Analysis of Global Channel Costs for the Pharmaceutical Industry

by

Eric C. Rimling

Bachelor of Science in Chemical Engineering
Texas A&M University, 2003

and

Wontae Thomas Seoh

Bachelor of Science in Industrial Engineering
Northwestern University, 2003

Submitted to the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degree of

Master of Engineering in Logistics

at the

Massachusetts Institute of Technology

June 2009

Signature of Authors.....
Master of Engineering in Logistics Program, Engineering Systems Division
May 8, 2009

Certified by.....
Dr. Mahender Singh
Research Director, SC2020 & MEHD
Thesis Supervisor

Accepted by.....
Prof. Yossi Sheffi
Professor, Engineering Systems Division
Professor, Civil and Environmental Engineering Department
Director, Center for Transportation and Logistics
Director, Engineering Systems Division

Analysis of Global Channel Costs for the Pharmaceutical Industry

by

Eric C. Rimling and Wontae Thomas Seoh

Submitted to the Engineering Systems Division
in partial fulfillment of the requirements for the degree of
Master of Engineering in Logistics

Abstract

The pharmaceutical industry creates products which often have more than one supply chain channel, defined as a route through the supply chain network from sourcing to the end market. Each channel's specific cost characteristics are important to the pharmaceutical industry's ability to maintain positive profit margins while meeting high customer service requirements. Determining the optimal supply chain channel involves the analysis of fuel costs, logistics, taxes, wage differences, and many more. Additionally, variables such as time and risk significantly impact the total cost of a supply chain channel, but are extremely difficult to quantify.

In this research, we identify the relevant channel costs and variables for the supply chain of a large pharmaceutical corporation. After identification, our study categorizes each cost based on level of measurability and causes of variability to develop a framework identifying the most relevant costs by four product types. We then analyze market forces that affect costs over a product's lifecycle. Finally, we develop an operational model for using the framework to compare costs across multiple supply chain channels and time horizons.

Thesis Supervisor: Dr. Mahender Singh
Title: Research Director, SC2020 & MEHD

Acknowledgements

First and foremost, we would like to thank our thesis advisor Dr. Mahender Singh for providing guidance and support throughout this process. We could not have reached the finish line without your insights and constant push for innovative thinking. Our appreciation also goes to Shardul Phadnis, for sacrificing his time to help us critically evaluate our work. A warm debt of gratitude goes to Bill Haas for his critique and keen attention to the elements of style. And thanks to the MLOG faculty Dr. Chris Caplice, Dr. Jared Goentzel and Dr. Jonathan Byrnes for your support throughout the year.

We would also like to thank our sponsor in the pharmaceutical industry Anthony B. for providing the topic and motivation to conduct this research. Thank you to John M., John K., David R., Helen, Lisa, David K., Phil, Philippe, Rachel, Gulden, Mark, James, and Vijay for making the time to discuss their unique perspectives of the pharmaceutical industry.

Eric C. Rimling:

I would like to thank my family, my parents Greg and Marilyn and my brother Todd, for providing support and advice through all the plans I've made and the places I've gone. I would also like to thank my friends for believing in me and encouraging me with their messages all year. Finally, I'd like to thank God for this incredible experience and making all of it possible.

Wontae Thomas Seoh:

First, I would like to thank my beautiful wife Hyungi Woo for her optimism, love and understanding throughout this academic year. I would also like to show my gratitude to my parents Bong Kyu and Jeong Hee Seoh and siblings Eugene, Marianne, and Daniel for unending believe in me. Finally, I would like to thank God for giving me the purpose and faith to achieve my goals.

Table of Contents

Abstract 2
Acknowledgements 3
List of Figures 7
List of Tables 8
1 Introduction 9
1.1 Project Background 10
1.2 Development of a Cost Framework 11
1.3 Research Roadmap 12
2 Pharmaceutical Industry Overview 14
2.1 Market Structure and Dynamics 14
2.2 R&D and Drug Introduction 16
2.3 Drug Lifecycle 19
2.4 Risks 21
2.4.1 Risk of Growth Attainment 21
2.4.2 Risk of Increasing Complexity 22
2.4.3 Risk of Technology Investment 22
2.4.4 Risk of High Attrition 23
2.4.5 Risk of Blockbuster Reliance 24
2.4.6 Risk of Market Timing 25
2.4.7 Risk of Product Differentiation 25
2.4.8 Risk of Regulative Force 26
2.5 Impact on Supply Chain Costs 26
3 Literature Review 28
3.1 Cost Allocation 28
3.2 Landed Cost Models 29
3.3 Relevant Models and Frameworks 31
3.3.1 Quantitative Models 31

3.3.2 Qualitative Frameworks 32
3.4 Our Contribution 34
4 Data Collection and Analysis 36
4.1 Interview Process 36
4.1.1 Format of Interviews 37
4.1.2 Finance 37
4.1.3 Sourcing Strategy 38
4.1.4 Distribution Hubs 39
4.1.5 Transportation/Logistics 40
4.2 Cost Identification 42
4.3 Categorization 44
4.3.1 Hard and Soft Costs 45
4.3.2 Variability Drivers 46
4.3.3 Categorization Profiles 47
5 Results and Insights 52
5.1 Product Type Matrix 52
5.1.1 Blockbuster Products 54
5.1.2 Specialist Products 56
5.1.3 Commodity Products 57
5.1.4 Underperforming Products 59
5.2 Introduction to Forces 60
5.2.1 Forces that Impact Pricing Power 61
5.2.2 Forces that Impact Demand 64
5.3 Channel Cost Operational Model 67
5.3.1 Quantifying Hard Costs 69
5.3.2 Quantifying Soft Costs 69
6 Model Extensions 72

6.1 Sensitivity Analysis Using Simulation Techniques 72
6.2 Net Present Value Analysis 73
7 Conclusion 75
References 77
Appendix A: The Balanced Scorecard 79
Appendix B: Import Landed Costs 80
Appendix C: Export Landed Costs 81
Appendix D: GE-McKinsey 9-Box Matrix 82
Appendix E: List of Costs by Product Type 83
Appendix F: List of Costs by Channel and Product Attributes 84
Appendix G: Finance Interview Notes 85
Appendix H: Sourcing Strategy Interview Notes 87
Appendix I: Distribution Hubs Interview Notes 88
Appendix J: Transportation/Logistics Interview Notes 89

List of Figures

Figure 2.1: R&D and Drug Introduction 16
Figure 2.2: Drug Development Timeline 18
Figure 2.3: Effective Patent Protection 1960 – 1990 20
Figure 2.4: A Pharmaceutical Product's Lifecycle 20
Figure 2.5: Attrition Rate in Pharmaceutical R&D by Phase 24
Figure 3.1: Total Cost Equation 31
Figure 3.2: Safety Stock Equation 32
Figure 3.3: BCG Growth/Share Matrix 33
Figure 3.4: Porter Value Chain Framework 34
Figure 5.1: Product Type Matrix 53
Figure 5.2: Product Type Matrix with Market Forces 60
Figure 5.3: Pricing Pressure Force 61
Figure 5.4: Barriers to Entry Force 62
Figure 5.5: Market Pressure Force 65
Figure 5.6: Market Growth Force 66
Figure 5.7: Channel Cost Operational Model 67
Figure 5.8: Holding Cost Equation 70
Figure 6.1: Net Present Value Equation 74

List of Tables

Table 2.1: Market Positions of the Top Pharmaceutical Companies 15
Table 2.2: R&D Process 17
Table 2.3: Average Cost Structure of Newly Developed Drug 22
Table 3.1: Quantifying the Impact of Risk 30
Table 4.1: Identified Costs 43
Table 4.2: List of Strategic Drivers 44
Table 4.3: Categorization of Costs Based on Measurability 46
Table 4.4: Categorization of Costs Based on Variability Drivers 47
Table 4.5: Channel Attribute Costs Profile Table 48
Table 4.6: Volume Based Costs Profile Table 49
Table 4.7: Value Based Costs Profile Table 50
Table 4.8: Product Attribute Costs Profile Table 51
Table 5.1: Blockbuster Relevant Costs 54
Table 5.2: Specialist Relevant Costs 56
Table 5.3: Commodity Relevant Costs 57
Table 5.4: Underperformer Relevant Costs 59
Table 5.5: List of Channel Attrittibute Costs 68
Table 5.6: List of Product Attribute Costs 68
Table 5.7: Demonstrative Table of Hard Costs for a Blockbuster Product 69
Table 5.8: Quantifying the Impact of Risk 71
Table 6.1: Demonstrative Table of Regression Coefficients for Sensitivity Analysis 73

1 Introduction

The pharmaceutical industry creates products which often have more than one supply chain channel, defined as a route through the supply chain network from sourcing to the end market. It is important to note that there are different types of players in the pharmaceutical industry ranging from companies that are primarily focused on bringing new drugs to the market by investing heavily on R&D, to companies that manufacture only generics with limited or no investment in R&D. In this research we will refer to the companies that have significant investment in R&D as pharmaceutical companies. The results, however, can be adapted to study any type of pharmaceutical company.

Each channel's specific cost characteristics are important to the pharmaceutical industry's ability to maintain positive profit margins while meeting high customer service requirements. Channel selection can be difficult due to dynamic factors, such as risk of counterfeiting or supply disruptions triggered by political instability, which are not always easy to quantify. Our research offers a solution to this problem by developing a framework to identify relevant channel costs and a process to quantitatively evaluate these costs.

The structure of the pharmaceutical industry adds a further layer of complication to channel strategy for branded pharmaceuticals. It takes many years and millions of dollars to develop a new drug but there is only a short time under which the drug receives patent protection. Pharmaceutical companies must use this short time to recoup their costs before the patent expires and they are faced with intense competition from generic competitors selling the same drug formula at a much lower price point.

In spite of the challenges, pharmaceutical companies have used certain channels to deliver drugs because of the assumed cost advantages. For instance, the Asian supply channel is one of the most economical due to low labor wages and production costs in the region. The cost savings from these operational areas outweighed the logistics costs to ship from this region to others around the world.

1.1 Project Background

Due to recent fluctuations in fuel prices, the pharmaceutical industry began to challenge the assumption that operational savings outweighed logistics costs in Asia. For instance, did supplying the U.S. market from Central America now make more sense than shipping from Asia due to the lower logistics costs? Our sponsor pharmaceutical company wanted to understand how to incorporate cost fluctuations when making supply chain decisions. They also wanted to find out how costs changed during a drug's lifecycle as it moves from patented to generic and how these changes should be incorporated into channel decisions.

We saw that the bigger problem was not just about fluctuating fuel prices or changes during a drug's lifecycle, but how to deal with various supply chain channel costs in general. Our solution was to develop a framework to capture relevant costs and identify market forces that impact these costs through underlying variability drivers. In our research, we define a variability driver as the primary cause of cost fluctuations. By simplifying the problem, we could understand the changing cost dynamics to better inform supply channel decisions.

1.2 Development of a Cost Framework

The first step to develop a cost framework was to isolate the costs that had the most impact on the supply chain. We began with research into the pharmaceutical industry to understand the unique aspects of the business and increase our knowledge of how the industry works. Once we gained a better understanding of the industry, we conducted interviews with representatives throughout our sponsor pharmaceutical company to gather information and costs they felt were relevant to their functional group. Through these interviews and additional research into landed costs, we generated a list of 30 costs that we felt represented the most significant factors affecting the pharmaceutical supply chain.

Once we had the basic list of costs, we needed to incorporate into our framework an understanding of which costs change, why they change, and what forces were causing these changes. By looking at trends and patterns within the costs as well as further research, we identified common variability drivers that changed within the different channels. The variability drivers included channel specific features, volume changes, value changes, and product attribute differences. Variability drivers explained what was changing our costs, but we next had to figure out why they were changing.

By laying the costs on a matrix according to their volume and value variability drivers, we discovered four market forces that had an impact on costs and explained why they were changing. These four market forces were Pricing Pressure, Barriers to Entry, Market Pressure, and Market Growth. This discovery was influenced by Michael Porter's research and his concepts helped clarify why the forces were present and what their impact was on the variability drivers.

The last part of our project was to transform our research into a simple decision making process to compare two channels based on their costs and arrive at the optimal solution for a specific product, even if it changed over time. We had already deconstructed a complicated problem down to the relevant costs that spanned organizational divisions, but we needed a process to analyze the cost components. The solution we developed is a three-step method to compare channel costs through quantifiable values. The method is easy to understand and arrives at one final number per channel that can be compared. Pending more detailed cost data, two other considerations can be added that make the analysis even more complete.

1.3 Research Roadmap

Our thesis is divided into sections that address the research areas already mentioned. Chapter 2 lays out the fundamental structure and dynamics of the pharmaceutical industry as well as the inherent risks a company is exposed to. Chapter 3 discusses previous research involving the identification of costs in a global supply chain and frameworks that can be used to analyze these costs. Chapter 4 reviews the information gained through our interviews and identifies the relevant costs in a pharmaceutical supply channel. This section also categorizes the costs based on Hard costs (which are easier to quantify) and Soft costs (which are harder to quantify but that impact decision-making), as well as the variability drivers for each cost.

Chapter 5 introduces the Product Type Matrix as a simple way to think about product categories. We explore the features, relevant costs, and business strategy for each product category before discussing the forces that act on the product categories. The conclusion of Chapter 5 develops the process for using our Product Type Matrix and

cost categorizations to make supply channel decisions. Chapter 6 expands upon this process with a sensitivity analysis and net present value equation that can make the process more complete if detailed cost data is available. Our Conclusion wraps up our findings and expands on the concepts discovered through this research in Chapter 7.

2 Pharmaceutical Industry Overview

The pharmaceutical industry is unique for a variety of reasons, from the complexity of the products to the regulations that govern every aspect of the business (Singh 2005). These constraints and market dynamics shape the way pharmaceutical companies do business and create a challenging environment for new competitors to enter. Although our research is specifically focused on analyzing channel costs of pharmaceutical supply chains, knowledge of the overall industry was crucial to understand the underlying forces that drive supply chain decisions. To gain this understanding, we took a closer look at a number of areas that make the industry unique.

2.1 Market Structure and Dynamics

The market structure of the pharmaceutical industry is a complex combination of large, multi-national corporations driven by incredible research and development budgets, and many smaller companies developing niche drugs or generics. The difference between these categories is vast and there are significant barriers to entry – such as economies of scale – to move from a niche provider to a large pharmaceutical provider. The powerhouse pharmaceuticals are characterized by a global spread and have R&D programs that run into the billions of dollars per year (PhRMA 2009). In 2008, an estimated $65 billion was spent on R&D in the pharmaceutical industry (ibid.).

The industry is also characterized with a high level of instability caused by competition. Table 2.1 shows how the position of the top pharmaceutical companies changed between 1982 and 2000.

Company	1982	1990	1995	2000e
Glaxo Wellcome	18	2	1	2
Merck	3	1	2	1
Hoechst Marion Roussel	1	5	3	5
Bristol-Meyers Squibb	10	3	4	8
Roche	8	16	5	6
Pfizer	6	15	6	3
American Home Products	4	10	7	7
Lilly	7	9	8	4
Pharmacia Upjohn	16	21	9	12
SmithKline Beecham	11	8	10	9

Source: Key Issues in the Pharmaceutical Industry (1999)

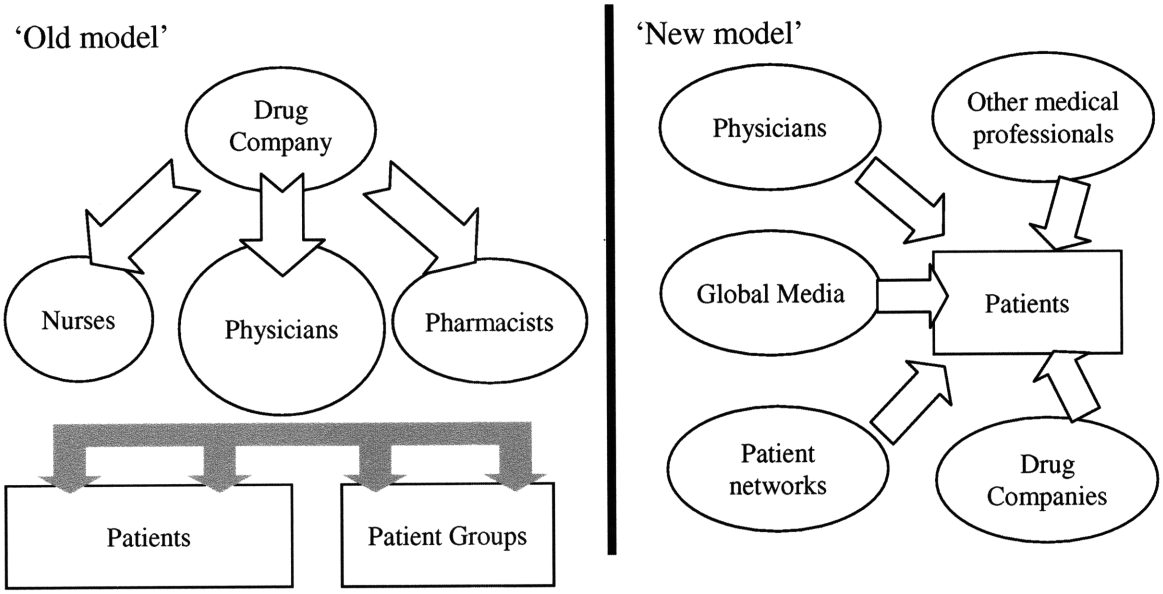
Table 2.1: Market Positions of the Top Pharmaceutical Companies

Innovation is vital in the pharmaceutical industry and the market offers rich rewards to players that are first to introduce a product in a particular therapeutic category. Sometimes one or two strong product launches can significantly boost a pharmaceutical company's sales and lead them to the top of the charts for an extended period of time (e.g. Lipitor and Viagra in the case of Pfizer).

The relationship between demand and pricing in the pharmaceutical industry is an interesting dynamic since it is very inelastic for branded drugs. In other words, a price increase does not cause more customers to leave the market, and a price decrease does not attract more customers to it (McIntyre 1999). For prescription drugs, the patient often does not know what drug they need or the dose they need it in and must rely on a doctor to make the right recommendation for them. In these cases, the price has almost no effect on whether the patient uses the drug since it is usually a necessity.

Pharmaceutical companies also face the problem of fixed demand. Since more people will not become afflicted with a disease through a marketing campaign, the best method for demand generation is to educate people on the symptoms of a disease they are trying to treat. This method works well to drive demand through doctors (so they

prescribe the drug) and as well as patients (so they request the drug). Figure 2.1 shows a change in the marketing model, towards a more direct to patient approach.



Source: A Healthy Business: A Guide to the Global Pharmaceutical Industry (2001)

Figure 2.1: R&D and Drug Introduction

2.2 R&D and Drug Introduction

Research and development is the foundation of the pharmaceutical industry and is required to bring innovative treatments to market and to remain a competitive player in the business. In large pharmaceutical companies, R&D consumes between 15% to 18% of sales (Greener 2001). This has resulted in cures and treatments that have helped millions of people live better lives, increasing overall social welfare and productivity.

Unfortunately, innovative drug discoveries do not come easily and many barriers must be overcome to launch a new commercial drug. Three of the biggest barriers are the low probability of success, long time between discovery and commercializing a product, and high upfront costs associated with the process (McIntyre 1999).

The first barrier is the low probability during the R&D process that a chemical compound will lead to a profitable commercial drug. McIntyre reports on the development numbers:

> *For every 10,000 drug candidates synthesized at the discovery phase, 1,000 will enter preclinical testing and only 10 will enter clinical testing. Out of those 10, only 1 will eventually become a new introduction (McIntyre 1999).*

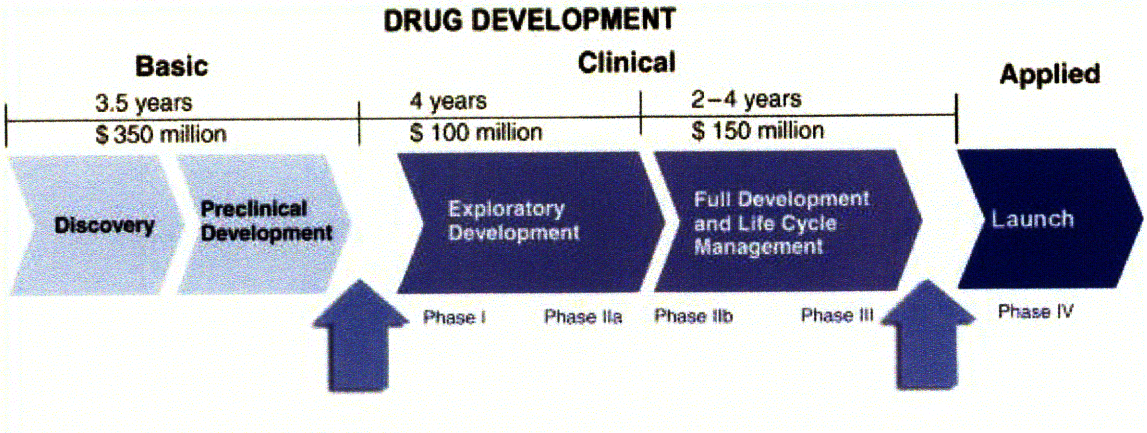
As a result, much of the money invested in R&D leads to abandoned drugs that will never regain their investment. Table 2.2 describes the R&D process in more detail.

R&D Phase	Description
Discovery (preclinical)	*Random screening*: approximately 10,000 chemical compounds are tested for therapeutic activity. *Rational drug screening*: between 500 and 1,000 chemical compounds are synthesized and tested for therapeutic activity. Pharmacological activity and toxicity determined for lead compounds and a patent dossier and Investigational New Drug application is submitted to appropriate authorities.
Development (clinical)	*Phase I*: 50-100 healthy volunteers are tested for absorption, metabolism, distribution, etc. (if drugs are expected to be toxic, such as cancer, studies may enroll terminally ill patients) *Phase II*: 200-400 patients tested for efficacy and toxicity. *Phase III*: larger randomized trials conducted on patients to determine efficacy and any adverse drug reactions. *Application for New Drug Application*: all raw data from preclinical, clinical, and animal testing submitted to authorities for marketing approval. *Phase IV*: post-marketing surveillance to collect data on any further side-effects and more generally to improve knowledge of the product.

Source: Key Issues in the Pharmaceutical Industry (1999)

Table 2.2: R&D Process

Another characteristic is the time consuming nature of R&D due to the number of trials and regulations a new drug must clear. Current estimates of the pharmaceutical R&D process suggest that the time from discovery to marketing is on average 12 years (DiMasi et al 1995). Figure 2.2 provides a breakdown of where the time and cost is allocated during the drug development process.



Source: Differences in Drug Development (2008)

Figure 2.2: Drug Development Timeline

Even though the odds are heavily stacked against new drug discoveries and the process is extremely capital intensive, R&D has the potential to generate huge profits. In the pharmaceutical industry, a highly profitable drug is called a blockbuster. A blockbuster is usually defined as a drug that achieves sales of more than $1 billion annually (Greener 2001). Blockbusters are important to the pharmaceutical industry for a variety of reasons: they fill a large consumer need for a product, they fund further R&D operations for the next blockbuster, and they help with company growth and the fulfillment of shareholder expectations (ibid.).

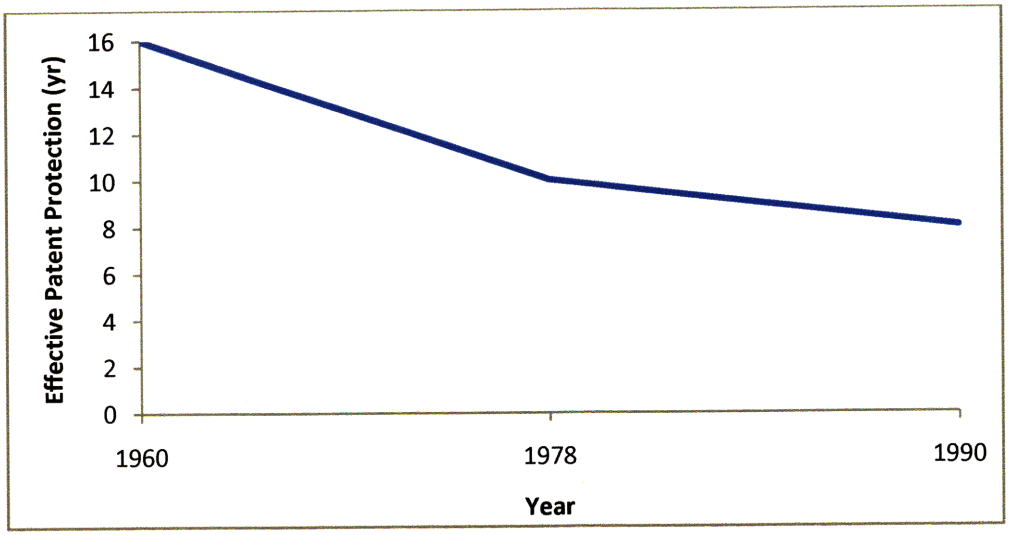
The significance of all this is that once a drug is approved, the full power of the operational side of the business must be aligned to immediately and efficiently take

advantage of the new drug's earning potential. As we discuss in the next section, the period of time a drug is under patent is extremely valuable.

2.3 Drug Lifecycle

The pharmaceutical companies must deal with products they have spent hundreds of millions of dollars to develop, have taken years to bring to market, and have complex manufacturing requirements. Yet once these challenges have been surmounted, companies have only a few years in which they can hold near monopoly power over the patented product. Despite this idiosyncratic nature of the industry, pharmaceuticals rank at the top of the industrial sectors of the Fortune Global 500 with a return on assets of 14.7% (Greener 2001). This swing from an extremely unprofitable R&D phase to an extremely profitable patented phase is a characteristic that makes the pharmaceutical industry unique compared to most industries.

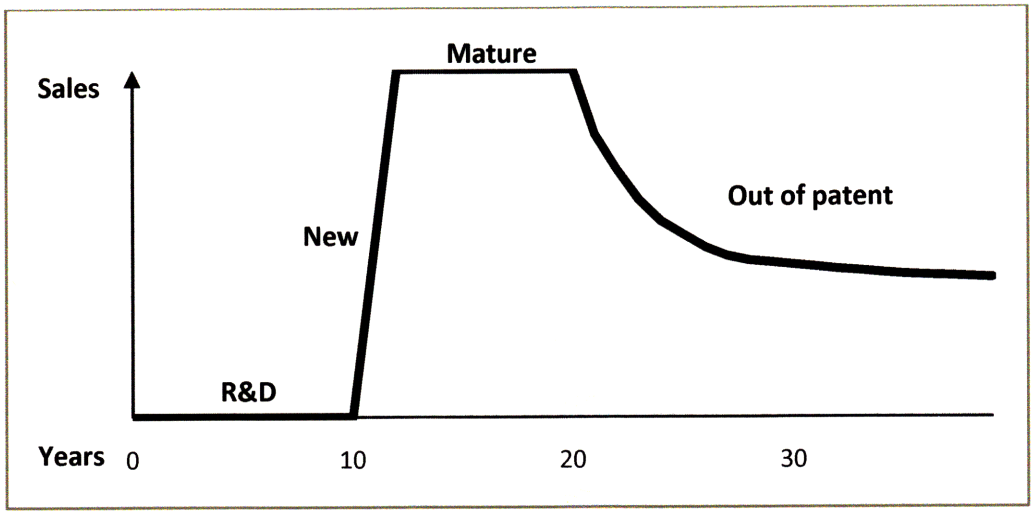
During the patented phase of a drug's lifecycle, the cost of R&D must be recouped as well as a sufficient profit is captured to fund further R&D for the next innovative drug. A patent application tends to be submitted at the discovery stage of the R&D process, approximately 10-12 years before a successful product might reach the market (McIntyre 1999). Patents last for 20 years in the U.S. but since the patent is filed so far in advance of commercialization, the longer the clinical trial phase, the shorter patent protection time the pharmaceutical company has to sell the drug at a premium. Figure 2.3 shows that as the R&D time of more recent drugs has lengthened (due to complexity and increasing government regulations), the effective patent protection on drugs has been falling.



Source: Keys Issues in the Pharmaceutical Industry (1999)

Figure 2.3: Effective Patent Protection 1960 – 1990

The lifecycle of pharmaceutical drugs has been researched and a well-established pattern has been developed. Figure 2.4 shows the lifecycle of a pharmaceutical from the beginning of R&D through the introduction of generic competition.



Source: A Healthy Business: Guide to the Global Pharmaceutical Industry (2001)

Figure 2.4: A Pharmaceutical Product's Lifecycle

Analyzing the lifecycle curve, it is apparent that companies should try to ramp up to mature sales volume *as soon as possible* and for *as long as possible* before competition

enters the market. To accomplish this, there have been two different approaches to lifecycle management over the years. Originally, companies would roll out their international launches over several months and growing sales in one market would help fund the launch in the next market (Greener 2001). While this was a safer approach, it took longer for drugs to reach their mature potential. The newer approach is to launch a product in several countries at once to ramp up sales as quickly as possible (ibid.).

2.4 Risks

Due to the long timeframe and serious upfront costs of the R&D structure, pharmaceutical companies face risk from a multitude of different areas. The eight primary risks in the pharmaceutical industry are as follows (Reepmeyer 2006):

1. Risk of growth attainment
2. Risk of increasing complexity
3. Risk of technology investment
4. Risk of high attrition
5. Risk of blockbuster reliance
6. Risk of market timing
7. Risk of product differentiation
8. Risk of regulative force

2.4.1 Risk of Growth Attainment

Pharmaceuticals have been one of the fastest growing markets over the last 40 years. From 1970 to 2008, the average annual growth rate of sales has been 10.4% (PhRMA 2009). This high and sustained growth rate has led to increasing shareholder expectations

of what the pharmaceutical industry is capable of. To continue this growth, big pharmaceutical companies must introduce at least two to four new drugs per year, a rate that many are not capable of achieving (Reepmeyer 2006).

2.4.2 Risk of Increasing Complexity

As discussed earlier, R&D fuels the innovative developments made by pharmaceutical companies every year. With the growing use of high performance screening technologies, the ability of researchers and scientists to develop more complex drugs is also increasing. The risk of complexity is that the R&D approval process must be met and the drug made commercially available in a timeframe that is profitable. The cost of R&D already accounts for the majority of a new drug's cost structure (Table 2.3) and increasing complexity threatens to push this percentage even higher.

Relative Contribution	Cost Factors
20%-40%	**Research, development, and licenses**
20%-35%	Margin
20%-30%	Marketing and distribution
15%-30%	Production
5%-15%	Technical and administrative costs

Source: Pharma Information (2002)

Table 2.3: Average Cost Structure of Newly Developed Drug

2.4.3 Risk of Technology Investment

Technology plays a crucial role in the pharmaceutical industry in two areas: the R&D phase of drug discovery and manufacturing phase of drug commercialization. Reepmeyer explains the technology changes:

> *The technological approaches used in R&D today are mostly based on improved computing power, the rise of advanced computer applications, and a better*

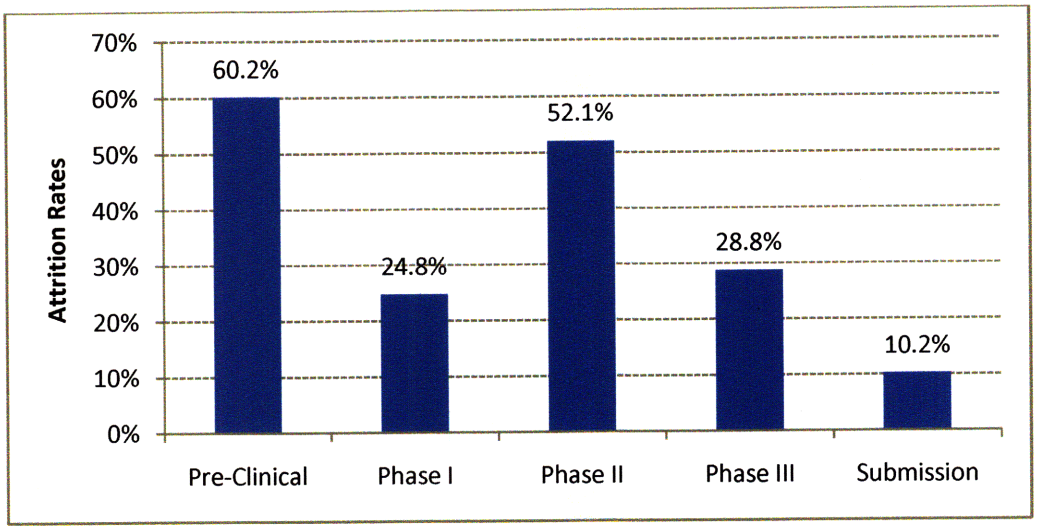
understanding of the human genome. High-throughput sampling is one example of new technology that is allowing the screening of more samples at a lower cost than ever before (Reepmeyer 2006).

On the production side, new equipment and processes must be developed to synthesize the complex new drug compounds. The risk of technology investment is high due to the many variables of the industry, including a drug's demand being less than anticipated or a competitor entering with a similar product that gains market share.

2.4.4 Risk of High Attrition

In most industries, a decision to terminate an R&D project is made on the basis of economic or financial reasons. In the pharmaceutical industry most R&D project are dropped due to scientific reasons, many in the late clinical stages due to lack of efficacy or safety concerns (Reepmeyer 2006). Obviously, a drug abandoned later in its development process results in higher financial loss.

Since the probability of commercializing a drug is low, the costs of abandoned R&D projects are often accounted for in the direct costs of approved drugs. Figure 2.5 shows the attrition rate at varying stages of the R&D process. Over 60% of drugs are abandoned in the Pre-Clinical stage alone.



Source: Risk-sharing in the Pharmaceutical Industry: The Case of Out-licensing (2006)

Figure 2.5: Attrition Rate in Pharmaceutical R&D by Phase

2.4.5 Risk of Blockbuster Reliance

For many years, pharmaceutical companies have relied on a series of highly profitable blockbuster drugs – a drug with at least $1 billion in annual sales – to recoup their heavy R&D expenses and achieve corporate growth. Some smaller pharmaceutical companies have used only one or two blockbusters to sustain profitability for many years, but the risk of relying on blockbusters is twofold.

First, as a blockbuster comes off patent and is exposed to generic competition, a significant revenue stream is greatly reduced. If the company does not have another blockbuster in their portfolio or in the late stages of development, both their stock price and sales can plummet (Reepmeyer 2006). The second risk is that with so much reliance on a small number of products, the company has significant exposure to unforeseen market events. These events could come in the form of a competitor who introduces a superior product with fewer side-effects or a drug that experiences an unpredicted safety issue.

2.4.6 Risk of Market Timing

In other industries, first mover advantage is usually important. In the pharmaceutical industry, it is crucial. As we discussed in the lifecycle model for pharmaceutical drugs, the growth rate and market share gained in the first year or two of a drug's introduction is extremely important in determining the overall sales for that drug. The longer the drug takes to reach mature sales volume, the less time remains before the patent expiration date and the introduction of generic competition.

The probability of a new drug turning out to be a success is increased by three factors (Reepmeyer 2006):

1. Being early to enter a particular therapy area or product class
2. Being positioned well relative to its existing competitors
3. Being accompanied by heightened pre-launch awareness

Another risk of market timing is that during the long R&D phase of a drug's development, a competitor could introduce a similar product in the same category. If this happens, companies will often lose significant market share to their new competition even if their own drug is highly effective. Unfortunately, with the complex approval and regulatory process, market timing is a hard thing to control.

2.4.7 Risk of Product Differentiation

Product differentiation is usually determined by a drug's clinical profile in four areas: efficacy, side-effects, dosage/administration, and cost (Reepmeyer 2006). Differentiation can be an advantage or disadvantage to a pharmaceutical company depending on whether they have the superior product on the market. If a competing drug offers similar benefits

in one dosage instead of three, they will have a differentiating factor that may be hard to overcome with doctors and patients.

2.4.8 Risk of Regulative Force

The pharmaceutical industry faces more regulation than almost any other industry. Everything from the R&D approval process, to the patent applications, to the pricing is governed by regulations. While ensuring the public is safe from harmful side effects, regulations can also play a critical role in the success of a drug. In a national healthcare system, if a drug is not recommended by the health authorities to be reimbursed, the market potential of the drug can decline significantly (Reepmeyer 2006).

2.5 Impact on Supply Chain Costs

After developing basic knowledge of the industry, identifying market forces was crucial for understanding the channel costs of the pharmaceutical supply chain. Two major concepts emerged that we develop later in our research.

First, during drug introduction and throughout the patented portion of the lifecycle, availability of the drug to end markets should be the major driver of the supply chain if the company is going to be profitable and successful (Singh 2005). Since years of upfront R&D costs and clinical trials have gone into the development, a drug must immediately capitalize on patent protection to start making a profit. The supply chain must be designed to meet this objective. Even if transportation costs are high, they usually pale in comparison to the opportunity cost of a lost sale and the sunk costs already involved in the drug introduction.

Second, once the drug comes off patent, the supply chain must change objectives to efficiently deliver the drug at the lowest cost. Since the profit margin is significantly reduced after competitive pressure rises, cost becomes the major driver of the supply chain. Transportation costs thus become a much higher percentage of total landed cost of the drug and must be minimized in order for the pharmaceutical company to continue its profitability.

3 Literature Review

Although research on channel costs in the pharmaceutical industry is limited, the cost and benefits of global supply chain systems is a much researched topic. The mass globalization during the past century can be attributed to the advances in communication and transportation technologies, which have caused an unprecedented increase in the global demand for products (Mentzer, Myers, Stank 2007). As demand spanned multiple regions and countries, companies were faced with increased competition.

To gain a competitive advantage, companies learned over time that sourcing goods from overseas could help them gain pricing advantages (Cook 2007). Extending this global strategy to their entire supply chain, companies began noticing tremendous gains in profitability and value. Our research looked at methods for measuring the costs and benefits of this global strategy through literature on Cost Allocation, Landed Cost Models, Relevant Models and Frameworks.

3.1 Cost Allocation

According to research by Cooper and Kaplan, most managers make decisions based on incomplete or inaccurate cost data (Cooper, Kaplan 1988). Much of this inaccuracy is due to outdated costing methods and increased complexity of systems and product lines in today's supply chain (ibid.). Furthermore, burden rates based on direct labor are increasingly becoming distorted. Particularly in the pharmaceutical industry, labor and other productivity variables can account for a significant source of costs, and improvements may be worth five to six percentage points of EBIT (Cremer, Losch,

Schrader 2009). Activity based costing models can provide methods that remove some of this distortion from cost data (Cooper, Kaplan 1988).

In the complex analysis of total costs within a supply chain channel, managers often have to decide between financial or operational metrics, but not both (Kaplan, Norton 1992). These should complement each other – with financial metrics explaining the results of actions already taken, and the operational metrics explaining the drivers of future financial performance. Kaplan and Norton's Balanced Scorecard is a useful tool in considering the cost and interrelationships between these decisions (ibid.). Furthermore, they provide a process for linking costs to a strategy for decision-making (Kaplan, Norton 1996). Additional information on the Balanced Scorecard framework and corresponding strategic methodology is found in Appendix A.

3.2 Landed Cost Models

To further identify costs within a global supply chain we explored landed costs. Cook suggests an approach to delineate the domestic and international channels by import and export landed costs (Cook 2007). These landed cost models provided us with examples of how other industries have evaluated these costs when making off-shoring decisions. The import landed costs outlined the variables that contributed to the cost of importing a good; export landed costs looked at the variables that contributed to the total costs for exporting a good.

In our research, we utilized Cook's landed cost models to identify relevant costs for a pharmaceutical supply chain. Furthermore, import and export landed cost variables identified risks that may occur in a global supply chain. For example, the rising cost of fuel and the fluctuations in global exchange rates have had transformative impacts on

supply chain channel evaluations. As fuel prices continue to rise, we may find that off-shoring to Mexico is more viable than China, even though the wage and manufacturing costs are much lower in China. A list of Cook's suggested import and export landed cost variables are found in Appendix B and C.

In addition to the landed costs, risk can also have a significant impact on landed costs for a company's supply chain. Risk is often viewed as intangible, uncontrollable costs, making it difficult to quantify. Cook's Risk Matrix provides a mathematical method for analyzing risk and its impact on the total landed cost. Although it does not quantify the actual costs associated with risk within a supply chain channel, Cook's Matrix provides a relative index which can be used to compare channel options. Furthermore, Cook introduces the concept of "Salience", which is significant because it allows the user to assign weights unique to each risk factor (ibid.). An example of a manufacturing Risk Matrix is provided in Table 3.1.

Risk	Importance (1-5)	Salience (1-5)	Total
Location of plant	3	1	3
Availability of qualified local talent	5	4	20
Currency Risk	2	3	6
Proprietary rights issues	2	2	4
Final classification of the product by U.S. Customs (CBP)	3	5	15
Total			**48**

Source: Global Sourcing Logistics (2006)

Table 3.1: Quantifying the Impact of Risk

Evaluating a supply chain channel requires the consideration of both absolute and relative costs, capabilities of the channel, as well as the evolution of the product and channel (Ranjan 2006). Relative costs including risk, quality, and time within the pharmaceutical supply chain channel, can be evaluated using a method of rating each

factor similar to Cook's Risk Matrix. Further analysis of these costs and their impact on the channel also requires mapping the particular industry (ibid.). The process of mapping should involve analysis of major forces within industry to develop a model or decision framework for analyzing their costs.

3.3 Relevant Models and Frameworks

Models and frameworks are vital to analyzing the behavior and impact of cost variables. Quantitative models provide insight into the cost implication of each variable. Qualitative frameworks describe cost behaviors and consider the changing impact of decision variables over time.

3.3.1 Quantitative Models

Pharmaceutical customers often require high service levels, especially for life-saving drugs. Due to this strict service level requirement, lead times can have a profound impact on safety stock requirements. Analyzing the impact of lead time can best be done looking at the Total Cost (TC) model (Silver, Pyke, Peterson 1998). In this model, Total Costs is broken into ordering costs, holding costs, and shortage cost as provided in Figure 3.1 below.

$$TC = A\left(\frac{D}{Q}\right) + \left(\frac{Q}{2} + k\sigma_L\right)vr + \frac{B_2 v\sigma_L G_u(k)D}{Q}$$

Figure 3.1: Total Cost Equation

The equation in Figure 3.1 assumes shortage costs are on a per unit basis. The per unit shortage cost is particularly relevant for the pharmaceutical industry in which each unit short has an impact on the user – some life-saving drugs may have extremely high

shortage costs. Additionally, lead time has a direct impact on holding costs and the shortage cost (ibid.). Safety stock levels are dependent on the service level factor (k) and standard deviation of forecast errors over the replenishment lead time (σ_L). Calculating the Safety Stock levels is provided by the equation in Figure 3.2 below.

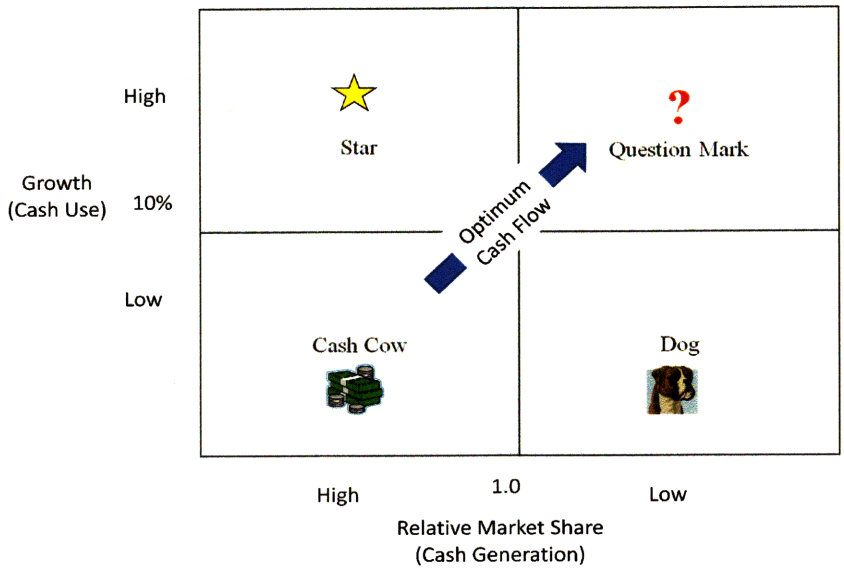
$$SS = k\sigma_L$$

Figure 3.2: Safety Stock Equation

These equations show that lead time also affects the safety stock levels. In particular, safety stock is a direct multiple of service level factor and the standard deviation of forecasts over the lead time. With high service level requirements and long lead times, one expects to hold higher levels of inventory. Shorter lead times result in lower inventory levels.

3.3.2 Qualitative Frameworks

Research on qualitative frameworks provides a structured method for analyzing unclassified information. The BCG "Growth/Share Matrix", in Figure 3.3 below, shows the relationship between capital use and generation (Henderson 1970).



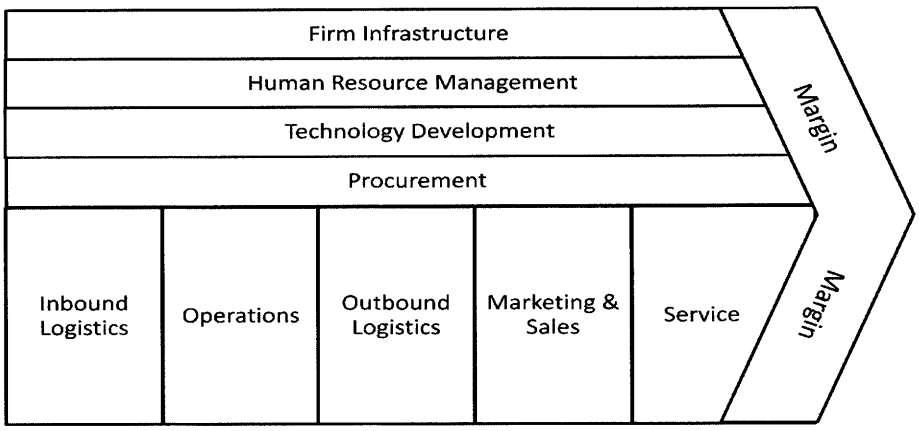
Source: The Boston Consulting Group on Strategy (2006)

Figure 3.3: BCG Growth/Share Matrix

The framework provides a method of identifying the current position of a product or business unit (Porter 1980). Furthermore, the predominant force within the pharmaceutical industry is intellectual property protection. The migration of products off patent can cause products to reposition within this framework. Our research will look to develop a framework that integrates lifecycle changes for the purposes of aiding strategic decisions through the lifecycle of the product or business unit.

Porter describes another framework which has been attributed to GE, McKinsey, and Shell (ibid.). The "strategic mandate" based on interpretation of this framework as Porter describes, is to "Build", "Hold", or "Harvest" the business unit based on its industry attractiveness and positioning. Again this model provides a strong recommendation for decision making, but omits long term implications from lifecycle maturation. A schema of this framework is found in Appendix D.

Porter's Value Chain model as depicted in Figure 3.4, provides a framework for looking at how the primary and supporting activities of a supply chain network provide competitive advantage for a firm (Porter 1985).



Source: Competitive Advantage (1985)

Figure 3.4: Porter Value Chain Framework

These activities provide a means to evaluate the way companies gain competitive advantage in its collection of activities to "design, produce, market, deliver, and support its product" (ibid.). Furthermore, Porter's research explores a method of cost allocation into three categories: purchased operating inputs, human resource costs, and assets by major category. Other methods include the grouping of costs by direct, indirect and quality assurance activities (ibid.). These allocation methods, in addition to the value chain framework, provide a means to evaluate the way costs impact a firms competitive positioning within its industry.

3.4 Our Contribution

Existing research on landed cost models will provide this study with a foundation for identifying the relevance and impact of cost variables for a large pharmaceutical supply

chain network. As an extension of Cook's broad landed cost study, our research will look to isolate total channel cost variables including both import and export landed costs and other production costs such as manufacturing costs, financing, inventory-in-transit, fuel costs, exchange rates, and physical logistics.

Another contribution from this research will be our categorization of these cost variables and an analysis of how changes may impact total acquisition cost values. The aforementioned research in this section describes various methods to categorize cost variables into an analysis framework. Our research will build on these existing frameworks by integrating the impact of lifecycle maturation into decision making process. Although this research will be conducted for the pharmaceutical industry, we expect this combined methodology to be applicable to other industries as well.

4 Data Collection and Analysis

The pharmaceutical company in our study organizes its supply chain channel into four core groups: Strategy and Planning, Finance, Operations, and Logistics. Other supply chain functions such as Procurement, HR Management, and Technology, as well as supporting functions including Sales/Marketing and Service also influence the supply chain activities within this organization (Porter 1985). For the purposes of our study, we focused on the core business functions that impact the channel costs of a supply chain network.

In order to best compare multiple channels we must identify landed costs, indicate how they impact the supply chain, and then organize these costs into a structural framework (Cook 2007). Accordingly, we identified relevant variables that impact the total acquisition costs of our supply chain channel through interviews. Next, we analyzed the impact of these channel costs based on measurability and variability drivers. Finally, we categorized each cost to better understand the key forces that drive cost in our supply chain channel.

4.1 Interview Process

A significant portion of our research was conducted with the help and guidance of professionals working at our case company. These professionals worked in a variety of business units in locations around the world. Through the interviews, we were able to gain insight into the pharmaceutical supply chain from a number of different perspectives. Each business unit considered only those costs, challenges, and metrics for which they were responsible. In the next few sections, we include the data gained from

the interviews and in later sections we categorize and analyze the data to develop meaningful trends.

4.1.1 Format of Interviews

We used a modified Delphi Study approach for our interviewing process (Dalkey 1972). These interviews were typically 30 minutes to 1 hour long and involved experts in the fields of sourcing strategy, logistics, manufacturing, and finance. Questionnaires (Appendix E) were sent to our panel followed by an interview. Iterative questions were asked based on feedback from previous questions according to Delphi techniques. Finally, our analysis was sent back to the panel to hone and refine cost identification and process results. As prescribed by the Delphi approach, our panel was segmented and interaction was minimized to remove bias from our results.

4.1.2 Finance

The Finance group plays a crucial role in managing transactions throughout the organization and checks expenses for each region. The group reviews buyer/seller relationships and handles customers who can range from pharmacies (in the European Union) to distributors (in the United States). The Finance group is responsible for monitoring shipping costs in the main Distribution Hubs that transfer products to other parts of the company and use efficiency metrics to evaluate their third party logistics (3PL) providers. Since the group is responsible for transactional efficiencies, they must find the right balance of owning and outsourcing the transportation requirements to arrive at the lowest channel cost. 3PL's offer agility and savings up front, but as a business grows and the product stabilizes, ownership of the transportation can be more beneficial. Fuel is a big cost but is built into many 3PL contracts.

Another function of the Finance group is setting budget guidelines and tracking how actual expenses are meeting these guidelines. With the high number of variable expenses, they must closely watch volume changes within different regions. Since the company operates on a global scale, a group located inside Finance handles the implications of exchange fluctuations as products move around the world.

Freight is one of the biggest costs in the Finance group, both of local service providers as well as within their own operation. Flexibility is an important factor and priority is placed on the ability to service the customer under any condition. This can include using a faster form of transportation (i.e. air versus ground) even if it is more expensive. High plant utilization is another key to lowering costs and capacity decisions are made to maximize their assets. Some expenses that are not easily measured but important to the Finance group are environmental, health, and safety costs (EH&S), security costs, and customs clearance costs.

4.1.3 Sourcing Strategy

The Sourcing Strategy group is responsible for determining where to manufacture products and ensures plants are right-sized to meet demand. There are four main decision factors when evaluating which plant should produce a drug:

1. Technology – Certain products require different technologies within the manufacturing locations, so some plants have different roles.
2. Complexity – Drugs also vary in their difficulty of production and might require the experience and knowledge of a certain plant. For instance, new products are usually low on the learning curve, so plants with high technical capabilities are used to develop and streamline the process.

3. Capacity – The volume of a plant is very important and the Sourcing Strategy group tries to maximize capacity utilization. They make sure a plant has enough volume to be efficient and cost-competitive in their manufacturing. As a drug becomes more popular, scale can become a big factor and plants can become undersized.
4. Factor costs – Plants in different locations have varying utility costs, labor costs, and facilities costs.

Lifecycle management plays a key role in Sourcing Strategy. As a drug moves through its lifecycle from patented to generic, cost becomes increasingly important as it comes off patent (usually around 10-12 years from launch). This can sometimes mean moving a drug during its lifecycle from a high capability/high cost plant to a lower cost plant once the production process is established.

Like many companies that have grown through acquisitions and mergers, the pharmaceutical company in our study must deal with legacy plants and try to eliminate redundancies in their system. Since taxes are a major expense to the company, tax incentives offered by different regions provide a strategic means to lower costs. Sourcing Strategy also evaluates logistics costs, migration costs, costs due to regulations, customer service costs, and quality costs. Some Soft costs that affect decisions are the stability of the political environment and the ease of doing business in a country. We used these costs as important components in our framework.

4.1.4 Distribution Hubs

We conducted interviews with managers of the major Distribution Hubs within the company's logistics network. The Distribution Hubs are responsible for coordinating the

physical and transactional flow of products as well as handling the required documentation for these transactions. The products can be in any state from base active pharmaceutical ingredients to finished drugs. The Distribution Hubs use a combination of warehousing and cross docking to move product efficiently through the hub, but also have ownership and control of products that flow through remote contract companies. The process of using remote companies allows control of the product while still taking advantage of tax havens.

The Distribution Hub is service oriented, and often expedites deliveries to provide high service levels. Other major costs include management of people, management of facilities, system overhead costs, and import/export licenses. Costs incurred to meet the regulations and quality standards are also included in our framework.

4.1.5 Transportation/Logistics

The Transportation and Logistics group handles the movement of product around the world and manages the supply planning to ensure product availability. The group works with Manufacturing to coordinate demand planning and interfaces with Finance if a product needs to go through a certain Distribution Hub.

Since the availability of lifesaving drugs is paramount, stockout costs are very high. The Transportation group tracks their performance using in-stock percentage and the number of days a drug is in stock per month. There are a few main concerns that this group must deal with:

1. Volume shipped – Many of the transportation costs are variable and scale with the amount shipped.

2. Service – Ensuring the customer has the product they need, when they need it, is of the utmost importance. The goal is to maintain high service levels even though this incurs higher costs.
3. Shipping requirements – Special product requirements including refrigeration, substance control, and hazardous material handling add complexity and logistics costs to the channel.
4. Damaged goods – Many of the products pharmaceutical companies deliver are easily damaged, either by physical destruction or by extreme temperature. This adds additional cost to the channel and is incorporated into our framework as shrinkage costs.
5. Utilization – Maximizing the efficiency of the Distribution Hubs as well as the transportation network is crucial to high utilization.

The Transportation group must also tackle the lifecycle issue. Patented drugs gain more from tax advantages while generic drugs have lower delivered costs if they are produced in regions with low factor costs or produced closer to the end market. Unfortunately, there is often a tradeoff between locations with tax-advantages and locations with lower operational and logistics costs. As the product moves from a patented to a generic drug, the optimal choice may shift for a pharmaceutical company to stay cost competitive.

Following the trend across many industries, the company is looking for fewer partnerships that are more strategic in nature. With this as the guiding philosophy, transportation providers are evaluated on four characteristics:

1. Service

2. Capability
3. Quality
4. Cost

To lower costs, ocean freight is used as much as possible. Since the value of drugs is high compared to their weight, one ocean container can be extremely valuable. This has led to problems with liability and insurance as the pharmaceutical company and the shipping company each try to manage the risk of product being damaged. Throughout the shipping process, the security of the goods must be maintained to ensure product safety and quality.

Since this group is customer facing, reputation is important. The brand's quality and availability are at stake so service is always prioritized over cost. New product launches are particularly challenging since demand is unknown and varies greatly as the product becomes increasingly popular. Air freight usually has to be used to ensure product availability despite the increased cost due to the high value density of the drugs.

One of the other challenges facing the Transportation group is ensuring availability in a highly price and product controlled market. Licenses must be obtained in every market a drug is sold and regulations control the batch sizes, the handling, the materials, and the movement of product within the network. Changing sources can take from 30 days to 2.5 years depending on the country and the regulations in place.

4.2 Cost Identification

The interviews provided a wealth of information about many aspects of the pharmaceutical supply chain and gave us a better picture of how the different functional

groups interacted. The next step was to identify costs from both the interviews and our research that could help with supply chain decision-making. Table 4.1 summarizes the costs we identified.

Costs Identified	Comments
3rd Party Logistics	The cost of transportation offered by 3rd party providers
Cost of Capital	The interest on the money borrowed to finance operations
Currency Exchange	The costs of dealing with a foreign currency
Ease of Business	The cost of doing business in a country (includes political, government, and regulatory considerations)
Environmental Fees	The cost of fees associated with environmental restrictions
Facilities Cost	The cost of facilities
Fuel Surcharges	The cost of fuel
Import/Export Fees	The cost of moving goods into and out of countries
Insurance	The cost to insure business operations
Inventory Holding Costs	The cost of storage and maintenance to keep excess inventory
Labor Costs	The cost of wages plus benefits
Lead Time	The additional costs incurred with extra lead time
Learning Curve Cost	The cost of new product launch and process improvement
Licensing Fees	The cost of licensing a drug for sale in a market
Mode	The cost difference between Air, Ocean, and Ground
Other Overhead	Any additional costs for maintaining the business
Port Charges/Taxes	The cost of utilizing a port
Quality	The cost of meeting target quality levels
Regulations	The cost of meeting government regulations in each market
Risk	The cost of unpredictable situations occurring
Safety Costs	The costs for implementing safeguards
Security Fees	The cost to prevent counterfeits or theft in the supply chain
Shipment Liability Costs	The incremental cost for shipping high value products (mainly applies to shipping ocean containers)
Shrinkage Cost	The cost of damaged or stolen products
Special Handling	The cost of shipping refrigerated products, controlled substances, or hazardous materials
Stockout Cost	The cost of a lost sale due to unavailability of a product
Taxes	The cost of government duties on product values
Technology	The cost of technology to produce or ship product
Utilities	The cost of utilities
Utilization	The cost of worker and machine efficiency

Table 4.1: Identified Costs

We also identified strategic drivers that have cost implications within a supply chain channel. These drivers, although they do not directly create cost, do create constraints and conditions that result in channel costs. For example, the decision to hold more control over one's supply chain channel will result in costs associated with the added need for oversight including 3PL, facilities cost, mode, regulations, and security cost. Table 4.2 provides a list of these strategic drivers.

Strategic Drivers	Characteristics
Capacity	The cost of ensuring enough supply to meet demand (this driver incorporates the following costs: facilities cost, labor cost, technology, and utilities)
Complexity	The additional cost due to the difficult process of making a drug (this driver incorporates the following costs: labor cost, learning curve cost, quality, technology, and utilities)
Control	The additional cost of managing supply chain functions in house for added oversight (this decision incorporates the following costs: 3PL, facilities cost, mode, regulations, and security cost)
Distance	The additional cost depending on proximity to market (this driver incorporates the following costs: fuel surcharges and mode)
Capability Flexibility	Ability to adapt production for other products (this driver incorporates the following costs: facilities cost, labor cost, and technology)
Capacity Flexibility	Ability to scale production (this driver incorporates the following costs: 3PL facilities, labor, and mode)
Service Costs	The cost of meeting customer's needs (this driver incorporates the following costs: 3PL, inventory holding cost, labor cost, mode, quality and stockout cost)

Table 4.2: List of Strategic Drivers

4.3 Categorization

Interviews were also helpful in identifying common characteristics among costs. For example, we discovered that in the pharmaceutical industry both freight insurance and currency exchange costs depend on the value of the product. Integrating details from our

interviews with our research, we arrived at a categorization method based on direct measurability (which we call "Hard" and "Soft" costs) and on their variability drivers.

4.3.1 Hard and Soft Costs

Companies often measure their total acquisition cost based on values that they can directly attribute to the activities of a supply chain. Costs such as licensing fees and taxes often have strict accounting values and are useful for decision making. Due to the direct measurability and defined impact of these costs, we call them "Hard" costs for the purpose of our analysis.

In addition, we found other variables that can have an indirect impact on total costs such as delivery lead time. For example, a longer delivery time may cause the market managers to order additional inventory and add increased inventory cost to the channel. We label these costs as "Soft" due to their indirect influence on total channel costs. Meanwhile, some Soft costs, such as the cost of flexibility and risk are harder to quantify. Based on methods proposed by Thomas Cook, we present a process of quantifying these costs in section 5.3.2. A list of costs categorized by Hard and Soft is presented in Table 4.3.

Costs Identified	Type	Costs Identified	Type
3rd Party Logistics	Hard	Ease of Business	Soft
Cost of Capital	Hard	Lead Time	Soft
Currency Exchange Costs	Hard	Learning Curve Cost	Soft
Environmental Fees	Hard	Quality	Soft
Facilities Cost	Hard	Regulations	Soft
Fuel Surcharges	Hard	Risk	Soft
Import/Export Fees	Hard	Safety Costs	Soft
Insurance	Hard	Utilization	Soft
Inventory Holding Costs	Soft		
Labor Costs	Hard		
Licensing Fees	Hard		
Mode	Hard		
Other Overhead	Hard		
Port Charges/Taxes	Hard		
Security Fees	Hard		
Shipment Liability Costs	Hard		
Shrinkage Cost	Hard		
Special Handling	Hard		
Stockout Cost	Hard		
Taxes	Hard		
Technology	Hard		
Utilities	Hard		

Table 4.3: Categorization of Costs Based on Measurability

4.3.2 Variability Drivers

Through our study, we discovered that variability can add tremendous cost into the channel. To measure the full impact of variability on our identified costs, we looked at factors that drove this variability and then modeled the forces that drove these changes. Interviews and research provided a basis for determining key variability drivers. We found that "Value" and "Volume" fluctuations accounted for a majority of variability in our system. For instance, taxes were value-based costs and could change when the value of the product changed. In the case of volume fluctuations, we saw that utilities costs

could vary based on the production volume. Other significant drivers of variability are listed in Table 4.4.

Costs Identified	Variability Drivers
Cost of Capital	Exogenous Rates
Fuel Surcharges	Exogenous Rates/Distance
Currency Exchange Costs	Exogenous Rates/Value
Ease of Business	Location
Environmental Fees	Location
Facilities Cost	Location
Other Overhead	Location
Safety Costs	Location
Learning Curve Cost	Location/Product
Licensing Fees	Location/Product
Regulations	Location/Product
Special Handling	Location/Product
Security Fees	Location/Value
Port Charges/Taxes	Location/Volume
Technology	Product

Costs Identified	Variability Drivers
Mode	Type
Damaged Product Cost	Value
Insurance	Value
Quality	Value
Shipment Liability Costs	Value
Stockout Cost	Value/Product
Lead Time	Value/Time
Import/Export Fees	Value/Volume
Inventory Holding Costs	Value/Volume
Risk	Value/Volume
Taxes	Value/Volume
Utilization	Value/Volume
3rd Party Logistics	Volume/Distance
Utilities	Volume/Location
Labor Costs	Wages/Employees

Table 4.4: Categorization of Costs Based on Variability Drivers

4.3.3 Categorization Profiles

From our categorization we found that many costs share common variability drivers. For instance, both shipping liability and quality costs depended on the product value. Therefore, any increase in product value would result in increased shipping liability and quality costs. Grouping these costs by common variability drivers, we found four main cost profiles: Channel, Volume, Value, and Product based costs. Costs which have other variability drivers can fall into these categories as explained in the following sections.

Costs which depend on the intrinsic characteristics of a channel, regardless of the product being distributed, can be broadly defined as Channel Attribute Costs. These costs contain political, environmental, and operational costs that may vary based on the particular conditions and attributes of the source region. Many of these costs are also determined by exogenous factors such as the cost of capital – which is based on interest rates and expected return. These costs provide a basic comparison of channels and are further described in Chapter 5. A list of these costs is provided in Table 4.5.

Cost Group	Type	Major Costs
Channel Attribute Costs	**Hard Costs**	Cost of Capital
		Environmental Fees
		Facilities Cost
		Other Overhead
		Utilities
	Soft Costs	Ease of Business
		Safety Costs

Table 4.5: Channel Attribute Costs Profile Table

Costs that change due to production volume fluctuations were grouped as volume based costs. Most of these costs increased with high volume production. For example, the cost of 3PL and port charges/taxes will increase with larger volume of products shipped. A complete list of volume based costs from our study is provided in Table 4.6.

Cost Group	Type of Cost	Major Costs
Volume Based Costs	**Hard Costs**	3rd Party Logistics
		Import/Export Fees
		Insurance
		Inventory Holding Cost
		Port charges/taxes
	Soft Costs	Risk
		Utilization

Table 4.6: Volume Based Costs Profile Table

Value based costs have the strongest influence on the total costs within a supply chain channel. As the name suggests, the extent of these costs varies with the value of the product. For example, the cost of insurance and taxes are often levied on the market value and profit margins of the product. In the case of the pharmaceutical industry, patented drugs can hold enormous value, especially on a cost per ton basis. Thus, value based cost within the pharmaceutical industry become quite significant when shipping products valued at upwards of $50 million per container.

Additionally, product values can have an impact on costs that are not directly variable with value. Labor wages and fuel surcharges are examples where the costs do not change with fluctuations in product value. However, when product values are low, the impact of labor wages and fuel surcharges become greater because they contribute a larger share of total costs. Although they are not directly variable with Value, their influence on total costs changes as value changes. Table 4.7 provides a list of these costs.

Cost Group	Type of Cost	Major Costs
Value Based Costs	Hard Costs	Currency Exchange Costs
		Fuel Surcharges[1]
		Import/Export Fees
		Insurance
		Labor Costs[1]
		Mode[1]
		Security fees[1]
		Shipment Liability Costs
		Shrinkage Cost
		Stockout Cost
		Taxes
	Soft Costs	Lead Time
		Quality
		Risk
		Utilization

Table 4.7: Value Based Costs Profile Table

Costs which depend on special product characteristics are categorized as Product Attribute Costs. These costs primarily vary based on unique rules, restrictions, conditions, and properties of the products being shipped. For example, some biologically engineered drugs require complex, dedicated plants for production. Furthermore, some may require temperature regulated shipping, resulting in additional costs. These costs are unique to each product and should be calculated on an individual basis as described in section 5.3. A list of costs which vary based on product attributes is listed in Table 4.8.

[1] Although not directly variable with Value, these costs gain a stronger share of total costs when the Value of products are low

Cost Group	Type	Major Costs
Product Attribute Costs	**Hard Costs**	Licensing Fees
		Special Handling
		Technology
	Soft Costs	Learning Curve Costs
		Regulations
		Stockout Costs[1]

Table 4.8: Product Attribute Costs Profile Table

These cost categorizations provided deep insight into the behaviors of our channel costs. In the following section we discuss how these costs can be used for evaluating channel strategy and a model for determining total acquisition costs.

[1] Stockout costs may be a "Soft" Product Cost in the case of life-saving drugs.

5 Results and Insights

Through the trends and groupings discussed in the previous sections we identified three categories of costs, namely channel costs, costs linked to volume and value, and costs associated with specific product attributes. This categorization was insightful but not very helpful in guiding the decision maker.

To address this shortcoming, we decided to explore the connection between variable costs and product type. In other words, we wanted to associate a cost that was variable with respect to volume and value to a type of product. Once the costs and product types were linked, we investigated business strategies for the four product types based on the underlying cost drivers. Finally, we created a process that could compare the cost of a product in two channels and figure out which option would be better during different periods of a product's lifecycle. In the next sections, we develop the models and frameworks necessary to achieve these goals.

5.1 Product Type Matrix

Based on our conversations with the pharmaceutical company representatives and research, we identified different product types that sell in various segments of the market. In general, the product types could be summarized into four broad categories based on their volume and value characteristics:

1. High volume, high value products
2. Low volume, high value products
3. High volume, low value products
4. Low volume, low value products

"Volume" and "Value" offer an effective means to capture the differentiating characteristics of various products, but these must be linked to market forces in order to develop meaningful business strategies for each one. Clearly, volume is driven by demand and value is related to the pricing power (or the profit margin) a product can command. Accordingly, we describe the four product categories as follows:

1. **Blockbuster**[1]**:** a product with high demand and high pricing power
2. **Specialist:** a product with low demand and high pricing power
3. **Commodity:** a product with high demand and low pricing power
4. **Underperformer:** a product with low demand and low pricing power

The product type matrix was created by arranging these product categories on a grid with a Demand axis and a Pricing Power axis as seen in Figure 5.1.

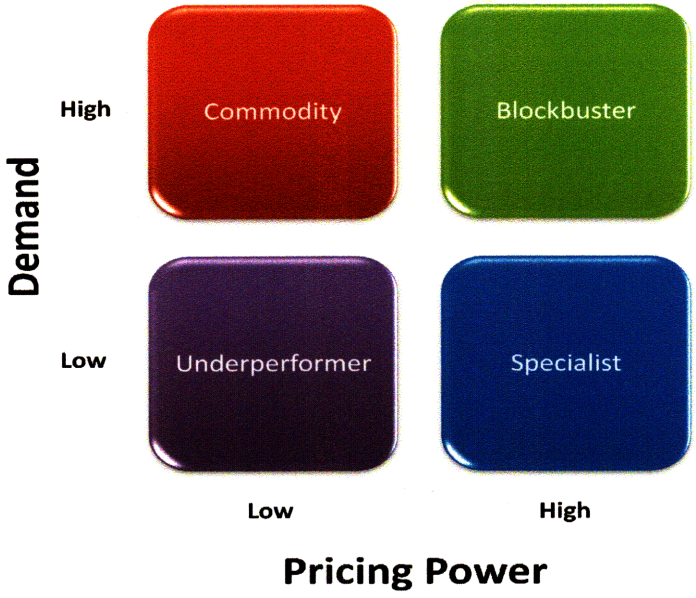


Figure 5.1: Product Type Matrix

[1] In our framework, the term Blockbuster refers to any product with high demand and high pricing power. This does not necessarily denote a pharmaceutical blockbuster, which is a drug with greater than $1 billion in annual sales.

With these four simple categories and knowledge of where a product fits into the matrix, the variability drivers, the most relevant costs, and the business strategy for the product can be determined. Even though our research focused on the pharmaceutical industry, these categories are not specific to that industry. Almost any industry has products that fall in most if not all four quadrants and this model can be adapted by altering the relevant costs associated with each product to the industry in question.

5.1.1 Blockbuster Products

A Blockbuster product is characterized by high demand and high pricing power. The variability drivers that affect this product type are costs that vary with both volume and value. An example of this type of product in the pharmaceutical industry is a hot, newly patented drug for which there is little competition in a large therapeutic category. The relevant costs for a Blockbuster are variable with both volume and value, as shown in Table 5.1:

Cost Group	Type of Cost	Major Costs
Blockbuster: Product with high pricing power and high demand	**Hard Costs**	3rd Party Logistics
		Currency Exchange Costs
		Import/Export Fees
		Insurance
		Port charges/taxes
		Security fees
		Shipment Liability Costs
		Shrinkage Cost
		Stockout Cost
		Taxes
	Soft Costs	Lead Time
		Quality
		Risk
		Utilization

Table 5.1: Blockbuster Relevant Costs

With little competition, the product will have overwhelming control of pricing power and command high margins for the parent company. It will also be in high demand with very few substitutes. Availability is incredibly important for this type of product since short-term demand can exceed supply and any stockout results in a lost sale.

The Hard costs for Blockbusters are largely related to the value these types of products have, both financially and physically. Tax implications are significant and currency exchange can be high. Shipment liability costs become a problem because one shipping container full of a Blockbuster product can be worth millions of dollars and some freight carriers don't want this liability. Physically the product needs to be protected from theft and damage, so security fees and shrinkage costs are very relevant.

On the Soft cost side, lead time affects the speed to fill demand and lower lead time leads to lower inventory levels. Since a Blockbuster is usually a high visibility product, quality must be outstanding to prevent bad press and a bad reputation. This ties into the large risk associated with a Blockbuster product, as it has a huge impact on the company's bottom line and brand equity.

The business strategy for a Blockbuster should be to ensure capacity and technical capabilities will be sufficient to support expected demand. It is important for facilities making the product to maximize utilization and there should be tight controls on the shipping channels to prevent counterfeiting and protect intellectual property. Production should take place in tax-advantaged locations even though these locations may not have the lowest factor costs. Service should be chosen over operational or logistics costs in order to ensure availability to the customer.

5.1.2 Specialist Products

A Specialist is a product characterized by low demand and high pricing power. The variability drivers that affect this type of product are costs that vary with value and to a much lesser extent, volume. Some examples of this type of product in the pharmaceutical industry are a niche, patented drug aimed at a small therapeutic category or a drug that has more side-effects than a competitor and has seen reduced demand. The product still has control of pricing power and commands high margins, but lacks the demand to be a superstar performer. The relevant costs for a Specialist are similar to a Blockbuster without as many volume-variable costs. The Hard and Soft costs are summarized in Table 5.2 below.

Cost Group	Type of Cost	Major Costs
Specialist: Product with high pricing power and low demand.	**Hard Costs**	Currency Exchange Costs
		Import/Export Fees
		Insurance
		Inventory Holding Costs
		Security fees
		Shipment Liability Costs
		Shrinkage Cost
		Stockout Cost
		Taxes
	Soft Costs	Lead Time
		Quality
		Risk
		Utilization

Table 5.2: Specialist Relevant Costs

The Hard costs for Specialists are still related to the value these types of products have and are similar to the Blockbuster. Inventory holding costs are more relevant for a Specialist because lower demand may cause product to sit on a shelf longer before being

sold into the channel. Due to its high value, excess inventory could quickly add cost to the supply chain.

The Soft costs for a Specialist are the same as those for the Blockbuster but less emphasis has to be placed on utilization since demand is usually being met by supply. The business strategy for a Specialist should be to ensure availability to take advantage of the profit margins but lower demand and expiration concerns add pressure for lean inventory. Production should take place in tax-advantaged locations but may be a secondary product in a facility behind a Blockbuster.

5.1.3 Commodity Products

A Commodity is a product characterized by high demand and low pricing power. The variability drivers that affect this type of product are costs that primarily vary with volume. An example of this type of product in the pharmaceutical industry is a popular drug that has come off patent but still has high utility with many people. The relevant costs for a Commodity are ones that are variable with volume. The Hard and Soft costs are summarized in Table 5.3 below.

Cost Group	Type of Cost	Major Costs
Commodity: Product with low pricing power and high demand.	**Hard Costs**	3rd Party Logistics
		Fuel Surcharges
		Import/Export Fees
		Insurance
		Labor Costs
		Mode
		Port charges/taxes
	Soft Costs	Risk
		Utilization

Table 5.3: Commodity Relevant Costs

Since the product faces very similar substitutes it must compete aggressively on price and has little pricing power in the market. Even though Commodities have lower profit margins, their large volumes can add significant revenue and are an important product category.

The Hard costs for Commodities are much different than the Blockbuster or Specialist since the profit margins are so much lower. With a commodity, the operational and logistics costs become more significant. Labor costs and import/export fees now add a more considerable cost. The taxable value of Commodities is much less and logistics related costs such as the mode chosen, fuel surcharges, and the 3rd party logistics provider selected account for a higher percentage of total cost.

On the Soft cost side, risk is still a relevant cost because the volume of Commodities shipped increases the odds that something could go wrong. Plant utilization is important not only to fill the large customer demand for Commodities, but also to maximize the fixed assets and lower per unit costs.

Due to lower margins, these products are more cost-sensitive and require optimization at a more granular level. The business strategy for a Commodity should focus on lowering operational and logistics costs while still ensuring enough capacity to meet expected demand. Production should be located near distribution markets rather than in tax-advantaged locations. Facilities making the product must maximize utilization and there should be an emphasis on using cheaper modes of transportation. A company cannot afford to airship or expedite Commodities and remain cost-competitive for long.

5.1.4 Underperforming Products

An Underperformer is a product characterized by low demand and low pricing power. Operational and logistics costs need to be minimized as much as possible to try to generate a profit. Examples of this type of product in the pharmaceutical industry are a Specialized product that came off patent or a Commodity that has lost significant demand due to strong competition. This type of product faces very similar substitutes, often with superior features or fewer drawbacks, and must compete exclusively on price. Underperformers have little to no pricing power and do not have the volume to make up for it. The relevant costs for an Underperformer are summarized in Table 5.4 below.

Cost Group	Type of Cost	Major Costs
Underperformer: Product with low pricing power and low demand.	**Hard Costs**	Fuel Surcharges
		Inventory Holding Costs
		Labor Costs
		Mode

Table 5.4: Underperformer Relevant Costs

Underperformer costs are all Hard costs as it struggles to survive in the market, anything that adds cost, such as labor, mode, or fuel need to be minimized. Since demand is low, inventory holding costs are very relevant to an Underperformer. These products might have been replaced by superior alternatives in the market rather abruptly; consequently obsolescence of excess inventory can be significant.

With an Underperformer product, a company must look for ways to minimize total acquisition costs across the supply chain. Possible strategies would be to manufacture in developing countries or cease production altogether. Marketing and exposure may be able to boost demand for an Underperformer, but if the product suffers a serious strategic or functional disadvantage it may have to be discontinued.

5.2 Introduction to Forces

Within the Product Type Matrix, products are not locked into a category and can shift from one category to another depending on certain forces as described in the following sections. When a product jumps categories, different costs become more relevant and the business strategy should change to take advantage of the new variability drivers acting on the product. This is especially important for the pharmaceutical industry as a drug moves through its lifecycle from patented to generic phases that are very different from each other. In the following sections, we analyze the types of forces that act on both a product's pricing power as well as its demand and develop some strategies to deal with these forces. A visual representation of the forces is provided in Figure 5.2.

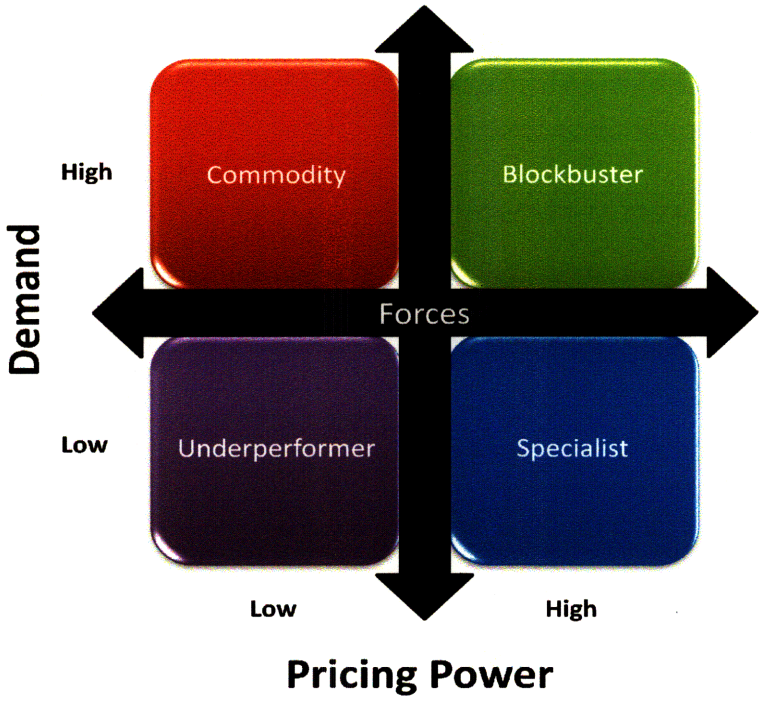


Figure 5.2: Product Type Matrix with Market Forces

5.2.1 Forces that Impact Pricing Power

There are two forces that impact pricing power: Pricing Pressure and Barriers to Entry. The forces act in opposite ways to either decrease or increase the pricing power of a product.

5.2.1.1 Pricing Pressure

Pricing Pressures can come in many different forms but they all have the same effect; they push the pricing power down. The profit margin on the product begins to shrink and it becomes more price-sensitive. Throughout this process, more emphasis must be placed on the operational and logistics costs to stay cost competitive. In terms of our matrix, Pricing Pressure moves a Blockbuster to a Commodity or a Specialist to an Underperformer as seen in Figure 5.3.

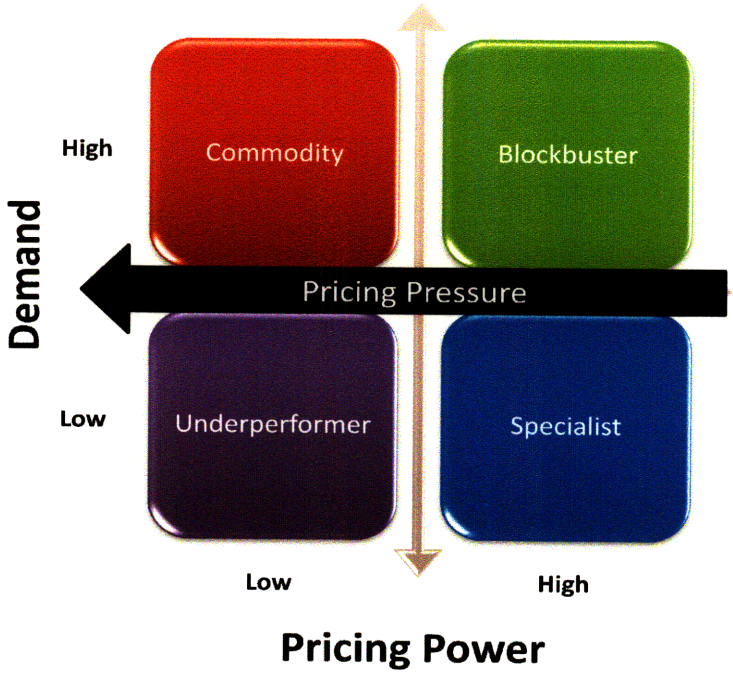


Figure 5.3: Pricing Pressure Force

A relevant example of Pricing Pressure in the pharmaceutical industry is the patent expiration of a drug. When a drug first enters a market, it has patent protection

and very strong pricing power. This results in high profit margins and allows the pharmaceutical company to recoup the costs associated with developing the drug. As the drug moves through its lifecycle, the patent expiration becomes a factor. Once the drug comes off patent, it is exposed to extreme Pricing Pressure from generic drugs that offer the same chemical formula for up to 50% less. Because of the Pricing Pressure force, a Blockbuster now becomes a Commodity and the pharmaceutical company must prepare its supply chain and lower its costs in anticipation of this event.

5.2.1.2 Barriers to Entry

If Pricing Pressure reduces pricing power, creating Barriers to Entry can increase or protect the pricing power of a product. With barriers erected around a product, a company has more freedom to set the price of the product at the level they desire as seen in Figure 5.4. Profit margins are insulated and the product enjoys success in the market.

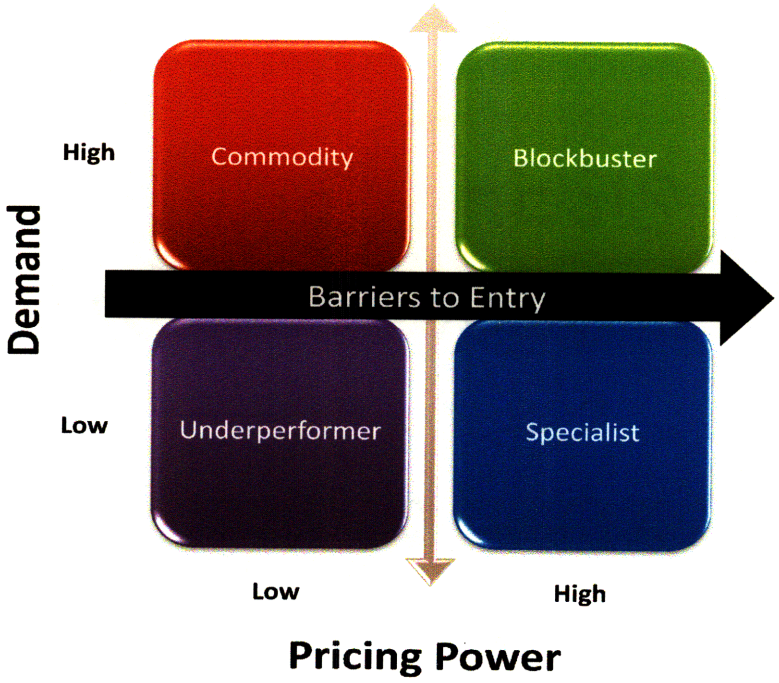


Figure 5.4: Barriers to Entry Force

We have identified five Barriers to Entry that are powerful in the pharmaceutical industry, but can also be applied to any industry using this model:

5. IP innovation
6. Brand equity and reputation
7. New technology
8. High capital costs
9. High risk

IP innovation is one of the strongest barriers since patents provide legal protection of a product for 20 years in the United States. It is also the barrier that pharmaceutical companies rely on to protect their Blockbuster products from generic competition. While IP innovation is powerful, it is finite in nature. Once the patent runs out, the product can be copied.

When this happens, the brand equity barrier becomes more important. If people are used to or trust a certain brand name they will continue to purchase that product even if lower cost substitutes appear on the market. Brand equity can sustain the profitability and pricing power of a product long after the product is copied and substitutes appear.

New technology and high capital costs provide more structural Barriers to Entry, as some players simply cannot match the resources of larger, established companies. In the pharmaceutical industry, the high price of R&D prevents some companies from developing the latest drugs while it gives the multi-national companies a strategic advantage. The smaller companies have to be quick followers and are not able to challenge the latest discoveries that require expensive technology and investments.

Finally, high risk can preserve pricing power by preventing some companies from entering a market and rewarding other companies that have successfully taken the risk. Higher levels of risk are associated with the first-movers and innovators in many industries and this is very true in the pharmaceutical industry as well. Only 1 out of 10,000 drugs that enter the discovery stage end up as a commercialized product. This is a large gamble with a high risk/reward ratio and allows companies that accept the risk to enjoy strong pricing power in the market if they are the first to commercialize a new drug.

5.2.2 Forces that Impact Demand

Similar to pricing power, there are also two forces that impact demand: Market Pressure and Market Growth. The forces act in opposite ways to either decrease or increase the demand for a product.

5.2.2.1 Market Pressure

Market Pressure has been a force as long as there has been competition in business. When a strong, new product enters a stable market, it usually takes demand away from the other products in the market. Demand degradation is even greater if the new competitors offer more features, better ease-of-use, or fewer problems than the current products. Figure 5.5 below describes the Market Pressure force.

Substitutes can have similar effects without being direct competitors. Substitutes can sometimes create disruptive shifts to totally new product categories and permanently reduce the demand for a product regardless of what a company tries to do. For example, obtaining news from the Internet has reduced demand for traditional newspapers even

though it is a totally different technology. The shift from compact discs to digital MP3s is another example of substitutes impacting demand for a product.

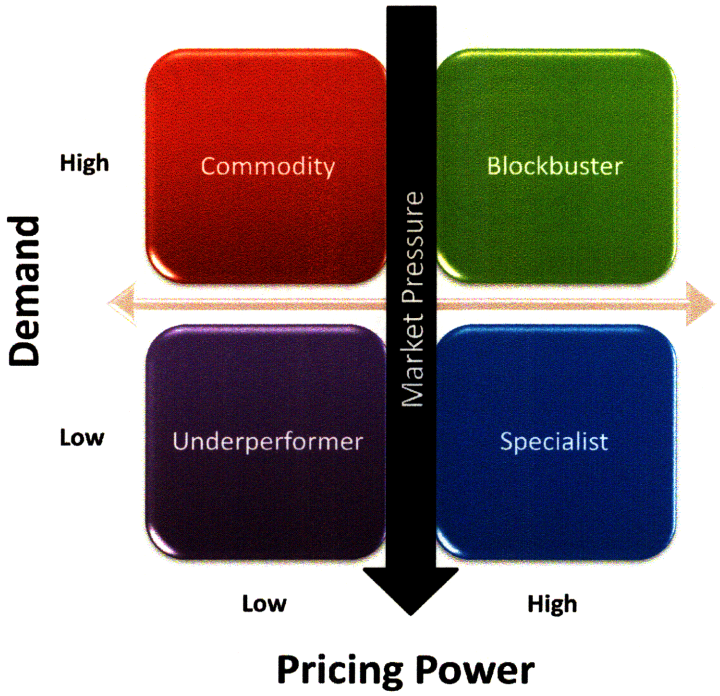


Figure 5.5: Market Pressure Force

Like other industries, the pharmaceutical industry is vulnerable to Market Pressure. New drugs that produce fewer side effects can move a former Blockbuster to a Specialist that is only prescribed for a certain class of patients. Since the drug development cycle is so long, a company can beat another company to market before they even have a chance to launch the drug. If the slower-to-market drug is inferior in its effectiveness to the first mover, millions in R&D could be lost as there will be less demand.

5.2.2.2 Market growth

The final force is Market Growth and it serves as a way to increase demand and counteract the competitive force (Figure 5.6). Even if new products enter a market, if the

whole market is expanding then there is plenty of demand to accommodate the new product. Market Growth can be accomplished through organic growth for a product or through marketing and advertising activities that shift consumer preferences towards a certain type of product. Underperformers can become Commodities by finding new markets to sell through or new ways to use the product that make it more desirable.

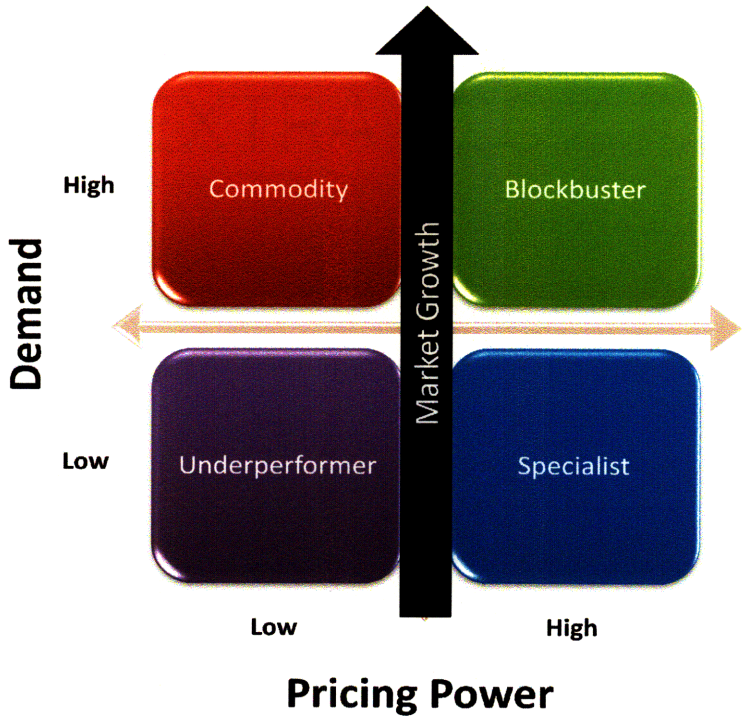


Figure 5.6: Market Growth Force

The pharmaceutical industry has seen Market Growth in a variety of areas and will continue to see growth as baby boomers age and the need for drug therapies increases. Uncontrollable events, such as pandemics and new virus strains, can instantly create Market Growth and generate large demand in a previously unknown or untapped therapeutic category.

5.3 Channel Cost Operational Model

The Product Type Matrix provides a framework for determining the primary channel costs based on demand and pricing power. Analyzing the market forces provides insight into how product costs change due to competitive and pricing pressures. However, in order to evaluate and choose the optimal supply chain channel, we linked the strategic elements from the framework and market forces to an operational method for evaluating costs. Figure 5.7 provides a visual representation of a method for quantifying total channel costs.

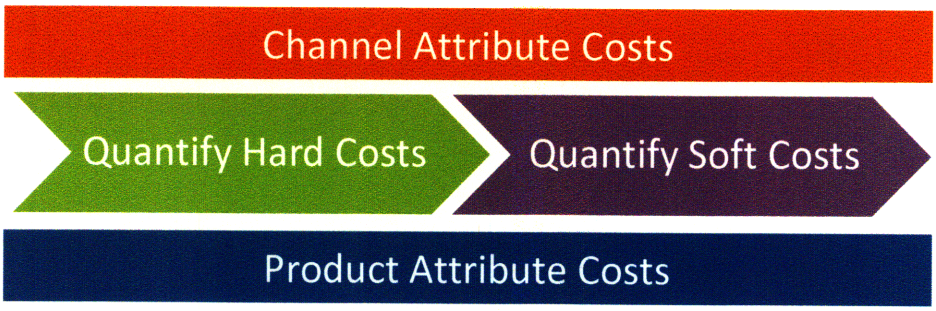


Figure 5.7: Channel Cost Operational Model

The top element, called Channel Attribute Costs, have the broadest scope of influence, with costs that apply across all product types within a channel. For example, Environmental Fees and Ease of Business depend on the location of the channel and do not depend on production or distribution decisions. In evaluating multiple channel options, these costs provide a baseline for determining basic feasibility of the channels. Although these costs help evaluate channel viability, looking only at Channel Attribute Costs is incomplete and could be misleading, since facilities can produce a dedicated line of products and most likely have varying amounts of each product type. A list of Channel Attribute Costs is listed in Table 5.5.

Cost Group	Type of Cost	Major Costs
Channel Attribute Costs	**Hard Costs**	Cost of Capital
		Environmental Fees
		Facilities Cost
		Other Overhead
		Utilities
	Soft Costs	Ease of Business
		Safety Costs

Table 5.5: List of Channel Attrittibute Costs

The bottom tier of our Operational Model, called Product Attribute Costs, identifies costs with the narrowest scope. These costs, such as hazardous material handling and special training, apply to the channel on a product specific basis. Although many pharmaceutical products have unique Product Attribute Costs, these costs also tend to be a small fraction of total costs. However, in the case of biopharmaceuticals, special requirements such as Cold Chain Shipping and Technology can be significant costs in the channel. A list of Product Attribute Costs is provided in Table 5.6.

Cost Group	Type of Cost	Major Costs
Product Attribute Costs	**Hard Costs**	Licensing Fees
		Special Handling
		Technology
	Soft Costs	Learning Curve Costs
		Regulations

Table 5.6: List of Product Attribute Costs

Finally, the middle tier of our Operational Model, describes a method for quantifying channel costs based on the Product Type. By quantifying both Channel Attribute and Product Type Costs, a company can most effectively and efficiently compare channel costs across its entire portfolio of product options. Since Product Type costs accounted for the largest proportion of channel costs, we will focus on quantifying costs based on Product Type.

5.3.1 Quantifying Hard Costs

We calculated our channel costs by identifying the Hard costs for the Product Type which will be produced. This determination was made by anticipating demand and pricing power characteristics of the product. For example, a Blockbuster drug is predominantly driven by Hard costs such as taxes, insurance, stockout cost, currency exchange costs, to name a few. These costs by definition are directly measurable for each product type. We must also keep in mind that many of these Hard costs are variable with respects to value and volume – see Table 5.7. This variability will play an important role in sensitivity analysis as described in section 6.1.

Cost Group	Hard Costs	Channel 1 Cost[1] ($/ton)	Channel 2 Cost[1] ($/ton)
Blockbuster	3rd Party Logistics	0.80	0.50
	Currency Exchange Costs	5.72	4.50
	Import/Export Fees	3.25	1.25
	Insurance	3.30	3.50
	Port charges/taxes	0.50	0.50
	Security fees	3.50	6.50
	Shipment Liability Costs	4.30	6.30
	Shrinkage Cost	5.22	5.30
	Stockout Cost	8.15	10.25
	Taxes	25.00	10.00
Total		**59.74**	**48.60**

Table 5.7: Demonstrative Table of Hard Costs for a Blockbuster Product

5.3.2 Quantifying Soft Costs

Soft costs are generally harder to measure due to their indirect impact on channel costs. One method of quantifying Soft costs is to find suitable proxy Hard costs. For instance, lead time, in itself, is difficult to assess in terms of dollar values. However, lead time can

[1] These values are for demonstrative purposes and do not reflect actual costs values

impact the stock requirements and thus has a strong relationship with inventory holding costs as it depends on the standard deviation of forecast errors over the lead time (Silver Pyke, Peterson 1998) – see Figure 5.8.

$$Inventory\ Holding\ Cost = \left(\frac{Q}{2} + k\sigma_L\right) vr$$

Figure 5.8: Holding Cost Equation

Obviously, not all Soft costs can be approximated using good proxies to calculate their Hard cost equivalent. For instance, in the case of a Blockbuster drug, although quality and utilization impact Hard cost values, it is still difficult to quantify. In this scenario, a regression analysis is needed to determine the level of influence for each Soft costs on the analogous Hard costs. To set up a regression analysis we began by deconstructing Soft costs based on available Key Performance Indicators (KPI) that are used within an organization to measure these costs. For instance, quality was measured by Defects per Thousand. Using a regression analysis perspective, Shrinkage cost can be set as the dependant variable and compared against quality variables. Further discussion on conducting a regression analysis can be found in numerous statistical resources and is beyond the scope of this research.

Another common method for quantifying Soft costs is to use an index based on a scale of importance and salience (Cook 2007). Although this method is useful in comparing two channel options, it does not provide a monetary value for this cost. To do so, we again recommend conducting a regression analysis, comparing changing Soft cost indexes with equivalent Hard cost levels. This will require the collection of changing Soft cost indexes over time. An example of this type of quantification is provided for a Blockbuster's cost of risk in Table 5.8 below.

Risk	Importance (1-5)	Salience (1-5)	Total
Local Conditions	2	3	6
Labor Conditions	4	4	16
Currency Risk	3	1	3
Intellectual Property Issues	5	2	10
Natural Disasters	2	5	10
Total			45

Adapted from: Global Sourcing Logistics (2006)

Table 5.8: Quantifying the Impact of Risk

6 Model Extensions

A natural extension of this study would be to incorporate the time value of channel costs decisions. This is particularly important for the pharmaceutical industry since the lifecycle patterns resulted in drastically different cost structures as products moved off patent. In order to model the long term costs implication of this channel we suggest conducting sensitivity analysis and a net present value study.

6.1 Sensitivity Analysis Using Simulation Techniques

A key insight from our cost categorization was the behavior of costs as variability drivers fluctuate. For a complete analysis of supply chain channel costs, we took into account the anticipated changes in the variability drivers over time. Furthermore, the level of variation for each cost can be vastly different for each industry or product. We recommend a regression analysis be conducted to identify the regression coefficients (beta estimates) for each cost.

Simulation techniques, such as the Monte Carlo method, can model potential risks and rewards due to fluctuating variability drivers. The Monte Carlo method generates pseudo random samples and can be a powerful way of creating rich probabilistic scenarios. Although, simulation is beyond the scope of this research, we recommend future analysis to incorporate a simulation of variability drivers to model their impact on supply chain channel costs. A sample table of Hard and Soft cost regression coefficients for a Blockbuster product is provided in Table 5.8 for demonstrative purposes.

Cost Group	Type of Cost	Major Costs	Regression Coefficients[1]
Blockbuster	Hard Costs	3rd Party Logistics	0.02/$ + 0.1/ton
		Currency Exchange Costs	(0.033 * Exchange Rate) / $
		Import/Export Fees	0.01/$+ 0.02/ton
		Insurance	0.17/$ + 0.001/ton
		Port charges/taxes (varies by location)	0.152/ton
		Security fees (varies by location)	0.03/$
		Shipment Liability Costs	0.04/$
		Shrinkage Cost	0.05/$
		Stockout Cost (varies by product)	0.1/$
		Taxes	0.3/$
	Soft Costs	Lead Time	0.03/day
		Quality	0.04/$
		Risk	0.067/$ + 0.089/ton
		Utilization	0.01/$ + 0.01/ton

Table 6.1: Demonstrative Table of Regression Coefficients for Sensitivity Analysis

For other product types, one should use the Product Type Matrix to determine relevant costs. For example, a Commodity product has a unique set of relevant costs including fuel surcharges. Therefore, the fluctuation of fuel prices will be more important in analyzing the long term channel costs of Commodity versus Blockbuster products.

6.2 Net Present Value Analysis

Once costs are quantified and alternative scenarios are explored, we must develop a simple method to compare the different channels. The best method to compare multiple investment options is to use a NPV analysis which takes into account the time value of

[1] The values are for demonstrative purposes only and do not reflect actual values

money as well as the opportunity of capital (Brealey, Myers, Allen 2007). Thus, we can use NPV analysis to not only compare two channels within similar time horizons, but also compare the changing costs as the products mature in their lifecycle. The formula for a simple NPV analysis is provided in Figure 6.1 below.

$$NPV = \sum_{t=0}^{\infty} \frac{CF_t}{(1+r)^t}$$

Figure 6.1: Net Present Value Equation

To analyze the complex series of cost data from the previous sections, we must combine NPV calculations for multiple time windows. First, we analyze the current situation and the length in which we expect current situation to continue. Then we add cost figures for future scenarios, using time windows that best determine the expected length in which future conditions will last.

7 Conclusion

The pharmaceutical supply chain channel consists of costs that can be both simple and difficult to quantify. Furthermore, the global nature of today's supply chain networks adds complexity and difficulty to the evaluation of these channel costs. The challenge in this research was to develop a method for evaluating differences in supply chain costs across multiple channels. In order to answer this question, we began by identifying all relevant costs.

Cost identification was vital for this research and provided a clearer picture of both the direct and indirect costs associated with a global pharmaceutical supply chain. Once costs were identified, our categorization process revealed that costs can be broadly grouped by Channel Attributes, Product Type, and Product Attributes based on the variability drivers for each cost. Our analysis of these variability drivers found that a large percentage of costs were dependent on fluctuations in value and volume of products.

We discovered that value and volume differences are largely tied to demand and pricing power. We categorized and developed our framework based on varying levels of demand and pricing power to arrive at four product types: Blockbuster, Specialist, Commodity, and Underperformer. Developing the framework based on product type was an important insight because it offered an effective and meaningful criterion to simplify and analyze the most relevant costs in a broad array of industries.

The identification of market forces explained how a product's demand and pricing power could change over time. Forces such as Pricing Pressure due to lifecycle maturation can cause a Blockbuster to lose their pricing power and become a

Commodity. Similarly, Market Pressure causes Commodities to become Underperformers and Blockbusters to become Specialists. Market Growth and Barriers to Entry help preserve or even increase demand and pricing power respectively. Identifying these forces was crucial for not only explaining supply chain channel costs that affect a product at a given point in time, but also incorporates new relevant costs as the pricing power and demand change.

Finally, we provided an operational model which quantifies both Hard and Soft costs to arrive at a single number, which can be used to compare multiple channels. Using the framework and operational model together provides a complete set of tools for analyzing channels costs, not only between multiple regions, but also across multiple time horizons.

References

Bauernfeind, D., Kuhn , S., Kuppers, S. (2008) Supply Chain Event Management in the Pharmaceutical Industry – Status and Outlook. In Ceyp, M., Emmerich, H., Ijioui, R. (Eds.), Strategies and Tactics in Supply Chain Event Management. (pp. 13 – 34). Berlin: Springer-Verlag.

Brealey, R., Myers, S., Allen, F. (2007) Principle of Corporate Finance, 9th Edition. New York, NY: McGraw-Hill/Irwin.

Cremer, P., Losch, M., Schrader, U. (2009) Maximizing efficiency in pharma operations. New York, NY: The McKinsey Quarterly.

Cook, T. A. (2007) Global Sourcing Logistics: How to Manage Risk and Gain Competitive Advantage in a Worldwide Marketplace. New York, NY: AMACOM.

Cooper, R., Kaplan, R.S. (1988) Measure Costs Right: Make the Right Decisions. In Harvard Business Review September-October 1988. Boston, MA: Harvard Business Publishing.

Dalkey, et al. (1972) About Delphi Method. Retrieved May 2, 2009, from Delphi Study Web Site: http://www.delphistudy.org/about.html

Greener, M. (2001) A Healthy Business: A Guide to the Global Pharmaceutical Industry. London, United Kingdom: Urch Publishing Ltd.

Mentzer, J. T., Myers, M. B., Stank, T. P. (2007) Handbook of Global Supply Chain Management. Thousand Oaks, CA: Sage Publications.

McIntyre, A. M., (1999) Key Issues in the Pharmaceutical Industry. West Sussex, England: John Wiley & Sons Ltd.

Norton, D. P., Kaplan, R. S. (1992) The Balanced Scorecard – Measures that Drive Performance. In Harvard Business Review January-February 1993. Boston, MA: Harvard Business Publishing.

Norton, D. P., Kaplan, R. S. (1996) Linking the Balanced Scorecard to Strategy. In California Management Review Vol. 39, No. 1. Berkley, CA: The Regents of the University of California.

Pharmaceutical Research and Manufacturers of America "PhRMA" (2009) Pharmaceutical Industry Profile 2009. from PhRMA Web site: http://www.phrma.org/files/PhRMA%202009%20Profile%20FINAL.pdf

Porter, M. E. (1980) Competitive Strategy. New York, NY: The Free Press, a Division of McMillan Inc.

Porter, M. E. (1985) Competitive Advantage. New York, NY: The Free Press, a Division of McMillan Inc.

Ranjan, V. K. (2006) Transforming Your Go-To-Market Strategy. Boston, MA: Harvard Business School Press.

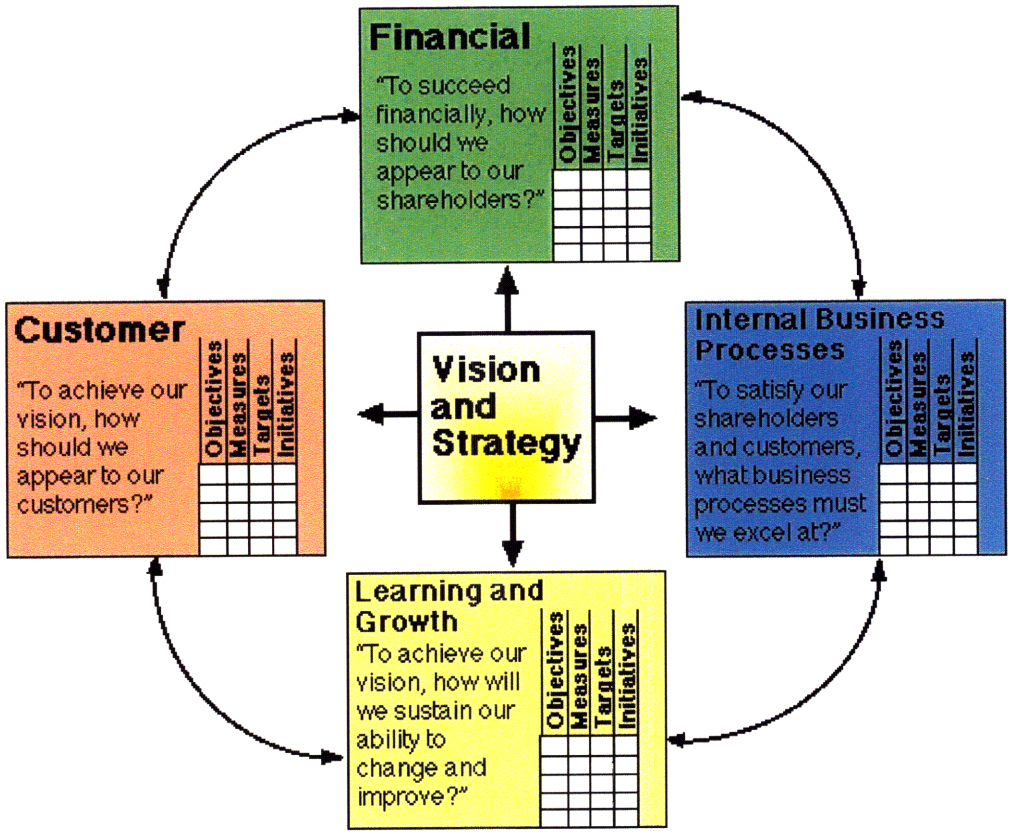
Reepmeyer, G. (2006) Risk-sharing in the Pharmaceutical Industry: The Case of Out-licensing. Heidelberg, Germany: Physica-Verlag.

Silver E.A, Pyke, D. F., Peterson, R. (1998) Inventory Management and Production Planning and Scheduling. Hoboken, NJ: John Wiley & Sons, Inc.

Singh, M. P. (2005). The Pharmaceutical Supply Chain: A Diagnosis of the State-of-the-Art. Unpublished master's thesis. Cambridge, MA: Massachusetts Institute of Technology.

Stern, C. W., Deimler, M.S. (2006) The Boston Consulting Group on Strategy. Hoboken, NJ: John Wiley & Sons, Inc.

Appendix A: The Balanced Scorecard



Source: http://www.valuebasedmanagement.net/methods_balancedscorecard.html

Linking the balanced scorecard to strategy has three different stages:

- Rapid Growth: Early lifecycle stage. Have to make considerable investments to develop and enhance new products and services.
- Sustain: Looking to earn excellent returns on investment
- Harvest: Mature lifecycle, looking at short payback windows with maximizing cash flow as the main goal.

Three financial themes to achieve their business strategies

1. Revenue growth and mix
2. Cost reduction / productivity improvement
3. Asset utilization / investment strategy

Appendix B: Import Landed Costs

Import Landed Cost
Purchase price
Method and cost for payment
Currency exchange costs
Foreign vendor packing charges
Foreign inland transportation charges
Foreign loading charges
Foreign inspection fees
Foreign port charges for CBP examination and no-load containers
International transportation charges (air, ocean, and ground transportation)
Ad valorem duties and taxes based on import value, specific duties and taxes based on import quantity, and compound duties based on both value and quantity
Merchandise processing fees based on 0.21 % of import value
Harbor maintenance fee for ocean shipments based on 0.125 percent import value
Anti-dumping fees based on CBP investigation into fair market price value methods, countervailing duty fees based on CBP investigation into foreign bounties grants, and subsidies paid to foreign vendors that may affect the price paid or payable
Security manifest fees
Fuel surcharge fees
Handling and freight transfer fees
Storage fees incurred on freight no picked up from the pier in 3 days from date of availability
International freight
U.S. inland transportation fees
U.S. warehousing, deconsolidation, storage, distribution, and break bulk fees
Messenger fees
U.S. Customers and Border Protection (CBP) examination fees
Other government agency examination fees (Agriculture, Fish and Wildlife Service, Environmental Protection Agency)

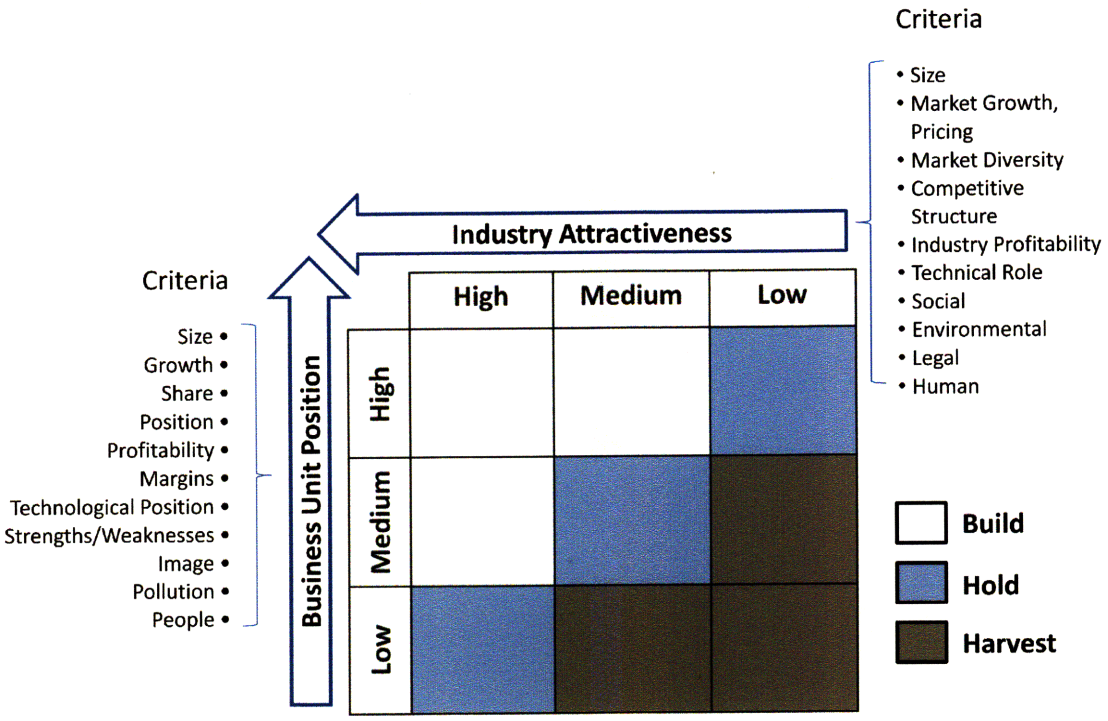
Source: Global Sourcing Logistics (2006)

Appendix C: Export Landed Costs

Export Landed Cost
Export packing
Warehouse in/out fee
Fumigation
Foreign inland freight
Automated Export System (AES) filing fee
Foreign loading
Foreign documentation fees (legalization, consularization), inspection fees
Insurance
Bank fees (Letter of credit fees, confirmation fees, messenger fees)
Ocean freight fees: currency adjustment factor, bunker fee, wharfage container fees (exceeding free time for loading)
Fuel fees
Security fees
Automated manifest system fee
Delivery charges (including accessorial charges: inside delivery, special delivery)
Duty
Value added tax (VAT)
Export forwarding fee
Document handling fee
Storage fees
Container inspection fees
Customers clearance
Messenger fees
Buying commission
Interest fees
Hazardous materials surcharge
State sales or other taxes or fees within that state that might be applicable for that product or business operation

Source: Global Sourcing Logistics (2006)

Appendix D: GE-McKinsey 9-Box Matrix



Appendix E: List of Costs by Product Type

Cost Group	Type of Cost	Major Costs
Blockbuster: Product with high pricing power and high demand	**Hard Costs**	3rd Party Logistics*
		Currency Exchange Costs
		Import/Export Fees
		Insurance
		Port charges/taxes*
		Security fees
		Shipment Liability Costs
		Shrinkage Cost
		Stockout Cost
		Taxes
	Soft Costs	Lead Time
		Quality
		Risk
		Utilization
Specialist: Product with high pricing power and low demand.	**Hard Costs**	Currency Exchange Costs
		Import/Export Fees
		Insurance
		Inventory Holding Costs
		Security fees
		Shipment Liability Costs
		Shrinkage Cost
		Stockout Cost
		Taxes
	Soft Costs	Lead Time
		Quality
		Risk
		Utilization
Commodity: Product with low pricing power and high demand.	**Hard Costs**	3rd Party Logistics
		Fuel Surcharges
		Import/Export Fees
		Insurance
		Labor Costs
		Mode
		Port charges/taxes
	Soft Costs	Risk
		Utilization
Underperformer: Product with low pricing power and low demand.	**Hard Costs**	Fuel Surcharges
		Inventory Holding Costs
		Labor Costs
		Mode

Appendix F: List of Costs by Channel and Product Attributes

Cost Group	Type of Cost	Major Costs
Channel Attribute Costs	**Hard Costs**	Cost of Capital
		Environmental Fees
		Facilities Cost
		Other Overhead
		Utilities
	Soft Costs	Ease of Business
		Safety Costs
Product Attribute Costs	**Hard Costs**	Licensing Fees
		Special Handling
		Technology
	Soft Costs	Learning Curve Costs
		Regulations

Appendix G: Finance Interview Notes

- All financials in the organization
- Shipping costs in a Supply Point to ship to other parts
    1. 25% of global logistics spend
- customer could be pharmacy (EU) or distributor (US)
- Handle the implications of exchange fluctuations (Trade group that's internally located in finance)
- Reviews buy/sell relationships
- Understand the implication of volume on costs
- Global budgeting usage and efficiency
- Determines expansion/shutdown needs
- Measures value of supply points for tax advantages
- Look at 3PL and 3PM efficiency metrics
- Key Performance Metrics
    1. Operational needs (not everything in HK)
    2. Then drive cost savings
- Supply Point uses
    1. Tax
    2. Lower visibility to competitors
    3. Central point to hedge expenses
- 3PL
    1. Good: multi-year contract
    2. Bad: held captive, enough spend for lower $
- Are assets the right size? Utilization efficiency
- First internal then outward
    1. Do current operations have capacity to service new lines
    2. Are there tax benefits within the country of demand

Costs:

1. Freight
    a. Local service provider
    b. Own operations

- Flexibility over total costs
    - Service to customer (Air freight)
- Own vs. outsource cost tradeoffs
    - 3PL and 3PM efficiency, scalability
- Customs controls

- EH&S (Environmental, Health and Safety)
- Security (who pays)
- Overhead
- Flexibility/ Agility of 3PL upfront versus ownership as business grows and product stabilizes
- Utilization maximization over cost efficiency

Appendix H: Sourcing Strategy Interview Notes

- Where to manufacture (41 sites)
- Network strategy
- Matching capacity to demand
    - A lot of locations are legacy or through acquisition (redundancies)
- Tax advantages (Ireland, Puerto Rico, Singapore)
- Capability is Important
    - Align products with BU's (e.g. Patented drugs require learning capabilities within the manufacturing functions)
    - Manage lifecycle (10 – 12 years)

Costs:

- Long term (M&A will cause redundant/excess sites)
- Fixed OH
- Trade Restrictions, local tax

Four main decision factors

1. Capacity at launch site
    a. Scale
2. Complexity
    a. Initial learning costs
    b. Efficiency
    c. Transportation
3. Technology
4. Factor Costs
    a. Labor
    b. Utilities

Also should consider tax benefits, political environment, and business friendliness of governments

- Lifecycle costs
- Logistics not huge (5% of patented drug costs)
- Migration (time-to-transition)
- Service (CSL)
- Proximity to market
- Quality, safety, environment (carbon tax), political
- Regulation (FDA approval)

Appendix I: Distribution Hubs Interview Notes

- Panama, Brussels, Hong Kong
- Prepares documents, handles controls
- Physical and transactional flow of goods
- Customs import/export
- Warehousing and cross docks (air and ground)
- Tolling – API, Transportation and Packaging all done remote. Supply points owns product for tax reasons
- 3 products manage flow
    - API
    - Semi-Finished
    - Finished
- Expedites routing through customized decisions
- No inventory responsibility
    - Service oriented, markets are inventory oriented
- Serve geographic more than BU
    - Different markets for each Supply Point
- Business friendly countries
- Need more load balance since Brussels handles majority

Costs:

- 60% of budget is logistics
- Manage people and facilities
    - Customer Service: transaction fulfillment/On time Delivery
    - Warehouse: order line efficiency
- Overhead for the system
- Regulatory agencies
    - Temperature regulations
- Complexity: modes, contracts
- Facility space
- Must meet quality to release product (EU)
- Import/export licenses (HK)
- Taxes
- Sunk costs

Appendix J: Transportation/Logistics Interview Notes

- Determines inventory each market should hold
- Make sure markets get product they need (demand planning)
- Movement of product around the world
    - Work with finance if product needs to go through specific Supply Point
- Uses different types: refrigerated, controlled substance, dangerous
- Tolling allows control while still getting tax advantage
- Availability of life-saving drugs paramount
    - High stock out costs (in-stock %, # of days in stock)
- Biggest concerns
    - Volume shipped
    - Service
    - Shipping requirements
    - Meeting orders perfectly (no missing lines)
    - Damaged goods
    - How many lines go through DC (utilization)
    - Socialized medicine – need more low cost products
- Tax/geographic tradeoff: depends on lifecycle
- Shift from demand for product to entitlement
- Freight audit and support
- Negotiate contracts (Finish Goods to Markets)
- Policy, procedure, & program WW
- Evaluate transportation providers by:
    - Service
    - Capability & Quality
    - Cost (looking for more ocean)
- Transportation Request for Pricing scorecard
- Fewer more strategic partnerships

Costs:

- Service > costs
- Fuel surcharge
    - Some contractors willing to do long term deals
- Availability in highly price and product controlled market
- High regulation: batch size, handling, materials, movement
- Reputation: brand, quality, availability
- Security
- Exchange rates

- Availability of ocean containers
- Liability ($50 MM containers)
- Damaged goods
- New product launches
- Capacity concerns
- Refrigeration
- Changing sources (may take anywhere from 30 days to 2.5 years)
- Outsourcing (certifications)
- Licensing (Cost, Time)