

Economic impact of
technology
interventions
streptokinase
economics essay



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About 14 million patients in India suffer from heart attacks every year. Of these, 2.8 million patients can benefit from a clot buster drug which would save the patient's life and provide room for further treatment such as medical stents if so required. Coronary heart disease claims over a million lives every year in India. There is a need for a safe and affordable clot buster drug. At the turn of the century, clot buster drug formulations were either imported or based on imported bulk drug and formulated domestically. They were expensive, equivalent to eighteen months (tPA) to two months (Streptokinase) of per capita income at that time. Cost matters more in India unlike in countries with universal health insurance as most Indians spend out of own pocket for health expenses. Given India's prowess in generic drugs, the production capacity gap in an area of health emergency with severe consequences seems an anomaly. The gap stems from the fact that clot buster drugs are biotechnology drugs which require competencies quite different from those of the usual drugs based on chemical synthesis.

CSIR-IMTECH, Chandigarh made efforts to develop a process to produce clot buster drugs. Initial efforts were unsuccessful, in part due to the complex nature of the animal sources based protein drug. Subsequent teams picked up the challenge again, chose a simpler molecule and after some misses, could develop a process for natural streptokinase and then recombinant streptokinase, both harnessed from micro-organisms. The misses were important steps providing crucial learning for the process development. Streptokinase technology was transferred to industry partners, natural Streptokinase to Cadila Pharma and recombinant Streptokinase to Shasun Pharma. Implementing the technology on the shopfloor faced difficulties. In

the case of recombinant streptokinase, regulatory approvals took time to obtain. The knowing-doing gap was bridged by closing the competency gap through sustained engagement between the CSIR-IMTECH scientists and the managers and technology staff of the licensees. Perseverance, team perseverance, allowing mistakes, dynamic learning from disciplined failure, give-and-take by both the scientists' team and the industrial practitioners' team, and a "can-do, must-do, done" mind-set were the keys to success. Leadership steering at both the Lab and the Industry with a commitment to collaborate and continual collaborating was crucial. This led the transition from the lab scale to industrial scale. The respective products were launched in 2001 and 2009.

The results are quite encouraging. Prices have dropped (by 65 percent, to less than one month of per capita income), availability has increased, access to a life-saving medicine has risen, and patients have realized a worth of over Rs. 16,000 crores due to the CSIR-IMTECH/licensees Streptokinase. The economic impact, or the additional benefit that would be lost if this CSIR-IMTECH Streptokinase technology intervention had not been there, is assessed based on medical impact of Streptokinase and using per capita income to be Rs. 2180 crores. The Lab itself accomplished net earnings valued at Rs. 1.8 crores and the Industry partners together realized value addition of Rs. 17 crores.

Innovating for affordable healthcare is inclusive innovation. The benefits to patients eclipse the benefits to those who generated the technology intervention. This pursuit of innovation continues. CSIR-IMTECH has taken the science of clot-buster drugs to a level where improved Streptokinase
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(smarter streptokinase) molecules will have the advantages of the far more expensive animal cell line based tPA but will be much more affordable.

Similarly, while access has expanded (about 120, 000 standard doses), there remain millions of patients in need of this life-saving drug. More needs to be done.

Introduction

Heart attacks, strokes, respiratory and cardiac failure have a common enemy in blood clots in the bloodstream that can block blood supply to the heart muscle, any part of the brain or the lungs. The consequence of blockage is damage to the heart muscle, the brain cells, or the lung tissue which is usually irreversible and debilitating, if not fatal. Extreme consequences can arise if the treatment is not administered within a window of few hours (3-4.5 hours, Klabunde (2007), Hacke et. al. (2008)). Then, the heart or brain tissue, as the case may be, gets damaged which is mostly irreversible. Treatments range from clot-dissolving medication to surgical intervention such as angioplasty or insertion of stents and open chest bypass surgery. Clot busters, as clot dissolving drugs are called, attack the clot itself to dissolve it and restore blood supply. Angioplasty is an invasive and expensive procedure where blocked arteries are opened up using medical stents thus making more space for the blood supply to be restored. Similarly, bypass surgery is invasive and very expensive (see appendix 1). Prevention in high-risk patients (hardened and narrowed/blocked arteries) is via blood thinner drugs that reduce blood density allowing blood to flow through the reduced space. Despite preventive treatment, clots can form and occlusion in blood vessels can occur. Then, clot buster drugs are life saviours.

In India, more than a million patients die due to coronary heart disease every year (appendix 1). Until the year 2001, no domestic production of clot-busters existed. The formulations were imported: among others, the lead formulations of Streptokinase - "Kabinase" by Kabi Pharmacia, Sweden and "Streptase" by Hoechst Marion Roussel, Germany - were priced then between Rs. 3000 to Rs. 4000 per vial (Krishnan (2000)). The dominant drug in this class of drugs, Tissue Plasminogen Activator (tPA) cost more than Rs. 30,000 per vial. Thus, clot buster drugs were expensive and the supply was short of requirement. In terms of per capita income at that time, this amounted to eighteen months of income for tPA and about two months of income for Streptokinase. The Streptokinase market was about 21 thousand vials of standard dose of 1.5 miu[1]. Lack of affordability could have restricted access. Given Indian pharmaceutical industry's prowess in generic drugs, realized through strengths in organic chemicals' synthesis and process engineering, this raises the question about the obstacles. The Indian pharmaceutical industry was essentially based on chemical entities whereas clot buster drugs are based on biotechnology[2] which was almost non-existent in India around the turn of the century. Thus, access to affordable life-saving clot buster drugs was limited domestically. To make it affordable, it had to be produced domestically. To produce it domestically, a suitable technology had to be developed. The technology had then to be transitioned from a laboratory scale to an industrial scale.

As in the case of affordable chemical drugs, the impetus of finding solutions and creating domestic capacity also came from CSIR Labs. In the case of generic chemical drugs, the core scientists came from Labs such as the NCL,

Pune, IICT, Hyderabad and CDRI, Lucknow. These scientists and their industry contemporaries developed and implemented safe and cost effective technologies in a short time span. In the case of biotechnology, processes are being developed by IMTECH, Chandigarh and IICB, Kolkata among others. A program at IMTECH tapped into finding a solution to the problem of an affordable clot buster drug. The program has roots in projects dating back to 1989. The scientists examined the prevalent clot buster drug – tissue Plasminogen Activator (tPA) – but then chose instead an alternate less complex protein Streptokinase for development.

This study examines the benefits realized from the Streptokinase project, specifically, the natural Streptokinase biotechnology drug licensed to Cadila Pharma and the recombinant Streptokinase drug technology licensed to Shasun Pharma Limited, to quantify the value creation and to assess the economic impact.

The Industry

The Indian pharmaceutical industry is among the top science based industries and focused on quality affordable drugs. It is estimated to be USD 21 billion or about Rs. 105, 000 crores with exports accounting for about 40 percent (USD 8. 7 billion) in 2009-10 (DOP (2011, 2012)). The industry is growing at over 10 percent per year. It is the sixth largest industry in India ranked by contribution to GDP (CSO (2011)). Globally, it ranks 3rd in terms of volume of production (10 percent of global share) and 14th largest in terms of value (1. 5 percent of global share). A reason for the low value share is the lower cost of drugs in India — 5 to 50 percent less than in developed

countries. Thus, the Indian drugs and pharmaceutical industry is focused on affordable drugs.

The Indian pharmaceutical industry is diverse. The number of units is quoted at over 20, 000. However, the actual number of drug manufacturing licenses issued is about 5877 (GOI (2003))[3]. Registered factories are about 3500 (CSO (2011)), the rest being smaller unregistered units. The units are spread across India and provide depth that accounts for the 10 percent global volume share. Apart from MNCs such as Glaxo Smithkline, Pfizer, Astra Zeneca, several Indian companies Ranbaxy, Dr. Reddy's, Cipla, Lupin and others have global operations. Biotechnology based drugs have taken root and are growing. Companies such as Biocon, Serum Institute of India, Panacea Biotec, and Reliance Life Sciences have adopted biotechnology. The biotechnology industry value exceeds Rs. 20, 000 crores in 2011-12 (BioSpectrum-ABLE Biotech Survey 2012).

Many Indian companies maintain the highest standards in purity, stability and international safety, health and environmental protection in production and supply of bulk drugs to buyer companies, who in turn are subject to stringent assessment by regulatory authorities in importing countries. These companies have secured regulatory approvals from USFDA, MHRA-UK, TGA-Australia, MCC-South Africa for their plants. Quality with certification is also a feature among many Indian pharmaceutical companies.

During the last decade, the industry has embraced new technologies and adapted to regulatory regimes more aligned to international regulatory regimes. New business models have emerged to cope with and thrive in this

environment. All of these have a bearing on the development of a domestic clot buster drug, namely, Streptokinase.

With the advent of product patents in India from the 2005 amendment to the Patents Act, the focus has shifted from process engineering to drug discovery. Process engineering remains important. Several drugs will go off patent over the next few years and supply of cost effective quality generics would benefit the industry and the consumers. However, drug discovery is the new mantra. Drug discovery is a highly uncertain multi-million multi-year activity. For every one new drug molecule approved, the pipeline requires about twelve molecules for clinical trials' candidacy. For every molecule reaching clinical candidacy, the pipeline of molecules is three molecules based on current success rates at each stage. The total costs spiral to over USD 600[4]million per new drug molecule in the USA over a span of a decade. Patent protection allows recovery of the investment but also makes the drug expensive. In India, the cost per new drug molecule can drop to less than USD 150 million due to lower costs (such as those of clinical trials). This lower cost is encouraging Indian drug enterprises to engage in drug discovery as they adapt to the product regime. However, even at the reduced cost in India, the drug would still be expensive and out of reach of many Indians.

Drugs' capacity building in India appears to be addressing reduction in costs and so also in the time span for drug discovery. Specialization along the chain of drug discovery via outsourcing is one emerging business model.

Thus, R&D is being shaped by Contract Research Organizations (CROs), Drug Discovery & Development (DD&D) and Clinical Trials Organizations (CTO).
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Manufacturing is by large integrated companies as also by Contract Manufacturers. Marketing is also by Contract Marketers and co-marketing alliances (IBEF (2010), KPMG (2006)).

While regulatory changes may be the trigger for drug discovery, demand for drugs for Indian diseases is also an impetus. Chief among these are drugs for infective diseases found in India but not much in developed countries such as tuberculosis, malaria, typhoid, cholera etc. These diseases are far more prevalent in developing countries such as India where affordability is a key issue. Profits from patented multi-billion drug molecules will be tough to realize for these diseases. Thus, effective new molecules for these diseases would have to be developed within India. A major initiative underway in this regard is the Open Source Drug Discovery (OSDD) project of CSIR which seeks to harness talent across boundaries, cutting costs and hopes to reduce drug discovery time. It is open source and thus drug molecules found will be distributed without the higher price due to profits associated with patents. Costs will be cut down to the collaborative nature of the initiative. Incentives to collaborators are based on contributing to drug discovery for debilitating diseases and the recognition among peers.

Also important are drugs for the so called “lifestyle diseases” such as diabetes (about 50 million diabetics in India as per Ramachandran et. al. (2010)) and hypertension (65 million hypertension patients in India as per Gupta (2004)), both high risk factors for emergencies such as heart attacks, strokes and respiratory failure. India is estimated to have about 14 million patients that suffer from myocardial infarction or heart attacks every year, of which 80 percent patients may not be receiving proper medical care
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(Financial Express (2002)). About 20 percent (2.8 million) of the cardiac patients' population in India could use a clot buster drug. Only a fraction (about 200,000 or under 10 percent) of these patients undergo bypass surgeries or angioplasty. The rest of the patients (2.6 million) could be treated with clot buster drugs administered within a window of 3-4.5 hours to the patient. Recall that there are over a million deaths every year due to coronary heart disease in India. With a growing number of diabetes and hypertension patients in India, and so increasing chances of blood vessel occlusion related deaths, having access to an affordable clot buster drug is going to be increasingly more important. An added advantage is the possibility of exports of these drugs since the diseases addressed are prevalent globally.

The Technology Gap, Development and Commercialization

A domestic clot buster drug was missing, as discussed earlier. The choice among three prevalent drugs narrowed to Streptokinase. Streptokinase is a 47kD[5] protein composed of 414 amino acids produced by several strains of beta hemolytic streptococci. It dissolves a clot occluding blood supply through a 3-step process. First, Streptokinase forms a complex with plasminogen (Pg). This 1:1 complex (the "Partner Pg") rapidly becomes proteolytically active. Second, the Partner Pg complex acts on "substrate" Pg molecules in circulation to convert them to plasmin (Pn), the active form of the pro-enzyme Pg. Plasmin is a protease that is capable of breaking apart cross-links between fibrin molecules, which provide the structural integrity of blood clots. So, third, the plasmin rapidly dissolves the pathological clot

occluding blood supply to the heart muscle in case of myocardial infarction, to brain tissue in case of stroke or to the lungs in case of respiratory failure.

The Lab, Research Capacity and Technology Development

Technology development has been enabled by science research and ongoing (and predecessor) projects at CSIR-IMTECH. The focus is science and technology related to microbial products. A key area is recombinant gene technology based products. One initiative relates to developing a domestic clot buster drug. The initial attempt in late 1980s focused on the prevalent drug - tissue Plasminogen Activator (tPA) which is naturally found in the human body in small quantities. Through recombinant gene technology, a pioneer of the field, Professor Collen and his organization Genentech USA produced tPA from animal cell lines in the early 1980s. Attempts to replicate tPA production in IMTECH did not fructify partly due to the volatile external environment prevalent at that time and so the lack of enough scientists to execute the task.

During the early 1990s, subsequently, another team of scientists at IMTECH chose an alternative to tPA, namely, Streptokinase for development - due to its simpler structure and higher probability of success in developing a novel process for domestic production. The process involved two key competencies - protein science and cloning science among others. Technical problems arose again in implementing the recombinant gene technology. The scientists decided to down-shift to developing a process for producing Streptokinase from natural sources. It involves two main processes - fermentation (protein production) and purification (separating the protein from the broth, purified to an extent that it is admissible to humans). This <https://assignbuster.com/economic-impact-of-technology-interventions-streptokinase-economics-essay/>

effort was successful lending both credibility to the process and boosting the morale of the scientists concerned. The first success helped to delineate the tasks possible from the tasks not possible (appendix 2). This paved the way for producing Streptokinase using recombinant gene technology increasing yield many times over. The key process innovation was the use of 2-step chromatography for purification.

Leadership

Throughout the years of development spanning 1989 onward, the scientists at CSIR-IMTECH were supported by the science leadership and management comprising four different institute directors and two different director-generals[6]. Leadership and institutional continuity combined with scientific ingenuity and perseverance to produce first natural and then recombinant streptokinase. The agenda continues and smart Streptokinase is under development which could be a life-saving and life-enhancing product not only for India and the developing nations but also for the developed countries.

The Technology Transfer, Technology Embedding and Commercialization

The lab scale success has to be transitioned to industrial scale and commercial success. Subsequent to the transfer of know-how on fermentation and purification processes and the strain, implementation at an industrial scale also faced many hurdles. While the science was established at the Lab with lab scale production, the transition to industrial scale volumes threw up challenges (see appendix 2). As at the Lab level, informed hit and trial, learning from failure, delineating what not to do from what to do

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helped to transition the technology to industrial scale. Standardization of the industrial biotechnology process entailed initial training, repeated training and embedding the technology in the licensee's premises. IMTECH engaged with the licensees and remained engaged thereby providing a lot of handholding in the journey from the lab to factory production. This case is an example of disciplined failure where learning from initial failure led to a course change, technological success, commercial success, and then again picking up the more difficult task and taking it to fruition.

CSIR-IMTECH first developed a technology to produce natural Streptokinase from Streptococci. It was developed in 4 years by 1998-99, licensed and transferred in 1999-2000 and launched commercially in 2001-2002. The recombinant Streptokinase was developed in 5 years by the year 2001-2002, licensed and transferred in 2002-2003 and commercially launched in 2009-10.

Natural Streptokinase know-how was licensed to Cadila Limited for fees of Rs. 20 lakhs and royalty based on ex-factory sales for 5 years. This drug was launched as STPASE injection in year 2001-02. Subsequently, recombinant gene technology was licensed by CSIR-IMTECH to Shasun Pharmaceuticals Limited, Chennai for a fee of Rs. 1 crore and royalty payments based on ex-factory sales for 5 years. The drug was launched in July 2009 and marketed by Lupin Pharma as LUPIFLO.

Comparison with prevalent alternate treatments

Prior to adoption of Streptokinase for clot-blockade led heart attacks, the treatments were generalized and included oxygenation and intensive care

(appendix 1). Subsequent to studies of randomized controlled trials establishing efficacy and superiority of Streptokinase, it was adopted widely specially in Europe. Later, other clot busting drugs were developed. Still later, open heart bypass surgery and then angioplasty using medical stents were developed. Clot buster drugs are more affordable than surgical treatments. Within the class of clot buster drugs, Streptokinase remains the most affordable. Its costs are lower since its production is micro-organism based unlike the others derived from animal cell lines.

Comparison with prevalent competing technologies – clot-busters

Clot-buster drugs in use are tissue plasminogen activator (tPA), Streptokinase, and Urokinase. Streptokinase competes with tissue plasminogen activator (tPA) which is the prevalent clot buster drug. tPA is preferred for its target (blood clot causing blockade) specificity. The advantage of tPA over Streptokinase is in the extent of systemic fibrinogenolysis generated by each. The resultant side effect of bleeding (due to suppression of clot formation by plasmin) can be higher for Streptokinase. However, studies have established that streptokinase is as effective in saving lives in myocardial infarction as is tPA, despite the nearly ten-fold higher price of the latter. tPA is expensive enough to be inaccessible to most patients for this life threatening condition. Recombinant tPA reduced prices but the cost remains many times over that of Streptokinase. Cost of treatment is of utmost importance as most Indians health expenditure is out of own pocket. Appendix 1 clearly indicates that while the treatments for myocardial infarction vary from Streptokinase to tPA to angioplasty and

bypass surgery, for a vast majority of Indians (with annual income about and below the current per capita annual income of Rs. 60, 000), the treatment affordable and so possible is administering of Streptokinase. The alternative to Streptokinase would be a mix of morphine, oxygenation, intensive-care.

Comparison with prevalent manufacturers

Producers of natural Streptokinase, for several years, were only MNCs such as Behring-werke (Germany) and Lederle (USA). In India, before CSIR-IMTECH's intervention, Streptokinase was imported, Streptokinase injections were sold by MNCs - "Kabinase" by Kabi Pharmacia, Sweden and "Streptase" by Hoechst Marion Roussel, Germany - and priced then between Rs. 3000 to Rs. 4000 per vial in year 2000 (Krishnan(2000)). tPA prices varied from Rs. 30, 000 per vial in year 2000-01 to about Rs. 19, 000 per vial in 2010-11.

In India, CSIR-IMTECH licensee Cadila Pharmaceuticals Ltd. manufactured Streptokinase as "STPASE" at an ex-factory price of Rs. 900 per vial (standard 1.5 miu dose) in 2001-02. The recombinant Streptokinase which has the same biological properties of natural Streptokinase (but much higher yields) was produced by CSIR-IMTECH licensee Shasun Chemicals and Drugs Limited, Chennai at an ex-factory price of Rs. 465 per vial in year 2009-10. This is the bulk drug price. It is marketed as "LUPIFLO" by Lupin Pharmaceuticals Limited and as "STUKINASE" by Samarth Pharma among other formulators.

Non-CSIR licensee entry also occurred after the first CSIR licensee entered. There were three entrants, two of whom have already exited. The third

entrant, Biocon, is successfully producing recombinant Streptokinase and marketing it as “ Myokinase.”

Data and Methodology

Lab data are obtained from CSIR-IMTECH. Industry data are obtained through questionnaires and interviews. Market data such as sales value and quantity numbers for Streptokinase formulations/brands along with data on company characteristics such as “ MNC/Indian,” date of launch, size of formulation – are from the IMS Health India database on Streptokinase. The data are collected at the stockist level and are representative of the Indian pharmaceuticals market with the exception of sales directly from producers/formulators to the hospitals.

Given the retrospective nature of this economic impact study, and the difficulties in collecting past data, the initial methodology proposed was a contemporaneous difference analysis between CSIR licensees and comparable enterprises. However, Streptokinase producer data could not be collected despite mailed questionnaires followed up with interviews[7]. Instead, for the industry analysis, market sales and volume data – for a panel of 20 years – are used to estimate a demand function with pooled OLS regressions. The pooled regressions permit segregation of estimates for CSIR licensees from others, and, of estimates over time[8].

Benefits of the Technology Intervention – Creating Value

Benefits to the Lab

CSIR-IMTECH developed a technology and plugged a production capacity gap for a life-saving drug. The first of the series of streptokinase molecules

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established the credibility of CSIR as a solutions provider based on their science rooted program for technology. IMTECH scientists successfully integrated science and application producing more improved molecules and earned fees and royalty in the process. The total value of fees and royalty received is about Rs. 2.5 crores and the investment in terms of salaries and cost of patents is about Rs. 65 lakhs in 2011-12 prices. The internal rate of return on the Lab's cash flows for Streptokinase works out to 36 percent[9]. Thus, the technology program is quite cost effective for CSIR.

Benefits to CSIR Licensees and the Industry

The direct benefit to the licensees in terms of value addition thus far (from 2001-02 to 2011-12) is about Rs. 17 crores in 2011-12 prices, the bulk of it, Rs. 16.5 crores, arising from the first licensee - Cadila Pharma Limited. The second CSIR licensee - Shasun Limited - has limited value added from its two years of Streptokinase operations. The first molecule served as a proof-of-concept for the industry and even more as a proof-of-value creation. It was followed by another successful molecule variant and commercial success with that also.

From no producer of Streptokinase in year 2000, there are now at least three producers domestically. The third producer Biocon, a non-CSIR licensee, is among three entrants, the other two having exited already. In 2001, before entry of the first domestic producer, CSIR-IMTECH licensee Cadila Pharma, there were about four Streptokinase brands and sales value was about Rs. 6 crores with about 20 thousand vials of standard dose. The value of the Streptokinase industry is over Rs. 20[10]crores in 2011 with about 118

thousand vials in terms of the standard dose of 1.5 miu and about thirty
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brands (including different vial sizes) marketed. While many factors are responsible for this value increase, demonstration of the proof-of-concept (technology works) and the proof-of-value (commercial success) by CSIR-IMTECH scientists and licensees may have been crucial. Without these, the country may still have been importing the drug at much higher prices. To that extent, the country is also saving foreign exchange.

The current market price of STPASE is reported to be about Rs. 1000 per vial and the prices of Streptokinase vials from Shasun's bulk drug vary from Rs. 715 to Rs. 2300. Myokinase, the third non-CSIR entrant Biocon's product, is reportedly selling at a price of about Rs. 2000 per vial. The average market price is about Rs. 1700 per vial (standard 1.5 miu dose). Prices of streptokinase by CSIR-IMTECH licensees are among the lowest in the industry, where over 30 versions of formulations are now being marketed domestically.

Industry Competition

With increasing market competition, prices drop and sales increase.

Competition can be enhanced more by entry of producers. A pioneering paper (Bresnahan and Reiss 1991) developed an empirical framework for measuring the effects of entry in concentrated markets by studying the relationship between the number of firms in the market, market size, and competition. Their analysis suggests that "competitive conduct changes quickly as the number of incumbents increases. In markets with five or fewer incumbents, almost all variation in competitive conduct occurs with the entry of the second or third firm. Surprisingly, once the market has between three and five firms, the next entrant has little effect on competitive conduct."

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In the absence of data on price-cost margins, they develop another key metric - the ratio of break-even sales S_{n+1}/S_n where "n" refers to the last incumbent producer and "n+1" refers to the entrant. This threshold is equal to one in perfectly competitive markets where the minimum efficient scale of production is quite low relative to the market size and there are no entry barriers. In concentrated markets, the threshold of break-even sales ratio is higher than one due to substantial fixed costs as well as entry barriers. A new entrant could incur higher fixed capital cost and/or higher variable costs (such as marketing costs to establish their product and realize sales). With increasing entry, this threshold - break-even sales ratio - should decline and approach the value of one as in perfect competition.

While we do not observe price-cost margins for all three domestic producers of Streptokinase - Cadila (entry in year 2001), Biocon (entry in 2008) and Shasun (entry in 2009) - we do have information on sales[11]and company provided break-even years. Using the Bresnahan and Reiss (1991) framework, the calculation of break-even sales (quantity of vials) ratio is found to be 2.8 for the second entrant (Biocon, relative to first producer Cadila Pharma) and 1.6 for the third entrant (Shasun Pharma, relative to Biocon)[12]. This quick examination points to a decreasing value of the break-even sales ratio and fast increasing competition with just three entrants, much in line with the findings of the Bresnahan and Reiss paper.

Benefits to the People and the Economy

Price Reduction, Affordability and Access