yes, in Pune R&D facility		Yes, in Pune R&D facility	Yes, in Hyderabad, Princeton, Laiden, Cambridge	Yes, in Aurangabad
Biosimilar manufacturing	Two integrated manufacturing	A dedicated facility at Pune. This facility	Currently setting up manufacturing	One integrated	One integrated facility at	One integrated facility at

capabilities	facilities at Bangalore, India and Johor, Malaysia	is in process of expansion for large scale manufacturing.	facility in Goa, India dedicated to production of monoclonal antibodies.	facility at Pune, India.	Hyderabad, India of GMP standards and containing E Coli and mammalian cell platforms	Aurangabad, India of GMP standards and containing bacterial, mammalian and E coli platforms
Biosimilar Clinical trial capabilities						
in house Clinical trials/ Clinical Research organisation	Clinigene, in-house CRO established in 2000.			Established Lupin Bioresearch Centre to conduct clinical and bioequivalenc e studies		Established chain of hospitals through a subsidiary of Wockhardt Hospitals in India to

						conduct clinical trials
Outsourcing of clinical trials					Merck will lead clinical development (Phase II onwards) and manufacturing of the compounds. Partnership with UK based clinical research organisation Argenta, for innovative drugs and biosimilars	
Biosimilars in Preclinical	1			**5**	**3**	
Biosimilar in Phase I	5					

Biosimilar in Phase II		**1**				**alphaferon 2b**
Biosmilar in Phase III	**1**			**1**	2	
Launch of novel molecule	In total 2 novel biologicals are approved for marketing in India. First received for marketing in 2006 and sold under brand name of BIOMAb EGFR is used in treatment of head and neck cancer. Second, Alzuman, first –in-class novel biological for psoriasis received marketing approval from DCGI in					

	2013 to introduced in the Indian market					
Biosimilar market capabilities						
No of biosimilars marketed in India	7 (recombinant insulin, Glaringe insulin, EPO, filgrastim, Herceptin)	1 (EPO)	1 (Etanercept)	2 (Filgrastim, peg filgrastim)	4 (Rituximab, filgrastim, darbepoetin alpha, peg-filgrastim)	3 (recombinant insulin, Glaringe insulin, EPO)
No of biosimilars sold overseas in other emerging country markets	Insulin in 40 countries and Glaringe insulin in 5 countries				Presence in small 13 emerging markets such as Myanmar and Vietnam with local partners	Recombinant insulin registered in 34 countries and Glaringe in 5 countries
No of biosimilars marketed in advanced countries	Completed Phase III trials in EU for Glaringe insulin				In partnership Merck Serono company aims to enter Europe market by 2017	

Market sharing agreements with overseas firms	Partnership with Pfizer (2009-2012) Partnership with CCM pharmaceuticals, a subsidiary of Chemical Company of Malaysia for Malaysian and Brunei markets (2013)				Partnership with GSK to develop and market selected products across emerging markets (2009)	
Biosimilar focussed acquisitions of overseas firms	In 2010, Biocon acquired Cuban company CIMAB's		Acquisition of 40% stake in Mabpharm, an			-

	49% stake in their joint venture, Biocon Biopharmaceuticals Pvt Ltd (BBPL) to manufacture of Biosimilar products. In 2009 Biocon acquired a majority stake in German pharmaceutical company AxiCorp GmbH (70%) in 2008, for a consideration of €30 million. This acquisition helps Biocon market and distribute its biosimilar insulin		Indian biotech company Acquisition of 25% stake in BioMab, a Shanghai based biotech company.			

	and analogues in the German market.					

Table 5 Entry into international generics market: Exports and foreign investment (Annual Reports, 2013, 2012; Athereye et al., 2010)

	Biocon	**Serum***	**Cipla**	**Lupin**	**DRL**	**Wockhardt**
Exports percentage of sales) (2013)	38%		55%	73%	83%	83%
Geographic distribution (2012)	UC	UC	North America: 18% Europe: 8% ROW: 29%	North America: 40% Europe: 2% ROW: 31%	North America: 39% Europe: 18% ROW: 26%	North America: 52% Europe: 24% ROW: 7%
International investments	Greenfield: 3 JV/Equity share: 2 Acquisition: 2	-	Greenfield: 2 JV/Equity share: 2 Acquisitions: 1	Greenfield: 1 JV/equity share: 4 Acquisitions: 3	Greenfield: 3 JV/Equity share: 3 Acquisitions: 5	GF: 4 JV/Equity share: 2 Acquisition: 3

Marketing in Western Country under own brand	UC	Main supplier of vaccines to WHO, UNICEF and Gates Foundation		USA	Ibuprofen in USA under own brand name	UK and Ireland

Table 6 Key R&D collaborations

Year	Indian firm	MNC	Nature of alliance	Territory
1995	Wockhardt	Rhein Biotech (Germany)	Development of hepatitis b vaccine	India and other emerging markets
2004	Biocon	Vaccinex (USA)	discover and co-develop at least four therapeutic antibody products	India and other emerging markets
2006	Biocon	Cuban Institute of Molecular Immunology (CIMAB)	Development of antibody for treating cancer of neck and head	India and other emerging markets

2007	Biocon	Abraxis (USA)	GCSF(product development and marketing)	Abraxis: NA* + EU Bicon: ROW*
2008	Intas	Apotex (Canada)	GCSF (Co-development + manufacturing)	Apotext: NA + EU Intas: ROW
2009	Biocon	Amylin	Co-development of novel peptide hybride for treatment of diabetes.	
2009	Biocon	Mylan (USA)	Co-development of five MAbs)	Mylan: NA + EU Biocon: ROW
2011	Lupin	Neuclone (Australia)	Access to cell line technology to develop biosimilar drugs used in cancer treatment	
2012	DRL	Merck Serono (Switzerland)	MAbs (joint development)	DRL: ROW + USA
2012	Serum	Bilthoven Biologicals (Netherland)	Injectable polio vaccine	India and ROW

2013	Intas	Basin Healthcare (Thailand)	Marketing and distribution of biosimilar products	China, Russia, Thailand, Africa
2014	Biocon	Advaxis Inc (USA)	Co-development of its lead drug candidate, ADXSHPV	India, emerging markets

Table 7 Diaspora connections

Company	Year	Current role	Overseas connection
Bicon	2010	Dr Abhijit Barve, R&D President	Working with Astellas, a US biotech company as a Global Development Project Leader
DRL	1999	Dr Cartikeya Reddy, Head Biologicals division	Working with Genetech Inc., as a Group Leader in the area of Cell Culture Process Development
Lupin	2010	Dr Cyrus Karkaria President, Biotech Division	Leading a biotech company in the US
Intas	2011	Dr Himanshu Gadgil, Sr Vice President, Biologicals	Principal scientist, Amgen
Cipla	2012	Subhanu Saxena, CEO	Head, Global Product Strategy, Novartis Pharma AG

Table 8 Key Biosimilar Competencies of Indian firms (IMS, 2010; Author's analysis, Annual Reports, 2013)

	Biocon	Serum	Cipla	Lupin	DRL	Wockhardt
Marketing	=	X	X	X	X	X
Hospital Sales Force	X	X	X	X	X	X
Hospital portfolio	X	X	X	X	X	X
Clinical trials	+	X	X	=	+	+
PK/PD	=	=	X	=	=	=
Preclinical	+	=	X	=	=	=
Biologcal characterisation	+	+	X	=	=	+
Physiochemical Characterisation	+	+	X	=	+	+
Manufacturing efficiency	+	+	X	=	+	+

+: strong competence **= : building capacity** **X: No competence**

Figures

Fig. 1 Evolution of the biosimilars regulatory guidelines (IMS, 2010, author's own analysis)

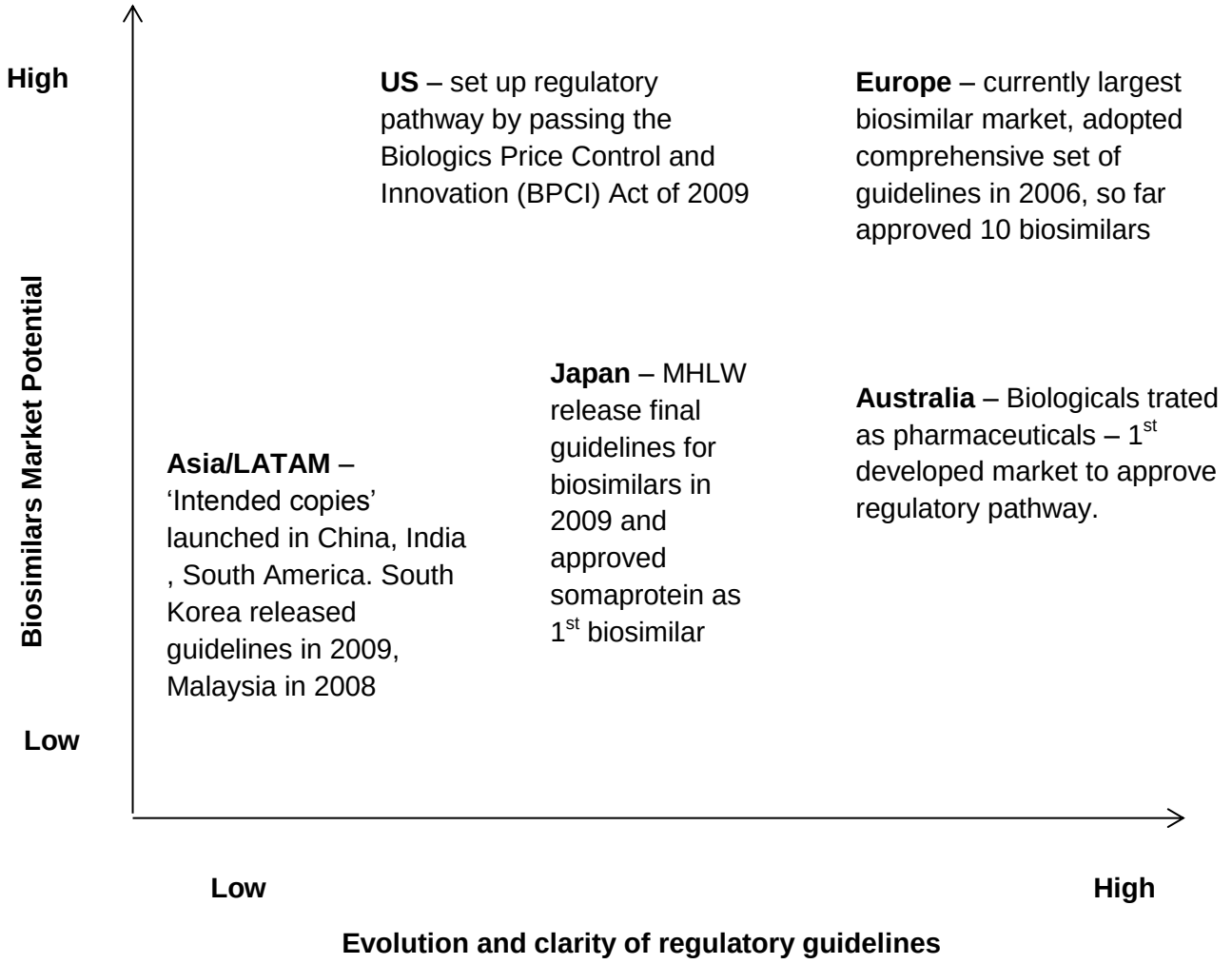

Fig 2 Market and technological capabilities matrix

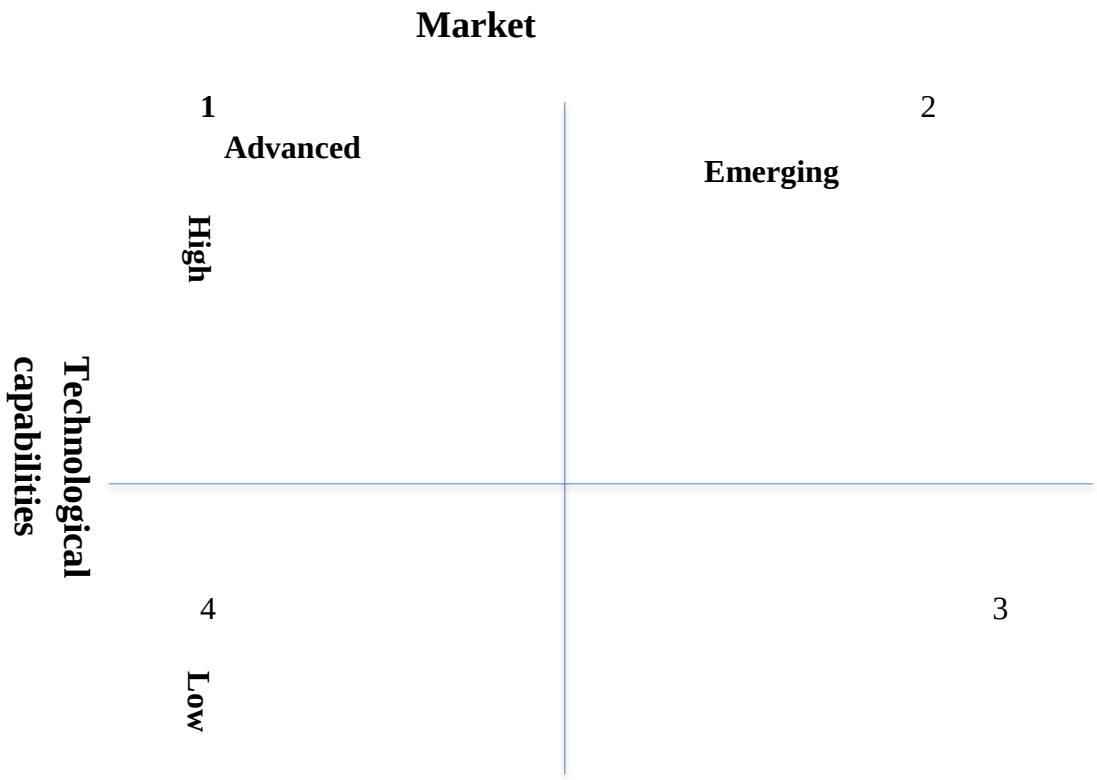

Fig 3 Biosimilars to Biological model

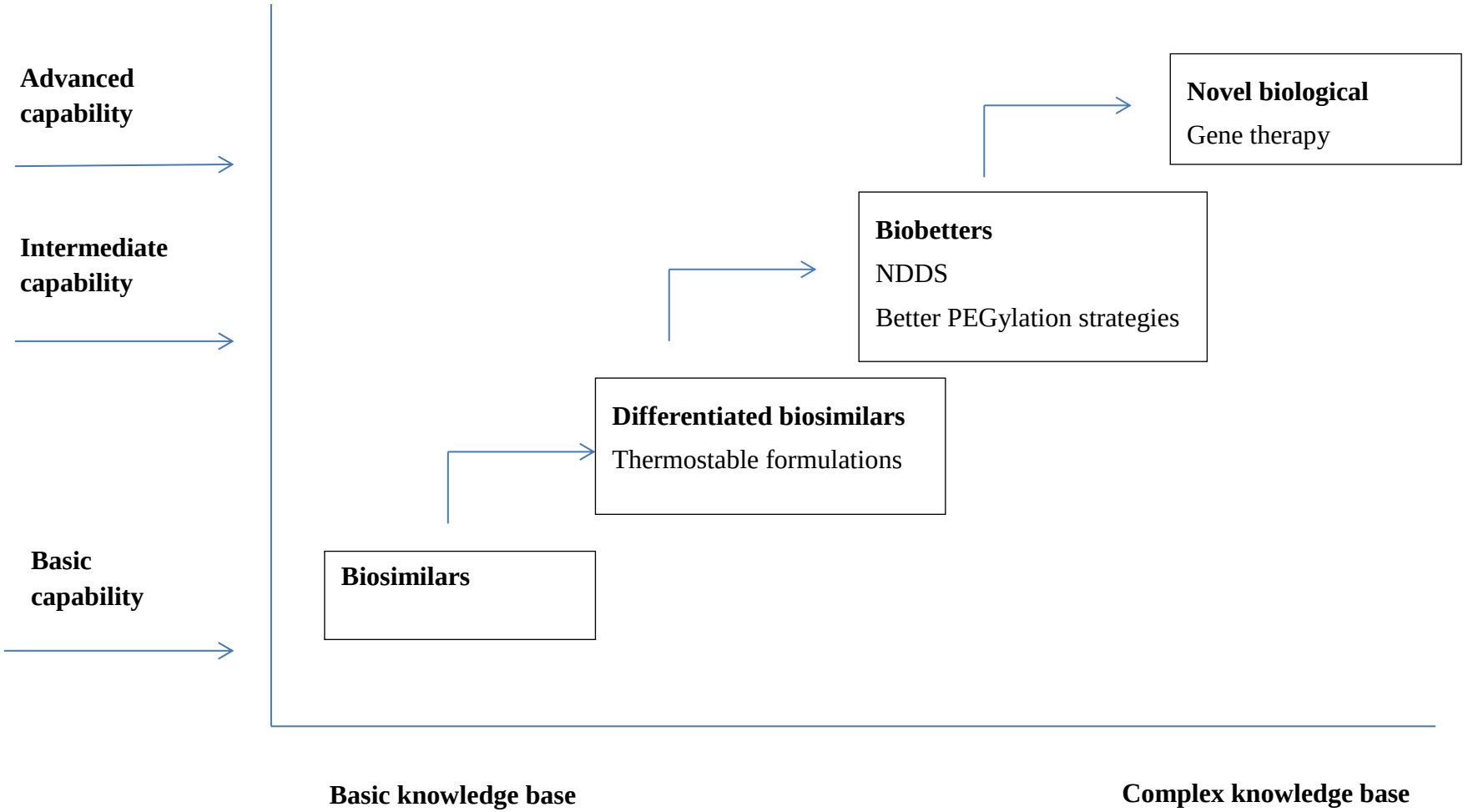

Fig 4 Technology capabilities – market matrix