

STRATEGIC ANALYSIS FOR A NOT-FOR-PROFIT BIOPHARMACEUTICAL ENTERPRISE

by

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PROJECT SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF BUSINESS ADMINISTRATION

In the
Faculty
of
Business Administration

Biotechnology Specialization

Management of Technology Program

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SIMON FRASER UNIVERSITY



Fall 2006

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ABSTRACT

Two Vancouver scientists, using proteomic methods, identified key antigens to confer resistance to *Chlamydia trachomatis*. They created a prophylactic and therapeutic vaccine for sexually transmitted *C. trachomatis* infections. The inventors aim to commercialize this new product.

This strategic analysis presents competitive and internal analyses. An evaluation of strategic alternatives based on these analyses follows. The inventors intend for the public at large, and not the shareholders, to receive the benefits of the product. This report proposes a strategic plan that fits the inventors' goals. Market entry strategies and a business plan will evolve from the strategic analysis.

This strategic analysis provides the British Columbia Centre for Disease Control (BCCDC) information to help them decide on a business development strategic plan for Canada, the United States, and developing country markets.

*To my husband Steven,
and to my nonagenarian grandfather,*

Richard Berchman Prindiville,

I dedicate this work.

*Your encouragement and loving support
made the last two years a pleasure to endure.*

Je vous aime!

ACKNOWLEDGEMENTS

The BC Centre for Disease Control's GE³LS unit sponsored this project. To Michael Donoghue and Kris Roberts, I award a special thank you for their enthusiastic support and assistance.

To my academic readers, Dr. Aidan Vining and Dr. Colleen Collins-Dodd, I extend sincere appreciation for their guidance and editorial comments.

To my family, especially my brother David and my little nephew Seth, I offer my eternal gratitude for their love and support, and infinite patience over the last couple of years.

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LIST OF ACRONYMS

ACRONYM	DEFINITION
AIDS	Acquired Immune Deficiency Syndrome
BCCDC	British Columbia Centre for Disease Control
BLA	Biologic License Application
CAGR	Compound Annual Growth Rate
CBER	Center for Biologics Evaluation and Research
CFR	Code of Federal Regulations
CIHR	Canadian Institutes of Health Research
CIPO	Canadian Intellectual Property Office
CMC	Chemistry, Manufacturing and Controls
CRO	Contract Research Organization
DNDi	Drugs for Neglected Diseases Initiative
EDC	Electronic Data Capture
EMA	European Agency for the Evaluation of Medicinal Products
EUDRACT	European Clinical Trials Database
F/P/T	Federal, Provincial and Territorial
FDA	Food and Drug Administration
Gates Foundation	Bill and Melinda Gates Foundation
GAVI	Global Alliance for Vaccines and Immunization
GE ³ LS	Genomics' Ethical, Environmental, Economic, Legal and Social Issues
GLP	Good Laboratory Practices
cGMP	Current Good Manufacturing Practices
GSK	GlaxoSmithKline plc
HIV	Human Immunodeficiency Virus
HPFB	Health Products and Food Branch
IDB	ID Biomedical Corporation
IND	Investigational New Drug Application
IOM	Institute of Medicine

ACRONYM	DEFINITION
IOWH	Institute for OneWorld Health
IP	Intellectual Property
ITI	International Trachoma Initiative
MIS	Management Information Systems
NACI	National Advisory Committee on Immunization
NGO	Non-governmental Organizations
NIH	National Institutes of Health
O/L	Out-License
OECD	Organisation for Economic Co-operation and Development
PHAC	Public Health Agency of Canada
PhRMA	Pharmaceutical Research & Manufacturers of America
PID	Pelvic Inflammatory Disease
PMPRB	Patented Medicine Prices Review Board
PPPs	Public-Private Partnerships
PREPARE	Proteomics for Emerging Pathogen Response
PWGSC	Department of Public Works and Government Services Canada
QA	Quality Assurance
R&D	Research and Development
SAFE	Surgery, Antibiotic therapy, Facial cleanliness, and Environmental change
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UBC	University of British Columbia
UBC CDC	University of British Columbia Centre for Disease Control
USPTO	United States Patent and Trademark Office
VAERS	Vaccine Adverse Event Reporting System
VRBPAC	Vaccines and Related Biological Products Advisory Committee
WHO	World Health Organization
WTO	World Trade Organization

1 INTRODUCTION

This analysis examines the viability of developing a not-for-profit biopharmaceutical enterprise. The clients for this strategic analysis are Dr. Robert Brunham and the GE³LS unit of the British Columbia Centre for Disease Control (BCCDC). They have requested a strategic analysis that reviews the potential to create a Canadian not-for-profit biopharmaceutical enterprise, in order to commercialize a chlamydia vaccine.

This analysis provides the BCCDC with analytical information and presents them with strategic alternatives. The purpose is to help them decide on a viable corporate strategy with which to enter the marketplace. The envisioned biopharmaceutical enterprise is referred to as “the new entrant” or “AXS*Vax” in this analysis. The primary commercial markets sought are Canada, the United States, and developing countries.

The analysis that follows is broken down into nine chapters. It begins with some background information about the key stakeholders, the current situation, the biopharmaceutical industry, and the market potential for a chlamydia vaccine. This introductory background information leads into an external analysis of the industry’s competitive forces. The strategic analysis then moves from a broader industry perspective to a more narrow firm-focused perspective. An analysis of value creation within a typical biopharmaceutical firm follows. From these external and internal analyses, strategic alternatives emerge. There are four strategic alternatives presented and evaluated. This strategic analysis concludes with a recommendation for Dr. Brunham and the BCCDC’s GE³LS unit.

The project to commercialize a chlamydia vaccine began in the summer of 2006. Two Vancouver scientists, using proteomic methods, identified key antigens to confer resistance to *Chlamydia trachomatis*. They created a prophylactic and therapeutic vaccine for sexually transmitted *C. trachomatis* infections (chlamydia). The inventors aim to commercialize this new product. The inventors are associated with the BCCDC and the University of British Columbia (UBC). Although they conducted their research under these entities, stewardship of commercial decisions regarding the *C. trachomatis* vaccine belongs to the principal inventor, Dr. Robert Brunham. Dr. Brunham is also the Director of the British Columbia Centre for Disease Control.

The inventors secured funding for proof-of-concept studies in late summer 2006. These studies began in September 2006. The completion date is December 2006. They are currently seeking financial capital for further pre-clinical studies.

Legal agents filed provisional patent applications for the vaccine invention in Canada and the United States on October 02, 2006. A provisional patent application allows a grace period to make a patent filing decision. This grace period, up to twelve months in the US, permits the inventors an opportunity to evaluate technical value, market value, business development strategies, and to secure needed financial capital. The inventors will perform a social and economic cost-benefit analysis before summer 2007. They will decide which national states to invest in full patent protection by autumn 2007.

2 OVERVIEW OF THE CENTRE FOR DISEASE CONTROL AND THE NATURE OF CHLAMYDIA INFECTIONS

The chlamydia vaccine is a recent discovery. This chapter summarizes the role of the key stakeholders. The primary stakeholders are the BCCDC and UBC CDC, collectively called the CDC, and the two scientists. A secondary stakeholder is Genome BC. The chapter concludes with an overview of the epidemiology of genital chlamydia infections.

2.1 Role of the Centre for Disease Control

The BC Centre for Disease Control (BCCDC) is an agency of the Provincial Health Services Authority, in support of the Minister of Health Services and all residents of British Columbia. The BCCDC has the responsibility to support comprehensive programs for the prevention and control of communicable diseases and environmental health. BCCDC works collaboratively with the University of British Columbia Centre for Disease Control (UBC CDC) concerning the surveillance, control and prevention of communicable disease.

The UBC CDC is the research unit for the BCCDC. Established in 1998, its main goal is to provide a coordinated approach to public health. The UBC CDC business unit discovered the chlamydia vaccine under the Proteomics for Emerging Pathogen Response (PREPARE) Project. Genome Canada, Genome BC, and the Vancouver Coastal Health Research Institute funded this research project.

Dr. Robert Brunham is the Executive Director of the BCCDC, Director of the UBC CDC, and is a professor in the Department of Medicine, Division of Infectious Diseases at UBC. He is

one of three PREPARE project leaders. He is also the principle inventor of the chlamydia vaccine. Dr. Brunham established the BCCDC as a national Centre of Excellence in infectious disease research and control. Under his direction, the BCCDC demonstrated its scientific excellence and proficiency in 2003. The BCCDC contributed to the control of SARS in Canada and prevented its spread into British Columbia.

Dr. Leonard Foster is a co-inventor of the chlamydia vaccine. He is head of UBC's Cell Biology Proteomics Lab. His expertise with the Thermo Electron LTQ-FT analytical equipment allowed for the profiling of the key protein-protein interactions in chlamydia challenges. This profiling allowed for the formulation of the prophylactic and therapeutic vaccine.

The UBC University-Industry Liaison Office will retain ownership of the patent. The BCCDC will manage the intellectual property (IP) rights. Dr. Robert Brunham has 100% decision rights on the commercialization proceedings. The shareholders are:

- 15% CDC
- 35% UBC
- 30% Dr. Brunham
- 20% Dr. Foster

The CDC will develop the chlamydia vaccine for the time being. Dr. Brunham will make the decision whether or not to form an independent enterprise to commercialize the vaccine.

2.2 Role of Genome BC

Genome British Columbia (Genome BC) is a research organization that invests in large-scale proteomic research projects and technology platforms. As well as funding the PREPARE

project, Genome BC's Commercialization Committee invested \$150,000 for the chlamydia vaccine's proof-of-concept studies. After the proof-of-concept studies are complete, more funding may be available.

2.3 *Chlamydia trachomatis* Bacterial Infections

Chlamydia is the most common bacteria causing sexually transmitted diseases/infections (STDs/STIs). The bacterium causing these STDs is *Chlamydia trachomatis*. It is an intracellular pathogen. "Chlamydia" is a term that can describe one of three major groups of human disease. There are by 18 recognized serotypes¹ of *C. trachomatis*². Serotypes A, B, Ba, and C are responsible for a leading cause of blindness worldwide called "trachoma". Trachoma is endemic in Africa, the Middle East, and Southeast Asia where it affects hundreds of millions of people. Serotypes L-1, L-2, and L-3 cause lymphogranuloma venereum (LGV), a sexually transmitted condition that causes genital or rectal sores. LGV is a rare disease in developed nations but is more prevalent in tropical and semitropical climates³. The remaining serotypes D, Da, E, F, G, J, I, Ia, J, Ja, and K are the sexually transmitted strains that cause genital infections. It is these serotypes that the chlamydia vaccine targets. Transmission occurs via oral, vaginal, or anal sex. Transmission can also occur from mother to child during childbirth.

C. trachomatis causes many types of infections, affecting all ages (Table 1). More than 50 percent of infected males and 70 percent of infected females are unaware of their condition⁴. *C. trachomatis* infections often spread without symptoms. Health professionals therefore call it a

¹ "Serotype" refers to a classification of microorganisms whereby subspecies are grouped based on cell surface antigens.

² Robert C. Brunham and José Rey-Ladino, "Immunology of *Chlamydia* Infection: Implications for a *Chlamydia trachomatis* Vaccine", *Nature Reviews Immunology*, Vol. 5 (2005): 151.

³ Kalorama Information Market Intelligence Report, "Women's Health: Worldwide Prescription Drug Markets", 4th Ed. (2006): 148.

⁴ Health Canada, "It's Your Health- Chlamydia" ©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, (2004), http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/chlamyd_e.html, (accessed October 2, 2006).

“silent” disease. Salpingitis, also known as pelvic inflammatory disease (PID), is the most important preventable cause of infertility in North America today. Evidence suggests a genital chlamydia infection is a potent co-factor enhancing the transmission of HIV. These last two indications make chlamydia a great public health concern worldwide.

Table 1: Epidemiology of *C. trachomatis*

Gender	<i>C. trachomatis</i> Indications	Symptoms
In Men	Prostatitis	Inflammation of the prostate gland
	Epididymitis	Inflammation of epididymis
In Women	Cervicitis	Inflammation of the cervical tissue
	Salpingitis/Pelvic Inflammatory Disease (PID)	Infects the reproductive organs and causes scarring which can lead to infertility
	Endometritis	
	Ectopic pregnancies	
	Premature birth	
	Pelvic pain chronic or acute	
In Children	Newborn ocular or pulmonary infection	Can lead to trachoma
	Trachoma	Ocular infection that may result in blindness after repeated re-infections

Source: author

There are more than 90 million reported new cases annually of which two-thirds occur in developing countries and an estimated 3 million occur in the United States⁵. This makes it a serious public health concern. After being in decline for many years, rates of chlamydia infection have risen steadily since 1997. Table 2 details the number of reported chlamydia cases in Canada. The total rate of cases per 100,000 people rose from 113.9 in 1997, to 197.1 by 2004. Health Canada stated a national goal of reducing this rate to 50 cases per 100,000 by 2010. The World

⁵ US Department of Health and Human Services, Center for Disease Control, “STD Fact Sheet: Chlamydia”, <http://www.cdc.gov/std/chlamydia/STDFact-Chlamydia.htm> (accessed October 9, 2006).

Health Organization (WHO) aims to eliminate chlamydia as a disease of public health importance by 2020⁶.

Current programmes for chlamydia include a single-dose antibiotic treatment and the use of condoms. The drug treatment programs are not affordable for much of the developing world where more than two-thirds of the world's cases occur. Drug treatments need to cost below \$1 to be affordable to developing countries. Vaccine immunization is an essential and affordable way to control infection with *C. trachomatis*⁷.

⁶ World Health Organization. "Initiative for Vaccine Research: Sexually Transmitted Diseases: Chlamydia", http://www.who.int/vaccine_research/diseases/soa_std/en/index1.html (accessed October 02, 2006).

⁷ Brunham and Rey-Ladino, "Immunology of *Chlamydia* Infection", 150.

Table 2: Reported Genital Chlamydia Cases in Canada by Age Group and Sex, 1997-2004

Year	Rate per 100,000 population	Age Group (years)										
		0<1	1-4	5-9	10-14	15-19	20-24	25-29	30-39	40-59	60+	
1997	Male	58.7	0.0	0.0	1.7	144.7	316.1	164.3	59.8	12.5	1.0	
	Female	167.8	0.4	1.0	38.5	971.3	924.1	325.8	81.9	13.2	1.2	
	Total	113.9	0.2	0.5	19.6	546.7	614.5	244.2	70.8	12.8	1.1	
1998	Male	73.7	0.0	0.3	3.5	183.8	394.1	217.0	75.1	15.2	1.5	
	Female	183.1	0.9	1.2	42.0	1063.7	1011.8	366.4	90.7	12.7	1.1	
	Total	129.0	0.5	0.7	22.2	612.0	696.8	291.0	82.9	13.9	1.2	
1999	Male	81.4	0.4	0.3	3.0	186.7	446.3	237.0	86.4	17.5	2.2	
	Female	193.6	1.0	0.9	43.5	1138.3	1064.6	386.1	94.8	14.8	0.7	
	Total	138.2	0.7	0.6	22.7	650.6	749.1	310.8	90.6	16.2	1.4	
2000	Male	88.9	0.3	0.1	2.9	219.4	470.4	260.6	94.2	20.6	2.0	
	Female	211.6	0.8	0.6	47.5	1234.3	1175.7	417.9	109.0	16.6	1.0	
	Total	150.9	0.6	0.3	24.6	713.5	815.7	338.5	101.5	18.6	1.4	
2001	Male	99.2	0.0	0.0	3.6	233.8	534.5	301.3	107.2	21.8	2.2	
	Female	221.8	0.7	0.3	49.6	1255.1	1233.4	465.7	118.8	17.1	1.0	
	Total	161.4	0.4	0.1	26.1	731.2	877.9	383.1	113.1	19.4	1.6	
2002	Male	112.3	0.1	0.1	2.4	253.2	602.6	349.6	123.6	26.2	2.9	
	Female	244.9	0.1	0.6	52.3	1364.5	1375.9	519.4	138.2	18.4	0.8	
	Total	179.4	0.1	0.4	26.8	793.5	980.9	433.4	130.8	22.3	1.7	
2003	Male	121.2	0.1	0.0	2.3	267.0	651.1	380.3	138.3	27.1	2.9	
	Female	256.2	0.3	0.2	55.1	1430.0	1443.6	541.4	147.6	18.8	0.9	
	Total	189.4	0.2	0.1	28.1	833.0	1038.4	459.8	143.0	23.0	1.8	
2004	Male	129.5	0.0	0.1	2.0	280.9	702.1	408.3	142.0	31.7	3.6	
	Female	263.2	0.3	0.6	51.8	1443.6	1489.4	557.6	160.1	21.9	1.4	
	Total	197.1	0.1	0.4	26.3	847.4	1087.3	482.4	151.0	26.8	2.4	

Data Source: Surveillance and Epidemiology Section, Community Acquired Infections Division, Public Health Agency of Canada, "Infectious Diseases: STI Surveillance and Epidemiology: 2004 Reported Genital Chlamydia Cases and Rates", http://www.phac-aspc.gc.ca/std-mts/stddata_pre06_04/tab1-1_e.html, (accessed October 02, 2006)

3 MARKET POTENTIAL FOR A CHLAMYDIA VACCINE

This chapter looks at the biopharmaceutical market, the *C. trachomatis* infections market, and current genital chlamydia therapies. This information provides background information for the competitive analysis presented in chapter 5.

3.1 Overview of the Biopharmaceutical Market

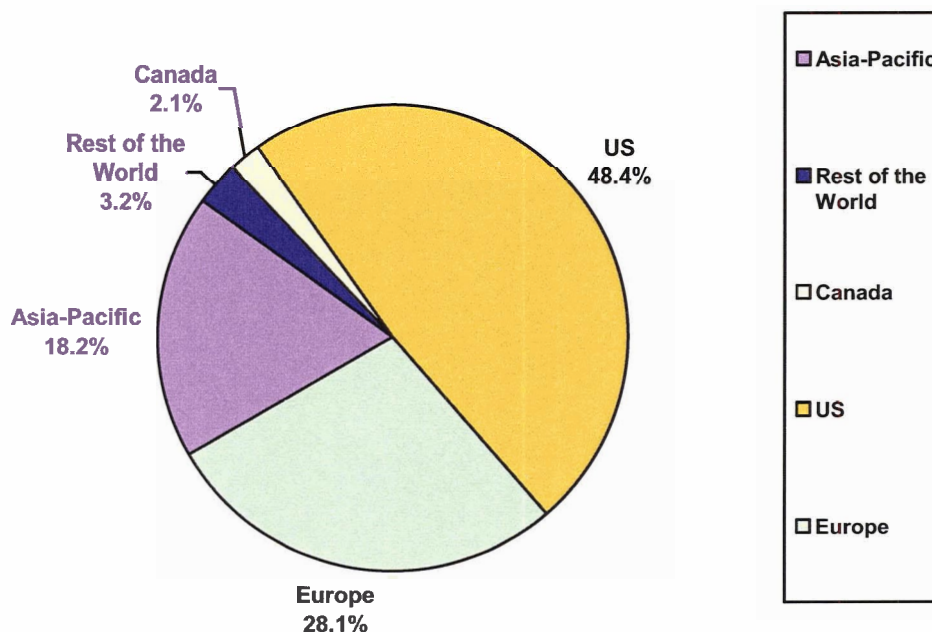
Many, 'life sciences' analysts, make a distinction between the pharmaceuticals market and the biotechnology market. Other analysts use the term 'pharmaceuticals industry' loosely to describe both market segments. The term, 'pharmaceuticals market', will herein refer to therapeutic and prophylactic products sold by large conglomerates. The term 'biotechnology market' will refer to products sold by innovative SME organizations. A collective term, 'biopharmaceutical', will be used to describe both market segments. This section describes the current biopharmaceutical market.

Datamonitor, an international business intelligence company, valued the 2004 global biopharmaceutical market at US\$603.9 billion⁸. Market values described herein reflect factory-gate prices. The industry's compound annual growth rate (CAGR) between 2000 and 2004 was 9.9%. The pharmaceuticals market segment is the most valuable sector of the industry. It generated revenues of US\$498.3 billion in 2004. This is equivalent to 82.5% of the global biopharmaceutical industry's value. The biotechnology market segment accounted for the remaining 17.5%. Should the CAGR remain at 9.9% from 2004-2009, Datamonitor forecasts the global biopharmaceutical industry to reach a value of US\$968.7 billion by 2009.

⁸ Datamonitor, "Global Pharmaceuticals & Biotechnology Industry Profile", Ref. Code 0199-2125, (2005), www.datamonitor.com

The current world population is approximately 6.5 billion⁹. The world distribution of biopharmaceutical market share (Figure 1) does not correlate to the world population distribution. There are many reasons for this. Economic (poverty), political (lack of patent protection or regulatory infrastructure), and the cultural issues are some explanations. It is clear that Latin America and Africa are very small market consumers. Industrialized regions are large consumers.

Figure 1: World Pharmaceutical Market Share by Value, 2005



Data Source: Datamonitor (2005)

Canada, with a population of 33 million, accounted for 2.1% of the global biopharmaceutical market in 2004. The Canadian biopharmaceutical market grew by 5.9% in 2005 to reach an estimated value of US\$11.3 billion. Datamonitor forecasts the Canadian market to have a value of US\$15.5 billion by 2010¹⁰. This value reflects an increase of 37.5% since 2005.

⁹ US Census Bureau, World Population Information, <http://www.census.gov/ipc/www/world.html>, (accessed November 4, 2006).

¹⁰ Datamonitor, "Pharmaceuticals in Canada Industry Profile", Ref. Code 0070-0372, (2005), www.datamonitor.com.

Table 3: Canada Pharmaceutical Market Value in Billions of Dollars

Year	C\$	US\$	% Growth
2001	10.2	7.9	n/a
2002	11.8	9.1	15.50
2003	13.1	10.1	11.20
2004	13.8	10.6	5.30
2005 (e)	14.7	11.3	5.90
2006 (e)	15.8	12.1	7.50
2007 (e)	16.8	12.9	6.80
2008 (e)	17.9	13.7	6.10
2009 (e)	18.9	14.5	5.90
2010 (e)	20.2	15.5	6.50

(e) = expected

Data Source: Datamonitor (2005).

The United States, with a population of 296 million, accounted for 48.4% of the global pharmaceuticals market in 2004. The US possesses the world's largest pharmaceuticals market.

Accounting for the fact that Canada's population is slightly less than 10% of the United States', revenues are low (Table 3 and Table 4) in Canada. This is likely because the Canadian government, unlike the situation in the US, influences the price of drugs through the Patented Medicines Price Review Board. Prices in Canada are 40% lower, on average, than that in the US. Consequently, Canadian pharmaceuticals export to the US has generated significant revenues. Despite this, market value per capita is lower in Canada.

Table 4: US Pharmaceutical Market Value in Billions of Dollars

Year	US\$	% Growth
2001	177.2	n/a
2002	196.3	10.80%
2003	219.2	11.70%
2004	236.6	7.90%
2005 (e)	258.6	9.30%
2006 (e)	284.9	10.20%
2007 (e)	312.5	9.70%
2008 (e)	342.3	9.50%
2009 (e)	373.9	9.20%
2010 (e)	408.2	9.20%

(e) = expected

Data Source: Datamonitor (2005)¹¹.

Since the turn of this century, governments in the majority of developed markets have initiated pricing reviews in order to balance public healthcare spending. This has placed significant downward pressure on pharmaceuticals market pricing. The US market may see lower prices in the future. This will likely shift some relative market power to the rest of the world.

3.2 Chlamydia trachomatis STD Market

This section segments the *C. trachomatis* STD market by sex and geographical area. Chlamydia infections and STDs affect women disproportionately. Women suffer from more frequent and more serious complications than do men. Approximately 70-75% of women infected with *C. trachomatis* are symptom-free. In 10%-20% of cases, women with chlamydia develop more severe complications, such as pelvic inflammatory disease (PID)¹².

In 2003, a US market analysis reported that women make over 75% of the healthcare decisions; they make more than 62% of physician visits; and they make 60% of prescription drug

¹¹ Datamonitor, "Pharmaceuticals in the United States Industry Profile", Ref. Code 0072-0372, (2005), www.datamonitor.com.

¹² Kalorama Information Market Intelligence Report. "Women's Health: Worldwide Prescription Drug Markets" 4th Ed. (2006): 179.

purchases. The report states, “Women are a segment that is not only worth appealing to, but is vital to any successful strategy in the pharmaceutical marketplace”¹³. Women are more sensitive to quality service from health care professional. Looking at women’s consumer patterns in developed countries and women’s health issues globally, a target market segment emerges. Table 5 below presents gender data from a 1995 WHO study. The number of incidence in females is higher than to males in most regions. Accordingly, sex and health education programs in the developing countries target women.

Table 5: 1995 Estimates Incidence of Chlamydia (Millions) for People Aged 15-49

Region	Men	Women
North America	1.64	2.34
Western Europe	2.30	3.20
Australasia	0.12	0.17
Latin America and the Caribbean	5.01	5.12
Sub-Saharan Africa	6.96	8.44
North Africa and Middle East	1.67	1.28
Eastern Europe and Central Asia	2.15	2.92
East Asia and Pacific	2.70	2.63
South and Southeast Asia	20.20	20.28
TOTAL	42.75	46.38

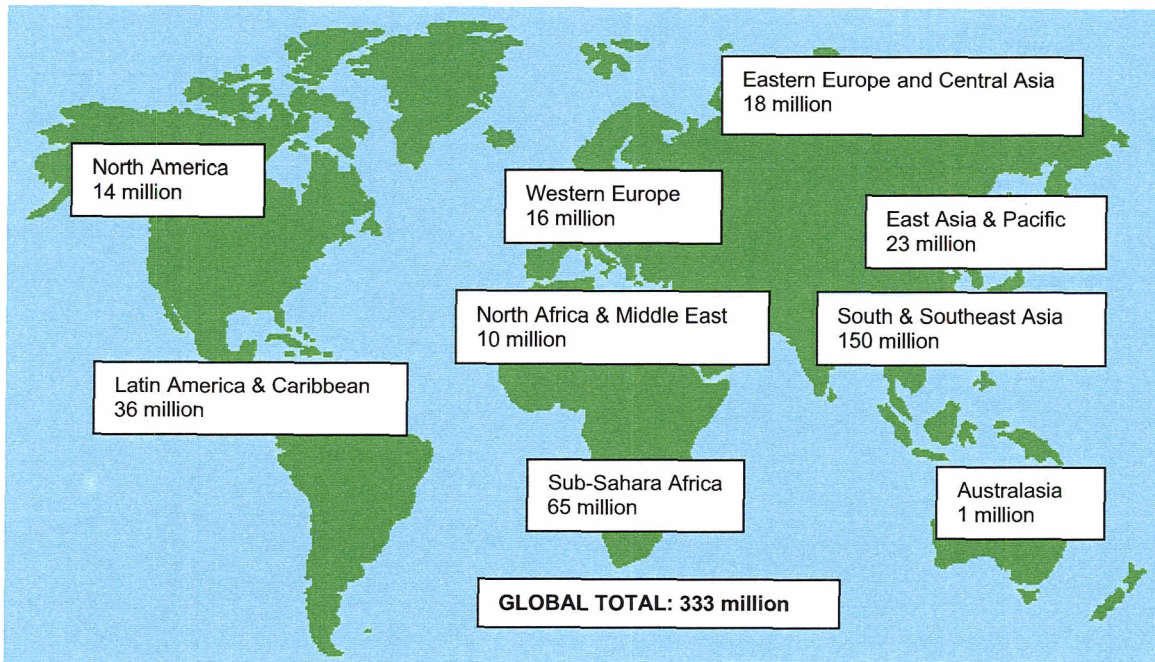
Data Source: Gerbase et al. (1998)¹⁴

Unfortunately, the information in Figure 2 is ten years old; however, the global distribution of the STD infections is still relevant. Developed countries account for the largest market value of biopharmaceutical sales. Nonetheless, the greatest need for a chlamydia vaccine is in the developing countries.

¹³ Steven Heffner. “Women’s Health: Has the Opportunity Been Handled Well?”. Kalamora Information a Division of Marketresearch.com, (2003), <http://www.kaloramainformation.com/editor/viewcontent.asp?prid=186>. (accessed November 8, 2006).

¹⁴ Antonio C. Gerbase, Jane T. Rowley, and Thierry E Mertens, “Global Epidemiology of Sexually Transmitted Diseases”, *The Lancet*, Supplement STD’s, Vol. 351 Issue 9119 (1998): Academic Search Elite

Figure 2: 1995 Estimates of New Adult Cases of Curable STDs (Gonorrhoea, Chlamydia, Syphilis, Trichomoniasis)



Data Source: Gerbase et al. (1998)¹⁵

An ideal target market segment for *C. trachomatis* STD treatment is young women. Targeting women in developed countries promises the largest market value. Targeting women in developing countries promises the largest market share.

3.3 Current Chlamydia Therapies in Development

Pfizer dominates the commercial market for chlamydia infection treatments. Zithromax[®] and Vibramycin[®] are leading antibiotics in their respective classes. Zithromax[®] was the first effective single-dose oral antimicrobial product on the market for treatment of chlamydia. It has a proven record of clinical efficacy. Zithromax[®] is the largest selling antibiotic in the world. In 2005, Zithromax[®] lost patent protection. Future product revenues typically erode, as soon as generics are free to move into the market.

¹⁵ Gerbase, Rowley, and Mertens, "Global Epidemiology of Sexually Transmitted Diseases", (1998)

Table 6 lists current treatments available or in development for chlamydia infections. Compounds in development, with the exception of one, do not directly target *C. trachomatis* infections. Four products in development are:

- SAVVY (C-31 G): a contraceptive with a surfactant that breaks down the lipid membranes of enveloped bacteria. It may protect against chlamydia and other bacterial STDs.
- PRO 2000 (naphthalene sulphonate polymer): an entry and fusion inhibitor that binds to the bacteria to prevent them from binding to and infecting healthy cells. It may protect against chlamydia and other bacterial STDs.
- BufferGel: a contraceptive. It has an acid buffer that keeps the vagina acidic and creates a physical barrier that stops or slows down the passage of pathogens into the vaginal and cervical walls. It may protect against chlamydia and other bacterial STDs.
- Unnamed vaccine product by Emergent Biologics. This is an injectable recombinant chlamydia vaccine with a novel adjuvant.

Table 6: Current Treatments Available or In Development for Treating Chlamydia

Product Name	Developer/Marketer	Stage
Zithromax	Pfizer	Market
Vibramycin	Pfizer	Market
BufferGel	ReProtect	Ph III
Pro 2000 Gel	Progenics	Ph II
SAVVY C31G vaginal gel	Cellegy	Ph I/II
Unnamed vaccine	Antex/Emergent Biologics	Pre-clinical

Data Source: data extracted in part from Kalorama Market Intelligence Report¹⁶

Antex/Emergent Biologics claim to be developing a chlamydia vaccine. Research by the author found that, presently, they are not actively developing this product. The company has repositioned itself to develop compounds to fight bioterrorism. There are few products in development and few additional new treatments directed at *C. trachomatis* infections. The market for a chlamydia vaccine is unexploited.

3.4 Summary of the Market Potential for a Chlamydia Vaccine

The biopharmaceutical market is a large and growing market. The United States represent almost half of the global pharmaceuticals market. Canada accounts for less than 5 percent of the US pharmaceuticals market. Despite a small global market share, there is a need for new chlamydia therapies to manage Canada's increasing incidence rate. There are few treatments currently in development. Only one investigational product is directly targeting genital chlamydia infections but it is not in active development. There is an untapped market potential for a chlamydia vaccine.

¹⁶ Kalorama Information Market Intelligence Report. "Women's Health: Worldwide Prescription Drug Markets", 4th Ed. (2006): 240-267.

4 MARKET ACCESS FOR A CHLAMYDIA VACCINE

This chapter looks at vaccine development, regulatory approval for vaccine commercialization, local distribution channels for vaccine delivery to the public, patent protection and rights and global access to the chlamydia vaccine. The purpose is to understand how to bring the chlamydia vaccine from concept and discovery to the marketplace.

4.1 The Incentive for a Vaccine

After some controversy, vaccines are making a comeback in the medical field¹⁷. Vaccines are preparations that, when administered, produce an immunological response and/or immunity to an infection. Traditionally, vaccines were prepared using live or attenuated pathogens to induce an immune response. With advances in recombinant technology, a new generation of vaccines emerged. They are considerably safer because they do not use pathogens. They also tend to be less expensive to manufacture than traditional vaccines. Margins on vaccines have traditionally averaged about 15 percent¹⁸. Margins on therapeutics drugs in contrast, have average around 35 percent¹⁹. The margins for vaccines will increase as new technology becomes available to reduce manufacturing costs. Public and private interest in vaccines is increasing. Government incentives and investor interest are growing along with society's interest. Large pharmaceutical firms, such as GlaxoSmithKline and Novartis, are actively investing in vaccine technology and development.

Today's new vaccine development strategy is to identify proteins that elicit an immune response. Bacterial cell surface antigens are prime candidates for vaccine development. *C.*

¹⁷ Ernst & Young, "Booster Shot: Global Vaccine Market is Reenergized", Progressions, (2006): 91.

¹⁸ Ibid.

¹⁹ Ibid.

trachomatis is a gram-negative bacterium. The bacterium adheres to the host cell before entering it. Once it enters the host cell, it changes form before replicating. In each of these states, its outer membrane exhibits a different set of proteins. Its unique biphasic lifecycle has made it very successful at evading the host's immune system and creating a chronic infection. Proteomic technology enabled Drs. Brunham and Foster to identify and isolate nine immunogenic antigens of interest on the *C. trachomatis* outer membrane. They prepared a vaccine incorporating these isolated antigens. The vaccine produced immunity in challenged mice. The scientists are expecting the chlamydia vaccine to have more than 95% efficacy. The objective is to create a vaccine to immunize 10- to 12-year old youths.

The US Institute of Medicine (IOM) considers a genital chlamydia vaccination to be most favourable when administered to 12-year old subjects²⁰. This type of vaccine falls into a category II classification of recommended vaccines for development²¹. A category II classification means that a vaccine strategy is "more favourable". It also means that a vaccination strategy would incur small costs (less than \$10,000) for each Quality Adjusted Life Years²². A category I is the highest and "most favourable" level.

The IOM of the National Academies released a report, "Vaccines for the 21st Century: A Tool for Decisionmaking" on March 01, 1999. The report develops an economic model for social investment in vaccine development in developed countries. The "burden" and "cost-effectiveness" spreadsheets for a hypothetical chlamydia vaccine candidate are available for download at no cost²³. This IOM report reflects a growing public and private interest in

²⁰ Ian Humphrey-Smith and Michael Hecker, *Microbial Proteomics: Functional Biology of Whole Organisms*, (New Jersey: John Wiley & Sons, 2006), 385.

²¹ US Health and Human Services, National Vaccine Program Office, "Analysis and Action Plan for the National Vaccine Advisory Committee", <http://www.hhs.gov/nvpo/nvac/vaccines21cer.html>, (accessed on November 05, 2006).

²² "Quality Adjusted Life Years" is a standard measure of health outcomes in cost-effectiveness analyses. It is more or less the summation of the acute and chronic problems caused by the illness.

²³ Institute of Medicine of the National Academies. "Vaccines for the 21st Century", Vaccine Candidates-Chlamydia, <http://www.iom.edu/CMS/3793/5648/12160.aspx> (accessed on November 05, 2006).

developing vaccines for immunization programs. There are scientific and medical incentives for developing a chlamydia vaccine.

4.2 Regulatory Roadmap for Vaccine Approval

In Canada, it is Health Canada's Health Products and Food Branch (HPFB) that regulates therapeutics, including vaccines. In Europe, it is the European Agency for the Evaluation of Medicinal Products (EMA) that regulates therapeutics. In the United States, the Food and Drug Administration (FDA)'s Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines²⁴. Since the United States is the largest target market, this section reviews its regulatory process. It is also a useful model because the FDA clearly defines the regulatory process for vaccines along the value chain²⁵.

The stages in the value chain for vaccine development are very similar to those of drugs and other biologics (Table 7). After the discovery stage and some optimization, investigators conduct proof-of-concept studies *in vitro* and *in vivo*. Animal studies are the only *in vivo* studies conducted at this stage. Government approval is necessary before human clinical trials can begin. In order to begin a vaccine's clinical trials, the sponsor must apply to the FDA for an Investigational New Drug application (IND). The IND describes the vaccine, its method of manufacture, and related quality control tests for release. The IND includes all data supporting the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal tests. Furthermore, the sponsor presents to the FDA the proposed clinical protocol for studies in humans. Upon review and acceptance of all this documentation, the FDA will permit the sponsor to conduct clinical trials.

²⁴ Authority for the US regulation of vaccines resides primarily in Section 351 of the Public Health Service Act and some sections of the Federal Food, Drug and Cosmetic Act.

²⁵ Food and Drug Administration, "The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective", *FDA Consumer Magazine*, Pub No. FDA05-3242, http://www.fda.gov/fdac/features/2002/402_drug.html, (accessed on November 08, 2006).

Table 7: Stages of Product Development and Regulatory Process

Stage	Studies	Number Of Human Subjects
Pre-Clinical	<ul style="list-style-type: none"> • Proof-of-concept • Animal pharmacology • Animal toxicology 	None (Animal and <i>in vitro</i> studies only)
IND		
Phase I	<ul style="list-style-type: none"> • Safety • Immunogenicity 	Tens (controlled)
Phase II	<ul style="list-style-type: none"> • Safety • Immunogenicity • Dose Ranging • Efficacy 	Hundreds (controlled)
Phase III	<ul style="list-style-type: none"> • Safety • Immunogenicity • Efficacy 	Thousands (controlled)
BLA		
Phase IV	<ul style="list-style-type: none"> • Post-market surveillance • Safety • Efficacy 	Market (uncontrolled)

Source: author

Once the FDA approves the IND, the sponsor may conduct pre-marketing (pre-licensure) vaccine clinical trials. The sponsor conducts clinical trials in three phases, as is the case for any drug or biologic. The initial human trials, referred to as Phase I, are safety and immunogenicity studies. The sponsor performs these studies for several months in a small number of closely monitored subjects, usually tens of subjects. Phase II trials are dose-ranging studies that last for several months to two years and may enrol several hundreds of subjects. Phase III trials typically enrol thousands of individuals. These studies provide the critical documentation of effectiveness and important additional safety data required for licensing. During these clinical trials, animal studies continue in order to assess long-term safety and efficacy. At any stage of the clinical or

animal studies, if data raise significant concerns about either safety or effectiveness, the FDA may request additional information or studies, or may halt ongoing clinical studies.

If all three clinical trial phases are successful, the sponsor will submit to the FDA a Biologics License Application (BLA). The FDA's multidisciplinary team (medical officers, microbiologists, chemists, biostatisticians) reviews this license application. They analyze the efficacy and safety information to make a risk/benefit assessment. They then recommend or oppose the approval of the vaccine. The proposed manufacturing facility concurrently undergoes a FDA pre-approval site inspection.

After CBER's review of the BLA, the sponsor and the FDA may present their findings to FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This is a non-FDA expert committee (scientists, physicians, biostatisticians, and a consumer representative). The committee may offer suggestion or advice regarding the safety and efficacy of the vaccine for the proposed indication.

Neither the FDA nor the sponsor can anticipate all potential adverse events. Observations of adverse reactions are more likely once the general population receives the vaccine. Recall that the market is an uncontrolled environment, meaning patients are not pre-selected. Therefore, Phase IV studies are uncontrolled market studies. CBER and the US Centers for Disease Control & Prevention (CDC) act as watchdogs because of the sponsor's principal-agent problem. The US government agencies jointly manage a post-marketing safety surveillance program, called the Vaccine Adverse Event Reporting System (VAERS). The VAERS program welcomes reports from all concerned individuals: patients, parents, health care providers, pharmacists, and vaccine manufacturers. The road to commercialization is an endless but rewarding journey.

4.3 Vaccines Distribution within Canada

The next matter of interest upon regulatory approval of the investigational product for commercial markets is distribution. The distribution channels for the influenza vaccine exemplify the distribution process within Canada²⁶. Firstly, there is the publicly-funded channel. Publicly-funded programs and administered health care systems distribute most influenza vaccines. Secondly, there is the private sector channel. The private sector acquires and administers influenza vaccines to individuals that are ineligible to receive immunization under publicly-funded programs.

The vaccine industry in Canada is unusual because of the role the Canadian governments play in providing channels of distribution. The federal, provincial and territorial (F/P/T) governments provide a push market for needed vaccines such as the influenza vaccine. The government bodies may purchase 50 percent of the annual public requirements for a vaccine. The governments secure long-term supply contracts, up to ten years in length, with the manufacturers or suppliers. This secures an adequate supply of influenza or immunization vaccines for all Canadians.

In 1976, the Conference of Deputy Ministers of Health approved the establishment of a continuing program for the combined bulk purchase of drugs and vaccines²⁷. The mandate of the program is to manage purchasing agreements for drugs and vaccines, on behalf of the F/P/T governments. It utilizes the procurement services of the Department of Public Works and Government Services Canada (PWGSC). The PWGSC coordinates the F/P/T Purchasing Program

²⁶ While the HPV cervical cancer vaccine may be comparable to the chlamydia vaccine, methods of distribution and pricing are still being negotiated in Canada. As such the example of the distribution the influenza vaccine is at this time more informative. The HPV (serotypes 6, 11, 16, 18) vaccine, "Gardasil", was approved by the FDA on June 08, 2006; by Health Canada on July 10, 2006; and, by EMEA on September 22, 2006. Current global distribution information on Gardasil™ is available from Merck & Co, http://www.merck.com/newsroom/press_releases/product/2006_0922a.html, (accessed on December 06, 2006)

²⁷ Competition Bureau Canada, News and Resources, "Acquisition of ID Biomedical b7 GlaxoSmithKline Inc.", June 19, 2006, <http://www.competitionbureau.gc.ca/internet/index.cfm?itemID=2139&lg=e>, (accessed on October 21, 2006).

for Drugs and Vaccines. It purchases approximately 52 different vaccines across Canada for use in public health campaigns²⁸. It orders the influenza vaccines for use in public health campaigns. The PWGSC pays the influenza vaccine suppliers and recovers the funds from the F/P/T jurisdictions.

The National Advisory Committee on Immunization (NACI) is a national committee of recognized experts in the fields of paediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health. One of NACI's functions is to recommend which vaccines should be included in immunization programs. The NACI reports to the Chief Public Health Officer of Canada, who heads the Public Health Agency of Canada (PHAC). The PHAC is responsible for the protection of the health and safety of Canadians. It is responsible for disease surveillance and ensuring vaccine safety. With respect to ensuring vaccine safety, the PHAC is responsible for vaccine-preventable disease surveillance, for monitoring adverse events following immunization, and, together with Health Canada, for investigating complaints arising from possible adverse events. When necessary, the PHAC assists in coordinating the supply management of influenza vaccine under the National Immunization Strategy. The provinces and territories are responsible for key decisions on coverage and distribution. In general, provincial health care programs cover high-risk populations. Ontario and Nunavut offer a universal program for influenza vaccine. The Health Products and Food Branch (HPFB) of Health Canada remains involved after approving vaccines for immunization. It investigates all complaints arising from possible adverse and it manages product recalls.

4.4 Intellectual Property Protection

The Canadian Intellectual Property Office (CIPO) oversees intellectual property rights in Canada. The patent issuance by CIPO's Patent Office offers commercial rights and owner

²⁸ Public Works and Government Services Canada, "Fact Sheets: Vaccine Procurement", <http://www.pwgsc.gc.ca/text/factsheets/vaccine-e.html>, (accessed on October 21, 2006).

protection. It offers the patent holder the right to prevent others from manufacturing, selling or using the invention in Canada. This right begins from the date of issue. It is valid for up to 20 years from the date of filing the application²⁹.

The United States Patent and Trademark Office (USPTO) administers the patent laws. It examines applications for patents to determine if the applicants are entitled to patents. As in Canada, the property rights are valid for up to 20 years from the date of filing the application. However, the United States remains the only country in the world to operate as a first-to-invent system³⁰. Prior art is thus very important!

For an invention to be patentable, it must be non-obvious, novel, and useful. In the United States and in Canada if the inventor describes the invention in a printed publication or uses the invention publicly, he/she must apply for a patent before one year has gone by. To do otherwise will forfeit any right to a patent. In many foreign countries, the inventor must file on the date of public disclosure in order to preserve patent rights.

Inventors also have the option of filing a “Provisional Application for Patent” in the United States³¹. Canada has a similar but informal system. In Canada, a “provisional” is simply an incomplete patent application. A provisional application, in either Canada or the US, provides the means to establish an early effective filing date in a patent application. This allows the inventor legal use of the term “Patent Pending” in connection with the invention. In the US, the applicant has up to 12 months to file a non-provisional patent application. If the inventor does not do so, he abandons the provisional application by the operation of law. On October 02, 2006, Drs.

²⁹ Canadian Intellectual Property Office, “A Guide to Patents: Patent Protection”, http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/pat_gd_protect-e.html#sec1, (accessed on November 6, 2006).

³⁰ United States Patent and Trademark Office, “General Information Concerning Patents”, <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent>, (accessed November 6, 2006).

³¹ United States Patent and Trademark Office, “Provisional Application for Patent”, <http://www.uspto.gov/web/offices/pac/provapp.htm>, (accessed on November 08, 2006).

Brunham and Foster filed a provisional patent for their chlamydia vaccine in both Canada and the United States.

4.5 Reaching Out to Developing Countries: Canada's Access to Medicines Regime

Canada is a leading donor to health funding in the developing world. Canada's commitment includes support to global health partnerships and multilateral institutions. Two notable partnerships include the World Health Organization (WHO) and the Global Alliance for Vaccines and Immunizations (GAVI). Canada also permits the exportation of patented pharmaceutical products to countries without manufacturing capabilities in response to foreign public health problems. Prices are determined based on the importing country's per-capita GDP. In providing this service, the Canadian patentee agrees to partially waive payment of compensation. Royalties vary with the state of poverty of the importing country. In return, the federal government offers reduced patent fees as an incentive for the patent holder³².

In August 2003, the World Trade Organization (WTO) members agreed to amend two provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These provisions hindered the export of essential medicines to developing countries faced with public health problems. Less than a year later, the Government of Canada passed "An Act to Amend the Patent Act and the Food and Drugs Act—the Jean Chrétien Pledge to Africa"³³. This Act, with the cooperation of Industry Canada, Health Canada, the Canadian International Development Agency, the Canadian Intellectual Property Office, International Trade Canada, and Foreign Affairs Canada, led to the establishment of Canada's Access to Medicines Regime (Regime). The Regime balances Canada's intellectual property and trade

³² Canadian Intellectual Property Office, "Use of Patents for International Humanitarian Purposes to Address Public Health Problems: Jean Chrétien Pledge to Africa Regime", http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p2-e.html, (accessed November 6, 2006).

³³ Government of Canada, Canada's Access to Medicines Regime, http://camr-rcam.hc-sc.gc.ca/intro/context_e.html, (accessed October 9, 2006).

obligations with the humanitarian objective of the WTO decision. In order to fulfil the humanitarian objective of alleviating public health problems in developing nations, the goodwill of pharmaceutical organizations to participate in the Regime is required. Medicines exported under the Regime must meet the same strict regulatory requirements as those produced for the Canadian market.

To participate in the Regime, the needed medicine must be eligible for export and organizations must have a sales agreement with the importing country. Non-governmental organizations (NGO) can act as purchasing agents of licensed pharmaceutical products on behalf of, and with the permission of, the importing country's government. Therapeutics eligible for export under the Regime are primarily from the WHO's Model List of Essential Medicines³⁴. Provisions are in place to add other products to the list.

To ensure that the Regime is used in good faith, if the cost of a generic product is more than 25 percent of the cost of its equivalent patented version in Canada, patent holders may challenge a licence in court.

4.6 The Global Distribution Incentive for the Chlamydia Vaccine

The pursuit of private interests has not lead to the efficient use, or a fair distribution, of resources in research and development³⁵. Many diseases are neglected in research and development institutes. Grants and funds support R&D for lucrative maladies. Less popular but equally devastating diseases receive little funding. North America, Europe and Japan account for 80% of the world pharmaceutical market. Market forces skew investments towards the health needs of those powerful industrialized nations.

³⁴ World Health Organization, "WHO Model List of Essential Medicines", 14th Ed., March 2005, <http://www.who.int/medicines/publications/essentialmedicines/en/index.html>, (accessed October 9, 2006).

³⁵ David L. Weimer and Aidan R. Vining, *Policy Analysis: Concepts and Practice*, 4th ed. (New Jersey: Pearson Prentice Hall, 2005), 37.

Change is on the way. Awareness of the lack of effective treatments for neglected diseases has been growing at a quick rate in the last decade. In 2005, the US National Vaccine Advisory Committee urged consideration of the global policy issues concerning vaccines against STDs other than HIV such as *Chlamydia trachomatis*, *Herpes simplex*, and *Neisseria gonorrhoea*³⁶. Canada's Access to Medicines Regime is a domestic example where public policy is helping to meet neglected public health needs. The inventors' patents protect their proprietary and commercial rights in industrialized markets. A return on investment is available in these markets. Yet, through Canada's Regime or public-private partnerships (PPPs), the chlamydia vaccine is accessible to developing nations. The commercialization of the chlamydia vaccine will meet global needs.

4.7 Summary of Market Access for a Chlamydia Vaccine

The goal is to create a vaccine with more than 95% efficacy to immunize 10- to 12-year old youths against genital chlamydia infections. Product development occurs in progressive stages. These stages reflect the regulatory process and the steps towards regulatory approval. National regulatory bodies provide commercial licenses for vaccines based upon safety and efficacy data. National patents protect commercial rights. Commercial distribution of vaccines in Canada occurs via both private and public channels. Canada, unlike the US, regulates drug prices to distributors. Global access to Canadian patented medicines is available at affordable prices to income-suppressed nations through government-sponsored programs. There is a growing need globally to develop vaccines for STDs such as chlamydia.

³⁶ US Health and Human Services, National Vaccine Program Office, "Analysis and Action Plan for the National Vaccine Advisory Committee", <http://www.hhs.gov/nvpo/nvac/vaccines21cer.html>, (accessed on November 05, 2006).

5 COMPETITIVE FORCES IN THE NOT-FOR-PROFIT BIOPHARMACEUTICAL INDUSTRY

A key challenge for start-up inventors is determining how to translate a promising new discovery into a commercial product. In order to decide which competitive strategy has a better chance of success, we need to look at the industry in which it will compete.

An industry is a group of organizations producing products and services that are close substitutes for each other. An analysis of an industry goes beyond competitors. Michael Porter writes, “The state of competition in an industry depends on five basic competitive forces”³⁷. He names these five forces as, “rivalry among existing firms”, “threat of new entrants”, “threat of substitute products or services”, “bargaining power of buyers” and “bargaining power of suppliers”³⁸. These five forces create barriers to entry. Collectively, these structural features determine the ultimate success potential of organizations within the industry³⁹.

This chapter will look at the competitive forces that shape the biopharmaceutical industry. The chapter begins with a description of the current situation for the chlamydia vaccine inventors. It then examines the structural features of the biopharmaceutical industry. Collectively, these structural features describe the external environment in which the chlamydia vaccine enterprise, a new entrant, will compete.

³⁷ Michael E. Porter, *Competitive Strategy: Techniques for Analyzing Industries and Competitors*, (New York: The Free Press, 1980), 3.

³⁸ *Ibid.*, 4.

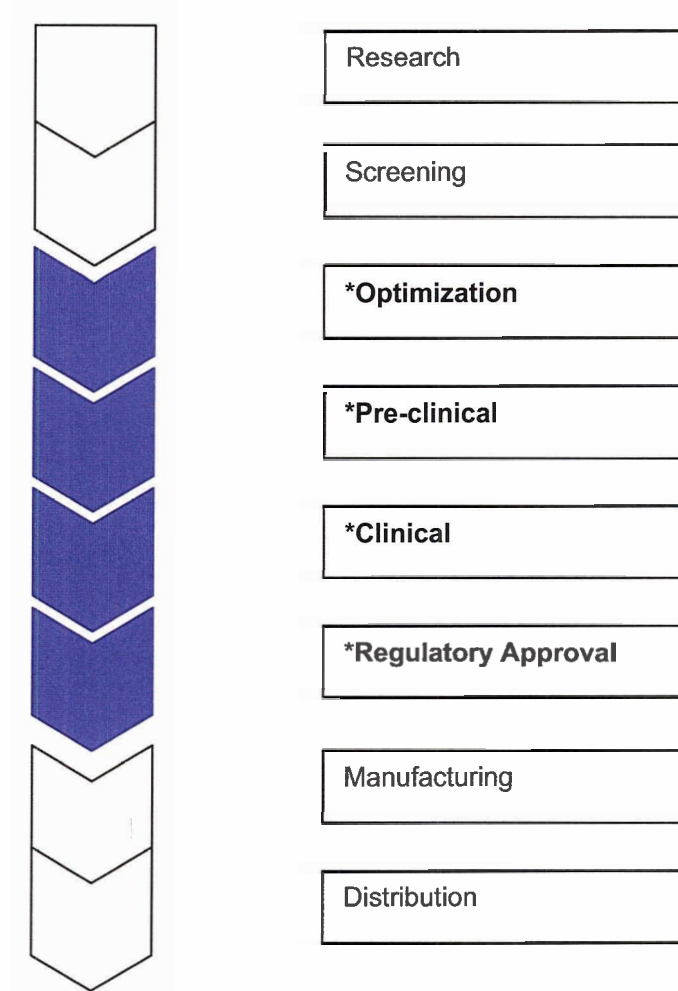
³⁹ *Ibid.*, 3.

5.1 Analysis of CDC's Current Situation

The inventors have not yet created a spin-off enterprise to develop and commercialize the chlamydia vaccine. The CDC is currently conducting proof-of-concept studies. Genome BC's Commercialization Committee funded these studies with a \$150,000 grant. The studies commenced in September 2006. While these studies are underway, the inventors are considering the next steps towards commercialization.

It is the inventors' intention that the new chlamydia vaccine be available in both developed and developing countries. The current strategy is to avoid collaborating with large pharmaceutical organizations. The inventors would like to emulate the Institute for OneWorld Health's (IOWH) business model (Figure 3), as a not-for-profit biopharmaceutical company, to develop and market the chlamydia vaccine.

Figure 3: Representation of the Institute for OneWorld Health’s Business Model



**** - These are activities performed by IOWH
Modified from <http://www.oneworldhealth.org/business/index.php>

The IOWH model focuses on its core competency in clinical product development. They develop abandoned patents or reposition existing drug patents for new indications in neglected market segments. Biopharmaceutical organizations and universities donated the patents or licenses that make up the most part of IOWH’s IP portfolio. The final manufacturing is outsourced to a local firm in the developing country. This local firm agrees to manufacture the product at cost. Local health agencies oversee market distribution in partnership with IOWH.

Pricing is likely established in a collaborative effort by all partners including WHO, IOWH, government health ministries and nongovernmental health authorities.

The chlamydia vaccine inventors stated an interest in potentially outsourcing clinical trials. The strategic analysis considers the ideas of outsourcing and using the IOWH as a model later in the report. First, we will analyze the environment into which the chlamydia vaccine enterprise, a new entrant, will compete.

5.2 Structural Features of the Industry

The structure of the industry has a strong influence in determining the competitive rules for a firm. A structural analysis of the industry is therefore conducive to formulating competitive, or business, strategy for an enterprise⁴⁰. This section presents the structural features of the biopharmaceutical industry in order to create a strategy for the new entrant with the chlamydia vaccine product⁴¹.

5.2.1 State of Rivalry (High)

Competitors are mutually dependent. Rivalry exists among competitors when “one or more competitors either feels the pressure or sees the opportunity to improve position”⁴². A strategic move by one or more competitors evokes a reaction by others in the industry. The reaction can range from “warlike” to “gentlemanly”. The new entrant in the biopharmaceutical industry will observe two distinct types of competitive behaviour. There are two apparent strategic groups. Porter defines a strategic group as, “the group of firms in an industry following the same or a similar strategy along the strategic dimensions”⁴³. The two strategic groups are the public-private partnerships (PPPs) group and the large pharmaceutical organizations group. If

⁴⁰ Porter, *Competitive Strategy*, 5.

⁴¹ Anthony E. Boardman and Aidan R. Vining. “A Framework for Comprehensive Strategic Analysis”. SFU BUS 780 course notes (2003): 10.

⁴² Porter, *Competitive Strategy*, 17.

⁴³ *Ibid.*, 129.

strategic groups target different market segments, then “their interest in and effect on each other is much less severe”⁴⁴. The PPPs strategic group is a network of academia, government, private firms and NPO working together towards a common goal. This strategic group is unusual because of their objective. They tend not seek “blockbuster” profits. Rather, they tend to work collaboratively towards the goal of finding a cure for an unmet medical need. The second strategic group is the large pharmaceutical organizations. This group is the classic rival type. They aggressively compete for market share and profits. There is rivalry within this group as well as within the industry. We will now look at the state of rivalry expected from two strategic groups in more detail.

5.2.1.1 Public-Private Partnerships Rivalry

Public-private partnerships have found a means to increase R&D capabilities and push new compounds through the pipeline quickly. The Bill and Melinda Gates Foundation (Gates Foundation), the Global Alliance for Vaccines and Immunization (GAVI) and others have funded many programs and PPPs initiatives to address market failures and galvanize research and development. Government centres of excellence, academic institutions, and biopharmaceutical organizations are working together to commercialize new therapeutic products. The engagement of this form of networked strategic group within the biopharmaceutical industry is expanding. Large pharmaceutical organizations also engage in PPPs. Many pharmaceutical organizations have incorporated internal programs to participate in ‘access to medicines’ initiatives. Within these initiatives, PPPs diversify risk and cost, and increase speed to the market.

National governments are doing their part for, and with, PPPs. To illustrate how states are participating, consider the controversial topic of high prices for HIV/AIDS medications in Africa. Patent rules were thwarting efforts to control diseases of public health importance in developing countries by restricting access to affordable medicines. In November 2001, the Doha Declaration

⁴⁴ Porter, *Competitive Strategy*, 139.

amended the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS). The revisions indicate that TRIPS should not prevent states from dealing with public health crises. Members of the Organisation for Economic Co-operation and Development (OECD) and those states affiliated with the Doha Declaration have government programs in place for the tiered-pricing of pharmaceutical imports and exports. Canada's 'Access to Medicines Regime' is an example of this. All member states have until the end of 2006 to implement programs such as Canada's Access to Medicines Regime. Least-developed countries are to implement pharmaceutical patent provisions by 2016⁴⁵. For the new entrant this means stronger international cooperation and stronger patent protection.

Today the idea of a 'not-for-profit' biopharmaceutical is a viable business strategy under the public-private partnerships model. Two prominent global 'not-for-profit' players include the Institutes of One World Health (IOWH), Drugs for Neglected Diseases Initiative (DNDi). Even though these business strategies only recently emerged in the biopharmaceutical industry, there is growing acceptance that PPPs can create a viable and potentially sustainable business model. Just as smaller biotech organizations collaborate with larger pharmaceutical organizations to develop a new product, there exists a small for-profit biotech company, Amyris of Berkeley, California, collaborating with IOWH to develop its anti-malarial drug⁴⁶. Under the partnership, Amyris will produce the drug at cost in exchange for the funding. IOWH will assist with clinical trials. Furthermore, under this agreement, UC Berkeley lifted royalty-fees due to the university⁴⁷. This example demonstrates one way that the state of rivalry is shifting. Cooperation in PPPs decreases

⁴⁵ World Trade Organization, "Doha Declaration Explained", http://www.wto.org/English/tratop_e/dda_e/dohaexplained_e.htm, (accessed November 05, 2006).

⁴⁶ Renuka Rayasam, "Bets On Biotech: The Non-Profit World Steps In To Finance For-Profit Drug Ventures". *US News and World Report*. September 17, 2006, <http://www.usnews.com/usnews/biztech/articles/060917/25biotech.htm>.

⁴⁷ Amyris is founded by five UC Berkeley scientists who discovered the core technology while at the university. Further information may be found at Amyris Biotechnologies' corporate website, http://www.amyrisbiotech.com/news_121304.html, (accessed December 06, 2006).

rivalry for new entrants. Under PPPs, entrepreneurs are creating new business models for biopharmaceutical development.

5.2.1.2 Competition Amongst Pharmaceutical Organizations

A second strategic group of rivalry is pharmaceutical organizations. This is the traditional strategic group of rivalry for new entrant. Large pharmaceutical organizations have a lot of capital and market power. These incumbents have a history of retaliation when their market share is threatened. Two strategically dominant pharmaceutical organizations facing the new entrant are Pfizer Inc. and GlaxoSmithKline plc. Pfizer is the industry's global market leader with a 10.1% share in 2004. Pfizer is also the market leader in *C. trachomatis* treatments. GlaxoSmithKline is the second largest industry competitor with a 6.5% market share in 2004. GSK is also the market leader in vaccines. These two pharmaceutical organizations are the largest rivals to the chlamydia vaccine entrant. Corporate highlights describe these rivals' competitive positions.

GlaxoSmithKline plc. Only four competitors dominate the vaccine market segment: GlaxoSmithKline, Sanofi Pasteur (the vaccine division of Sanofi-Aventis), Merck and Wyeth. GSK's roots began in 1715 in London, England. Headquarters remain there today. GSK employs over 100,000 people in 116 countries. It sells products in 130 countries. It is a global leader in the area of vaccines. GSK supplies one quarter of the world's vaccines. Its products include vaccines for hepatitis A, hepatitis B, influenza, measles, mumps, rubella, typhoid and chicken pox. In 2005, total product revenues amounted to £18.7 billion. Of this amount, vaccine revenues accounted for £1.4 billion. By the year's end, they had 25 vaccines in the clinical market and development. In 2005, they increased vaccine sales by 15%. Strategic moves created 10% of this increase⁴⁸.

⁴⁸ GlaxoSmithKline, s.v. "Investors", from <http://www.gsk.com/investors/index.htm>, (accessed October 18, 2006).

One strategic move was the acquisition of Vancouver's ID Biomedical Corporation (IDB) in last quarter of 2005. IDB operated in the areas of vaccine research, development, manufacturing, sales and marketing. They had facilities operating in Canada and the United States. IDB supplied 75 percent of the annual public influenza vaccine requirement purchased in Canada. Post-merger, GSK assumed, and now supplies, 75 percent of the annual public influenza vaccine requirement purchased in Canada. They have a supply contract until 2008. Sanofi Pasteur Ltd. supplies the remaining 25 percent. GSK's vaccine export capability expanded significantly with the acquisition. GSK now has two state-of-the-art manufacturing facilities in Quebec, located in Laval and Ste. Foy. The company's global vaccines division, GSK Biologics, will also establish a core research centre in Laval⁴⁹. It expects to complete its expansion of this vaccine research and production facility in 2007.

GSK has been active in helping developing countries through several programs. GSK cites improving access to medicines as its "strategic business driver" and part of its corporate responsibility⁵⁰. It is the only pharmaceutical company working on all three World Health Organization (WHO) priority diseases. Almost 100 countries benefited from GSK's humanitarian product donations in 2005. WHO heralded GSK for delivering the industry's largest single donation of pharmaceutical drugs. GSK agreed to donate 6 billion albendazole tablets over a 20-year period at an expected cost of US\$1 billion⁵¹. In 2005, they donated 136 million of these tablets to help eliminate lymphatic filariasis (elephantiasis). For over 20 years, GSK has offered preferential pricing treatments to more than 63 developing countries. This includes their vaccines. In one year alone, GSK provided over 540 million vaccine doses at discounts sometimes below

⁴⁹ GlaxoSmithKline, Canadian Newsletter, Summer 2006, http://www.gsk.ca/en/media_room/newsletter/pdf/GSKNewsSum06.pdf, (accessed October 20, 2006).

⁵⁰ GlaxoSmithKline, "Access to Medicines, CR Report 2005", http://www.gsk.com/responsibility/cr_report_2005/access-to-medicines/index.htm, (accessed December 06, 2006).

⁵¹ GlaxoSmithKline, "2005 Annual Report", <http://www.gsk.com/investors/annual-reports.htm>, (accessed October 18, 2006).

the price level suggested by WHO⁵². They have provided vaccines at discounts to UNICEF, WHO, GAVI and the Pan-American Health Organization.

GSK recognizes the importance of PPPs. GSK works closely with the Gates Foundation. Within PPPs, GSK provides the research, development, technology, manufacturing and distribution expertise. Other partners and governments help fund the development and delivery costs.

Pfizer, Inc. Charles Pfizer Sr. founded the company in 1849. Headquarters are in New York, USA. Pfizer is the industry's leader. Pfizer accounts for 7.7% of the industry market value share⁵³. Pfizer employs over 100,000 people in 180 countries. There are approximately 70 manufacturing facilities. Revenues for 2005 were US\$51.3 billion. Revenues in 2005 for their drug Zithromax[®] were US\$2.0 billion.

Zithromax[®] (azithromycin) was the number one prescribed oral antibiotic in 2005. Its patent expired though in November 2005. In the fourth quarter of 2005, four generics came into the market. In less than two months of generic availability, generic azithromycin constituted 90% of the total adult prescriptions. One of these four generics came from Pfizer's Greenstone subsidiary. Pfizer's generic had captured 49% of the total generic prescriptions⁵⁴. Its corporate brand is strong.

For more than 30 years, Pfizer has helped underprivileged people access the medicines they need. In 2004, Pfizer invested US\$98 million in cash donations and US\$1.2 billion in

⁵² Ibid. These drug tablets, albendazole, are for treating lymphatic filariasis or elephantiasis.

⁵³ Datamonitor. "Global Pharmaceutical and Biotechnology Industry Profile". (2005): 3. www.datamonitor.com

⁵⁴ Pfizer, "2005 Annual Report", <http://www.pfizer.com/pfizer/annualreport/2005/financial/financial2005.pdf>, (accessed October 18, 2006).

product donations⁵⁵. In 1998, Pfizer collaborated with the Edna McConnell Clark Foundation to establish the International Trachoma Initiative (ITI)⁵⁶. Developed as a public-private partnership, this initiative uses WHO's innovative plan called the SAFE⁵⁷ strategy. SAFE combines curative medicine, community-based public health approaches and educational tools⁵⁸. Pfizer's role is to provide the medicine. It has donated Zithromax[®] to programs in Morocco, Tanzania, Egypt, Sudan, Vietnam, Mali, Ghana, Nepal, Niger and other countries. To date, Pfizer has donated 38 million doses of Zithromax[®]. Pfizer plans to increase that donation to 135 million doses over the next five years to fight blindness caused by *C. trachomatis*.

The overall state of rivalry is high. In the chlamydia market segment, Pfizer is the dominant competitor. In the vaccine market segment, GSK is the dominant competitor. Both these organizations are mature industry players. They have existed for more than 100 years. They have economies of scale and scope that help them maintain their competitive positions. They protect their market share. They may do this by blocking distribution channels. They may also do this by hostile takeover of the intellectual property. The latter recently occurred to local biopharmaceutical company, AnorMED Inc. After AnorMED refused an unsolicited bid for Mozibil[™], their oncology product in late-stage clinical trials, Genzyme Corporation tendered an unsolicited bid to purchase the company in April 2006. What followed was interest from other biopharmaceutical firms which led to a price war between itself and Millennium Pharmaceuticals, Inc. This culminated into a Board of Directors shake-up by September 2006. The end result is

⁵⁵ Pfizer, s.v. "Improving Access To Medicines", http://www.pfizer.com/pfizer/subsites/corporate_citizenship/report/improve_access.jsp, (accessed October 18, 2006).

⁵⁶ Pfizer, s.v. "International Programs", <http://www.pfizer.com/pfizer/subsites/philanthropy/access/intl.programs.index.jsp>, (accessed October 18, 2006).

⁵⁷ World Health Organization. "SAFE: Surgery for trachiasis, Antibiotic therapy, Facial cleanliness and Environmental change", <http://www.who.int/bulletin/volumes/84/8/05-028696.pdf>. (accessed October 20, 2006).

⁵⁸ Pfizer, s.v. "Global Health: International Trachoma Initiative", <http://www.pfizer.com/pfizer/subsites/philanthropy/caring/global.health.trachoma.jsp>, (accessed October 18, 2006).

that by November 07, 2006, Genzyme's acquisition of AnorMED was complete. The new entrant, whether for-profit or not-for-profit, can expect retaliation from this rival group. The incumbents will protect their market share. However, within the PPPs rivalry group, cooperation reduces the level of competition because each member brings unique core competencies, working towards a common goal. Rivalry between the new entrant and the large pharmaceutical organizations is less intense within strategic alliances and joint ventures.

5.2.2 Buyer Bargaining Power (Moderate)

The chlamydia vaccine new entrant buyers include centres for disease control, government agencies, hospitals, and pharmaceutical organizations. Organizations have greater power than individual customers do⁵⁹. For developing countries, as long as the price for the vaccine remains below \$1/day, there is an opportunity in these nations. In developed countries, the bargaining power of buyers is much stronger.

Canada's federal government (the Government) committed \$300 million in 2004 to support the introduction of new vaccines⁶⁰. The provinces and territories placed funding programs for one or more of these vaccines. A new chlamydia vaccine would likely have the Government's support in a push market.

The bargaining power rests on other buyers should the Government not support publicly funded vaccinations against chlamydia. The buyer with the most power would be the channel distributors. Buyers refer to a formulary when they stock products. It is a challenge for any biopharmaceutical company to have its drug product listed on the regional formulary.

⁵⁹ Anthony E. Boardman and Aidan R. Vining, "Using Service-Customer Matrices in Strategic Analysis of Non-Profits", *Nonprofit Management & Leadership*, vol. 10, no. 4, (Summer 2000): 403.

⁶⁰ Public Health Agency of Canada, News Release, May 17, 2004, http://www.phac-aspc.gc.ca/media/nr-rp/2004/2004_01_e.html, (accessed on November 4, 2006).

With the exception of the United States, almost all Western governments control drug prices in varying ways. In Canada, the Patented Medicines Prices Review Board (PMPRB) limits the prices set by manufacturers for all patented medicines sold in Canada. PMPRB regulates the factory-gate price only. Manufacturers sell the patented medicine to wholesalers, hospitals and pharmacies at or below this price. Prices charged by wholesalers or retailers are not controlled. The PMPRB determines the factory-gate prices following these guidelines⁶¹:

- Prices of new patented-drugs are limited so that the cost of therapy is in the same range of the cost of therapy for existing drugs sold in Canada used to treat the same disease.
- Drug prices are limited to the median of the prices for the same drugs as charged in other specified industrialized countries. These countries (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.) are set out in the Patented Medicines Regulations.
- Prices of existing patented drugs cannot increase by more than the Consumer Price Index (CPI).
- Canadian prices of patented medicines can never be the highest in the world.

Be aware that parallel trading (arbitrage) occurs in this industry. The grey market is a lucrative business within the distribution channels. Medihealth, a pharmaceutical wholesaler in the United Kingdom, exemplify how this works. In January 2004, Medihealth received 3,997 boxes of Nasonex, Schering-Plough's prescription nasal spray. They purchased these in France

⁶¹ Patented Medicine Prices Review Board, s.v. "Frequently Asked Questions", <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#1>, (accessed on October 20, 2006).

for the factory-gate price of US\$11.80 per bottle⁶². Medihealth repackaged the product in its back rooms to meet UK regulatory packaging standards. Medihealth then sold the product wholesale with a US\$3 mark-up. This resulted in a quick US\$55 million in additional profits⁶³. Britain re-exports 20% of its prescription drugs. In fact, Britain financially rewards pharmacists when they arbitrage. The reason for allowing this is that it keeps health care costs down. Some countries like Germany mandate that pharmacies have a portion of their stock coming from parallel trade or else face penalties. Legal pharmaceutical arbitrage in Europe and North America's free-trade zone is presumably more than a US\$15 billion business. Compare this to the pharmaceutical industry's annual revenues for prescription drugs. In 2003, revenues amounted to US\$350 billion. Revenues in 2004 for over-the-counter drugs and prescription drugs amounted to US\$604 billion. Arbitrage is not a priority issue for governments or some pharmaceutical organizations. Overall, there is a growing industry movement to control arbitrage.

GlaxoSmithKline initiated legal action against a Dutch wholesaler trader in 2004. Authorities in Belgium intercepted a shipment of GSK's HIV/AIDS Combivir drug. This shipment was intended for the African market but the distributor diverted it to Europe. Combivir is worth 33 cents in Africa. It is worth US\$10 in Europe. This Dutch trader was allegedly behind 23 other trades involving 44,000 packs of diverted drugs. GSK fought for tighter trade regulations. The EU courts maintain that parallel trade is legal. The World Trade Organization (WTO) addressed parallel trading at the Cancun General Council Meeting on the Doha Agreement in 2003. New supplier-buyer contract restrictions are now permissible. These new restrictions limit the volume shipped to markets where orders appear to exceed local needs.

⁶² As in Canada, the French government caps drug manufacturer's selling price.

⁶³ Richard C. Morais, "Pssst.... Wanna Buy Some Augmentin?", *Forbes.com*, April 12, 2004, http://www.forbes.com/free_forbes/2004/0412/112.html.

Stronger packaging controls and colours distinguish donated or tiered-priced drugs from mainstream market products. GSK and others are following these new standards⁶⁴, ⁶⁵.

For the new entrant, the bargaining power of buyers is moderate. Most industrialized nations cap factory-gate prices. However, the new entrant should be aware of pricing arbitrage, or parallel trading. In this context, the distributors have more power than the new entrant does. In many areas, parallel trading is an acceptable and legal business practise. The new entrant can protect itself by implementing the Doha Agreement standards.

5.2.3 Supplier Bargaining Power (Low)

The bargaining power of suppliers is low. There are high switching costs between suppliers. Drug development organizations operate in a highly regulated environment. Switching increases the costs associated with meeting regulatory requirements.

For pre-clinical studies, the suppliers are the material and equipment suppliers, the contract research organizations (CROs) for manufacturing test articles, and the Good Laboratory Practices (GLP) animal study sites.

For clinical studies, CROs must conduct all manufacturing under current Good Manufacturing Practices (cGMP) conditions. All supplies and equipment in the manufacturing process must meet cGMP standards. For example, all new equipment requires an “IQ/OQ/PV” before it may be used. This is a costly and timely process. It requires specialized technicians. All new methods must be qualified and validated before manufacturing must begin. Quality Assurance (QA) must perform audits. There is a lot of documentation required.

⁶⁴ GlaxoSmithKline, “News Topics: Importing Medicines to the United States”, http://www.gsk.com/media/ca_overview.htm, (accessed October 18, 2006).

⁶⁵ Kevin Outterson, “Resolving Dysfunctional Pharmaceutical Arbitrage and Counterfeit Drugs Through The Proposed Pharmaceutical R&D Treaty”, http://www.who.int/intellectualproperty/submissions/en/pharma_arbitrage.pdf, (accessed October 18, 2006).

For the chlamydia vaccine, materials and skills required for product manufacturing are not complicated compared to other vaccine manufacturing processes. Biologics in general require more specialized training than chemical entities. There is a higher risk of contamination. Biologics are also more sensitive to environmental conditions such as temperature and pH. The new entrant would require specialized CROs.

Due to the high degree of regulation and specialization, there are high sunk costs to becoming a supplier in biologics. Consequently, there is high competition between suppliers. As a result, the new entrant has more bargaining power than the suppliers do.

5.2.4 Threat of Entry (High)

The threat of entry into an industry depends on the barriers to entry coupled with the retaliation from existing competitors. If barriers are high, and/or sharp retaliation is expected, then the threat of entry is high⁶⁶.

This section looks at the barriers to entry for the new entrant. The state of rivalry section previously mentioned retaliation from incumbents. This section touches on it again because it increases the threat of entry for the new entrant.

5.2.4.1 Barriers to Entry

There is a high cost of capital required to finance a not-for-profit biopharmaceutical company. Business, scientific and regulatory expertise is required to operate such an enterprise. The level and range of acumen needed is a strong deterrent for new entrants. This section looks at five factors that create barriers to entry.

⁶⁶ Porter, *Competitive Strategy*, 7.

- i. **Product Differentiation.** Established brand names and customer loyalties to the established organizations creates a barrier to entry for the new firm. Currently Pfizer holds most of the market share of therapeutics for *C. trachomatis* infections.

There are few “virtual” or “not-for-profit” biotechnology organizations in existence to create a talent pool of experienced senior managers or build a strong brand image. To date there are two dominant organizations: the Institutes of OneWorld Health and Drugs for Neglected Diseases (DNDi). The new entrant can expect a high investment to access markets and overcome customer loyalty to the incumbents.

- ii. **Capital Requirements.** Procurement of start-up capital and sustainable funding is a great challenge. The Institute of OneWorld Health (IOWH) illustrates this challenge. The IOWH is the first biopharmaceutical non-profit organization (NPO). Ms. Victoria Hale, CEO of IOWH, approached the Bill and Melinda Gates Foundation (Gates Foundation) for capital funding in 2001. The IOWH has received 96% of its funding from Gates Foundation. Grants from the foundation total US\$ 144.8 million⁶⁷. Funding is still a challenge for IOWH. The Gates Foundation is actively trying to help IOWH expand their funding base. They are doing this through public marketing and education.

To develop the chlamydia vaccine within a PPP model, sources of funding include government sources and UN regional block sources. Government sources include US NIH, CIHR, NSERC, Genome Canada, Genome BC, and Western Economic Diversification Canada. UN regional blocks include WHO, World Bank, WHO/TDR. Recently, GAVI formed the International Finance Facility for Immunisation Company (IFFIm). Its function is to accelerate the availability of funds for health and immunization programs. Regional equity

⁶⁷ Angela Rickabaugh Shears, “Curing the Third World: How Donors Can Help Develop Drugs Critical to World Health”, *Philanthropy Roundtable*, September 25, 2006, <http://prt.timberlakepublishing.com/printarticle.asp?article=1420>.

capital is available through BC Discovery Fund, BC Advantage Fund, Discovery Capital, MDS Capital Corporation, PenderFund Capital Management, RBC Technology Ventures, UILO New Ventures Fund, Working Opportunity Fund, WUTIF Capital Inc., BC Innovation Capital, BC Knowledge Development Fund.

To start a biopharmaceutical corporation in British Columbia, many sources of government grants and tax incentives would be accessible such as NRC-IRAP, and SR&ED tax credits. However, many loans available through government sponsored programs do require an interest payment or a small return on investment which may be difficult for a not-for-profit biopharmaceutical enterprise.

Foundations that are likely sources for funding include the Gates Foundation⁶⁸, The Wellcome Trust Foundation⁶⁹ and the Rockefeller Foundation⁷⁰. Individual philanthropists are also a consideration.

Grants and loans are difficult to obtain. High capital requirements and difficulties accessing capital as a new entrant increase the threat of entry for the new entrant.

- iii. Switching Costs.* A vaccine does not exist on the market for chlamydia. The current antibiotics available for *C. trachomatis* treatments are oral tablets. Administration of the drugs to the patients is simple. Switching to a vaccine would require training and perhaps new equipment. There may be higher resistance from health care workers in the developing countries due to this switching cost. However, the social benefits may outweigh the one-time cost. Costs facing the customer for switching from one supplier to another increases the threat of entry for the new entrant.

⁶⁸ Bill & Melinda Gates Foundation, "Global Health Grantmaking Areas", <http://www.gatesfoundation.org/ForGrantSeekers/GlobalHealth/>, (accessed October 8, 2006).

⁶⁹ The Wellcome Trust, "International Funding", <http://www.wellcome.ac.uk/>, (accessed October 8, 2006).

⁷⁰ The Rockefeller Foundation, "Grantmaking", <http://www.rockfound.org/Grantmaking/Health>, (accessed October 8, 2006).

- iv. **Access to Distribution Channels.** Existing organizations may have strong relationships with key distributors. Typically, incentives such as price cuts help distributors place the new firm's products into its channel. However, with a not-for-profit product, cash incentives are not feasible. Using parallel traders amongst developing countries may push the product into the market but could harm the brand reputation of the vaccine. Access to distribution channels may be difficult for the new entrant.

- v. **Government Policy.** The governments regulate all pharmaceuticals and medical devices. They also regulate product import and export. The degree of regulation varies by country. Patents are proprietary rights to the firm in the issuing country only. The Doha Declaration will be effect by 2007 in all 149 WTO member states. It will have an impact. It could increase parallel trading. To date counterfeit drugs are much more of a public safety concern and financial loss to pharmaceutical organizations. Government policy can increase the threat of entry for the new entrant. This is due to the high cost of regulation but it can also protect the new entrant.

5.2.4.2 Expected Retaliation from Incumbents

As previously discussed, Pfizer is the current market leader in treatments for *C. trachomatis*. They have an established partnership through the ITI with the UN, WHO, NGOs and governments to deliver azithromycin to income-suppressed countries. Pfizer's brand name and customer loyalty is strong. Pfizer has economies of scale and scope. They have excess capital to cover the costs of defending its market position against new entrants. Pfizer's Zithromax[®] is the leading prescribed antibiotic. Pfizer's retaliation to the generic azithromycin entrants demonstrates its fortitude. Pfizer's generic azithromycin captures 90% of generic drug prescriptions. Pfizer has the capital, the market power and the experience to fight off new entrants. Retaliation is very likely.

5.2.5 Threat of Substitute Products (Moderate)

This section looks at substitutes for the chlamydia vaccine. The most commonly used treatments are a single dose of azithromycin (Zithromax[®], Pfizer), or a week of doxycycline (Doryx) twice daily. Alternatively used antibiotics are erythromycin, ofloxacin, and amoxicillin. These latter prescribed antibiotics are for patients that have complications, such as pregnancy, and cannot use Zithromax[®]. The single oral dose Zithromax[®] /azithromycin tablet is the most commonly prescribed treatment for *C. trachomatis* infections.

Pfizer's Zithromax[®] is also available as an intravenous (i.v.) injection. It is available in a lyophilized form. The reconstituted solution is stable for 24 hours when stored below 30°C or 86°F. The recommended treatment of adult patients with pelvic inflammatory disease is 500 mg in a single daily i.v. dose, for one or two days⁷¹. The i.v. therapy recommends a supplemental single, oral daily dose of 250 mg to complete a 7-day course of therapy. The advantages of this treatment are not clear.

While the chlamydia vaccine may be a superior product, the cost/benefit ratio for Pfizer's azithromycin may be more favourable to that of the vaccine. Pfizer's brand and customer loyalty may be a large barrier. Its distribution networks are strong.

A recent WHO study found only 28 manufacturing sites capable of performing the vaccine development process that meet international quality standards⁷². Few distributors understand the sensitivities of handling vaccines. This may also make Pfizer's drug more

⁷¹ US Food and Drug Administration CDER, s.v. labels, "Zithromax", NDA 50-733/S-005, <http://www.fda.gov/cder/foi/label/2001/50733s51bl.pdf>, (accessed October 5, 2006).

⁷² World Health Organization, Julie Milsten, "Economics of Vaccine Development and Implementation: Changes Over the Past 20 Years", http://www.who.int/immunization_supply/introduction/economics_vaccineproduction.pdf, (accessed October 20, 2006).

appealing. The chlamydia vaccine must undergo local regulatory approval as well as WHO approval for distribution through UN agencies⁷³.

The chlamydia vaccine is likely to be the only product of its class on the market. It will be the only product creating immunity to *C. trachomatis* genital infections. A direct substitute does not exist but a close substitute, azithromycin, does exist. The chlamydia vaccine is a disruptive technology to Pfizer's product.

5.3 Summary of Competitive Structural Analysis

Overall, the biopharmaceutical industry's attractiveness is moderate. It is a mature industry with growth segments, such as, STD vaccines. Two key competitive forces are rivalry and threat of entry. Two strategic groups represent the new entrant's rivals. Public-private partnerships are one strategic group that is growing in fortitude. While retaliation is unlikely from this group, it may be difficult to compete with such established networks for scarce resources. The pharmaceutical group represents the second strategic group. Within this group, there are two key competitive organizations. GlaxoSmithKline is the commercial leader in the vaccine market segment. Pfizer is the commercial leader in the chlamydia infections market segment. Both companies have operated in the industry for over 100 years. They have achieved competitive advantages such as economies of scale, economies of scope. They also have large internal and external capital resources. If they experience a threat from a new entrant in their market segment, they retaliate. GSK bought ID Biomedical. Pfizer retaliated against generic new entrants using its distribution channels' and customers' loyalty. The chlamydia vaccine new entrant can expect retaliation if collaboration is not established before applying for a market license.

⁷³ World Health Organization, "Procedure for Assessing the Acceptability, in Principle, of Vaccines for Purchase by United Nations Agencies", <http://www.who.int/vaccines-documents/DocsPDF06/812.pdf>, (accessed October 20, 2006).

Government policy creates a barrier to entry due to the high cost associated with regulatory requirements. However, government policy with respect to property rights is assisting biopharmaceuticals in international trade contracts. Overall, government policy protects the new entrant. Expected future changes will be beneficial to the new entrant.

6 STRATEGIC VALUE CREATION THROUGH INTERNAL CHARACTERISTICS

A value chain analysis looks at an organization's activities and its linkages between these activities. It analyzes how the activities and linkages create or reduce value for the end user⁷⁴. Porter's model is widely used in all industries to derive competitive advantage from an organization's internal characteristics. Its framework however, reflects that of a manufacturing company. A biopharmaceutical organization is not in the manufacturing business. Rather, it is in the information procurement and management business. This chapter uses Porter's model but with modifications.

6.1 Value Chain Analysis for a Typical Biopharmaceutical Organization

Boardman, Shapiro and Vining (2004) define strategic assets as, "resources and capabilities that not only create a competitive advantage, but are unique, sustainable, and in addition can be employed elsewhere within the organization, in other markets or in other countries (replicable)"⁷⁵. Resources are the tangible and intangible assets that are valuable and not easily imitated. Capabilities are the linkages, or the coordination of activities, that combine resources to create value⁷⁶. These strategic assets create a firm's core competencies. Core competencies lead to competitive advantage. Will it be via a cost advantage, a differentiation advantage or a mixture of both? A value chain analysis answers this question.

⁷⁴ W. Jack Duncan, Peter M. Ginter, and Linda E. Swayne, "Competitive Advantage and Internal Organizational Assessment", *Academy of Management Executive*, Vol. 12, No. 3, (1998): 6.

⁷⁵ Anthony E. Boardman, Daniel M. Shapiro, and Aidan R. Vining, "A Framework for Comprehensive Strategic Analysis", *Journal of Strategic Management Education* 1(2), (2004): 19.

⁷⁶ Duncan et al., "Competitive Advantage and Internal Organizational Assessment", 10.

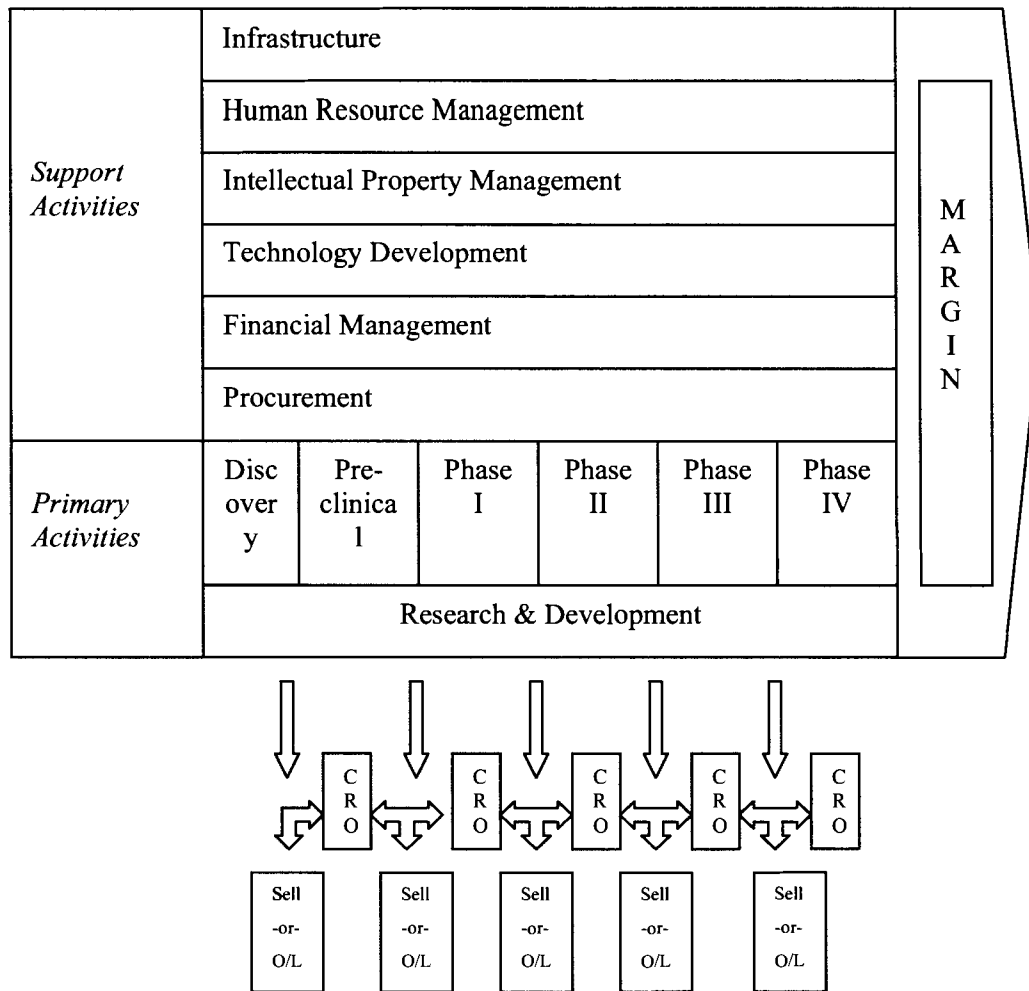
This section will present areas of value creation since the chlamydia vaccine enterprise is in the formation stage. Creating a sustainable competitive advantage is the result of maintaining a value differential between one's product and the competitors' in the eyes of the customers. In the case of the chlamydia vaccine enterprise, the result of obtaining a competitive advantage would be the public health and UN agencies seeing the chlamydia vaccine as more valuable than antibiotic tablets.

The ability to develop and maintain a sustained competitive advantage in the biopharmaceutical industry is arduous work. A company must be flexible and adaptable. This is more important today than market positioning, or location, especially in technology sectors⁷⁷. Many emerging biotechnology organizations look for acquisition by larger pharmaceutical organizations as their primary exit strategy.

This chapter assumes that the inventor will form an enterprise that develops the vaccine through to market approval. A modified version of Porter's generic framework depicts a biopharmaceutical enterprise's value chain (Figure 4). This framework reveals strategic activities that create value, which the generic model may have obscured. The primary activity domains now reflect the incremental stages in product value.

⁷⁷ Duncan et al., "Competitive Advantage and Internal Organizational Assessment", 7.

Figure 4: Typical Biopharmaceutical Value Chain



Adapted from Michael E. Porter's generic value chain model.

This new model shows that at each primary activity linkage point there is exists choices for progression. There are two key choices. The choices are to perform the next activity domain either in-house or to outsource it. If the activity is outsourced, two more options are available. They are, 1) out-licence or sell to a strategic partner, or 2) contract out the work. Performance outcomes of the last activity domain (such as financing, resources, and capabilities moving forward), affect the decision to outsource.

6.1.1 Primary Activities for Vaccine Development

Primary activities are the main value creation processes. Biopharmaceutical organizations are data creators and processors. In order to obtain and maintain a market license, national regulatory bodies require safety and efficacy data. The information capital increases as it moves along the chain. The intellectual property value also increases as information capital value increases. This is why later stage licensing agreements have higher financial returns.

Ultimately a tangible product for the market is created but not until there is an approved BLA. To create data for a BLA, two primary activities are required. They are R&D and clinical trials. Each phase in the clinical trials is separate to reflect a new activity unit and a jump in value creation.

6.1.1.1 Research and Development

The inventors have strength in their intellectual capital. Their expertise in proteomics, emerging infections diseases, and STDs is difficult to replicate. They have both resources and capabilities. This will be valuable throughout the value chain system. Research and development does not end when the product enters clinical trials. On the contrary, research and development is ongoing as new methods are developed and validation for product modifications, manufacturing specifications and quality control. Research and development also produces the CMC data required for INDs and BLAs. R&D does not stop.

When forming the company, it is advisable that recruited scientists be able to add value as the product moves along the value chain. For example, a scientist with experience in scaling up vaccine production would be valuable. Quite often in biologics, the scale up process initiates novel problems. Expertise in research and development will add value along the value chain. It will nurture a core competency creating a competitive advantage.

6.1.1.2 Clinical Trials

There are two ways to increase value during clinical trials. A biopharmaceutical firm will create value by managing product development costs and by managing processes. This section describes these two value creation objectives.

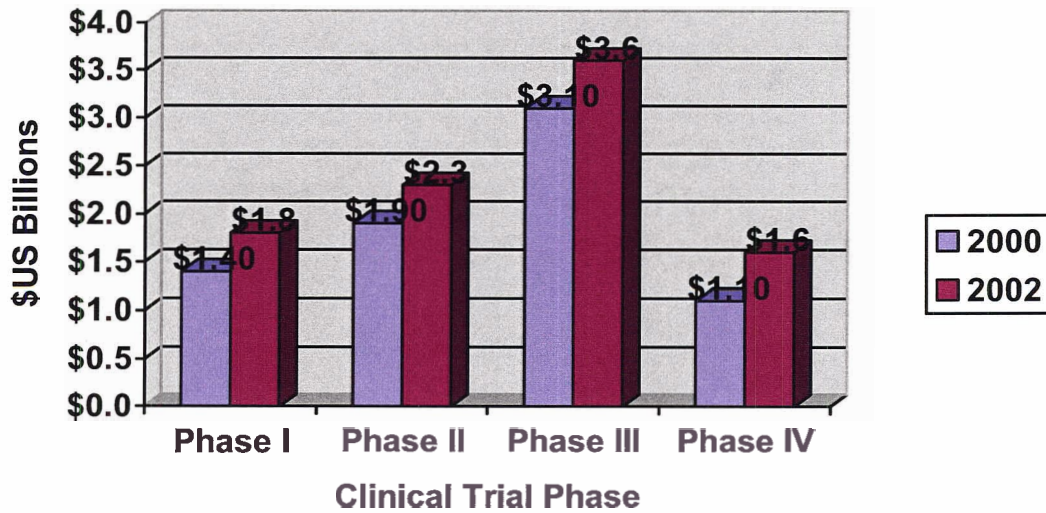
i. Managing Development Costs to Create Value. Clinical trials make up the bulk of the value chain. The probability of a BLA submission increases as a product moves from one clinical phase to the next. This higher probability of a BLA corresponds with a reduction in risk of failure and an increase in proprietary value.

A 2001 study (Figure 5) estimates that early-phase trial spending has a 16% annual growth rate. Mid-phase trial spending has a 7% annual growth rate. Late-phase trial spending has a 20% annual growth rate⁷⁸. In order to match this cost growth, pharmaceutical organizations need to launch two products a year for a 5 % annual growth, five products a year for a 10% annual growth and nine products a year for a 15% annual growth⁷⁹. This is an enormous task. Managing the product pipeline efficiently keeps cash flow positive.

⁷⁸ CentreWatch, PhRMA 2001 Annual Member's Survey, www.centerwatch.com/careers/career03.ppt, (accessed on October 25, 2006).

⁷⁹ Ken Lacey and David Blumberg, "Networked Pharma: Pharma's New Business Model Breaks Apart the Value Chain and Focuses on Core Capabilities", *Pharmaceutical Executive*, (2003), <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=59370&searchString=networked%20pharma>

Figure 5: Total PhRMA Spending On US Clinical Development



Source: author, modified from CenterWatch and PhRMA

There is a 2001 landmark study from Tufts Center for the Study of Drug Development (Tufts). The study states that out-of-pocket cost per approved drug is US\$ 403 million. The study data incorporates both classes of drugs, new chemical entities and biologics. Average expected capitalized cost to bring an investigational drug to market approval is US\$802 million. The cost of capital used in the study was 11%. Contributing to this average capitalized cost are the time-value of money (50%), clinical failures (39%), Phase I successes (3%), Phase II successes (3%), and Phase III successes (5%)⁸⁰. In the study conclusion, the authors predict that R&D initiated in 2001 with approvals obtained in 2013, would see pre-approval out-of-pocket costs rise to US\$ 970 million and pre-approval capitalized cost rise to US\$ 1.9 billion⁸¹. The estimated internal rate of return is close to the cost of capital⁸².

⁸⁰ Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Gabrowski. "The Price of Innovation: New Estimates of Drug Development Costs". *Journal of Health Economics*. 22 (2003): 151-185.

⁸¹ *Ibid.*, 181.

⁸² *Ibid.*, 182.

Table 8: Average Out-Of-Pocket Clinical Development Costs For Investigational Compounds (US\$ millions, 2000)

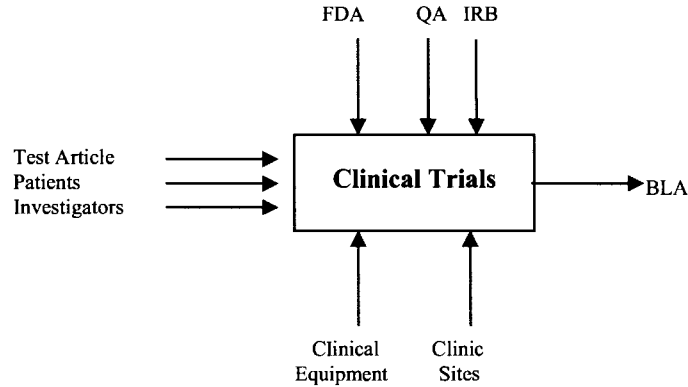
Testing Phase	Mean Phase Length	Mean Time to Next Phase	Mean Cost Full Sample	Median Cost Full Sample	Standard Deviation Full Sample	Probability of Entering Phase	Expected Cost	Mean Cost Approved Drugs	Median Cost Approved Drugs	Standard Deviation Approved Drugs
Phase I	21.6	12.3	15.2	13.9	12.8	100.0	15.2	15.2	11.7	14.3
Phase II	25.7	26.0	23.5	17.0	22.1	71.0	16.7	41.7	31.5	30.2
Phase III	30.5	33.8	86.3	62.0	60.6	31.4	27.1	115.2	78.7	95.0
Long-term animal	36.5	0	5.2	3.1	4.8	31.4	1.6	4.4	0	5.4
Total			130.2	96.0			60.6	176.5	121.9	

Data Source: Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Gabrowski, "The Price of Innovation: New Estimates of Drug Development Costs", Journal of Health Economics, 22 (2003): 162-171.

The mean cost in Table 8 includes successes and failures. In brief, if trials proceed ideally, clinical development costs require approximately US\$100 million dollars. The average time estimated between the start of clinical trials to submission of a BLA is 72.1 months. The average time estimated between the start of clinical trials to approval of a BLA is 90.3 months⁸³. We will now look at creating value over these 90.3 months through managing clinical processes.

ii. Managing Processes to Create Value. Managing clinical trial processes can lead to leaner operations and also provide differentiation and/or cost leadership advantages thereby creating value. A typical process (Figure 6) for clinical trials has three inputs and one output. The inputs are the test article, the patients and the clinical investigators. These are tangible items. The output is the BLA. This is a compilation of documents.

Figure 6: Clinical Trial Process Map



Source: author

Despite today’s technology, 70 to 80 percent of clinical trials are still paper based⁸⁴. It is not an exaggeration to say that, for one BLA review, the FDA receives truckloads of paper

⁸³ Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Gabrowski, “The Price of Innovation: New Estimates of Drug Development Costs”, *Journal of Health Economics*, 22 (2003): 164.

⁸⁴ Paul Bleicher, “Tools Are Just the Beginning: Should Companies Wait for Fully Integrated Systems”, *Pharmaceutical Executive*, (2005), <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=170721&searchString=Tools%20Are%20Just%20The%20Beginning>.

documents. Since 1997, the FDA has actively worked to enable electronic submissions of information. In 1999, the FDA issued the first industry guidance documents for sponsors on how to submit drug applications in electronic format, as opposed to the traditional paper approach. These type guidance documents are referred to as 'eSub-Guidances'⁸⁵. The first three eSub-Guidances issued are:

- FDA January 1999. "Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations"
- FDA January 1999. "Guidance for Industry: Providing Regulatory Submissions in Electronic Format—New Drug Applications (NDA) "
- FDA November 1999. "Guidance for Industry: REVISED Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)]"

The FDA issued its first regulation requiring submission of data via electronic means in 2003⁸⁶. The goal is to speed up the review process for NDAs, BLAs and ANDAs. The changes to 21 CFR parts 314 and 601 became effective on June 08, 2004. While this regulation pertains to labels only, it has sets a precedence for electronic future submissions.

The hold back to seeing more regulations like these is that few sponsors can afford integrated electronic data capture (EDC) systems. A fully integrated e-clinical development

⁸⁵ US Food and Drug Administration CBER, "Regulatory Submissions in Electronic Format, Guides and Rules", <http://www.fda.gov/cber/esub/esubguid.htm>, (accessed October 31, 2006).

⁸⁶ US Food and Drug Administration CBER, "Federal Register, Rules and Regulations", <http://www.fda.gov/cber/rules/labelelec.pdf> (accessed October 31, 2006).

process is not yet available. Integrating software from stand-alone systems has been problematic. There are partially integrated systems available. Many organizations face the strategic dilemma of investing in partially integrated e-clinical systems or waiting for future developments. Pharmaceutical organizations, such as GSK, Bayer, and Wyeth have invested hundreds of millions of dollars on new systems that were outdated by the time installation and implementation was completed. Wyeth now outsources the majority of its clinical data management to reduce administrative and infrastructure costs⁸⁷.

Many CROs are not investing the large sums of capital that pharmaceutical organizations have to develop fully integrated EDC systems. They have stand-alone or partially integrated e-clinical systems that they update regularly. CROs have created their core competencies in adopting EDC systems for clinical trials. It is not surprising that 25 percent of global R&D budget spending is on CROs for clinical trials. Accenture studies found that outsourcing clinical development saved organizations up to \$25 million for each successful project⁸⁸.

Linking supply chains and value chains drives the drug development process. New biologics are available in smaller supplies. They typically have lower stability. It is not practical to leave enough supplies at every investigation site for months while investigators enrol patients. However if EDC systems are linked between the investigator, sponsor and the manufacturer or supplier, sponsors can have the study materials shipped in a just-in-time mode. Returning to Figure 6 process inputs systems linked by EDC systems create lean systems. This speeds up the clinical development process and increases efficiency. Reduced costs and quicker submission/approval of the BLA are the result.

Global regulatory changes are inducing the change to EDC technology. EMEA already expects sponsors to submit electronic submissions a clinical registry called, the European Clinical

⁸⁷ Lacey and Blumberg, "Networked Pharma", 2003.

⁸⁸ Lacey and Blumberg, "Networked Pharma", 2003.

Trials Database (EUDRACT). The FDA is following suit. E-submission requirements will soon create a competitive threat for those organizations whose technology does not meet the reporting challenge⁸⁹. It is an ‘invest or divest’ decision at each phase of clinical development for value creation.

6.1.2 Support Activities for Vaccine Development

Support activities enable and improve performance of primary activities⁹⁰. There are six support activities. They are procurement, technology development, intellectual property management, human resource management, financial management and infrastructure. A brief description illustrates how each of these activity domains enables the primary activities to add value.

6.1.2.1 Procurement

Procurement represents the activities in obtaining supplies for the values chain. These are the raw materials and equipment for R&D and clinical trials. UBC CDC has access to state-of-the-art equipment and raw materials. For clinical trials, outsourcing test article manufacturing to a cGMP certified contract manufacturer facility could provide cost benefits. In-house test article manufacturing requires a separate cGMP location as well as further quality control and quality assurance services.

6.1.2.2 Technology Development

The technology department assists the laboratory with bioanalytical method development and validation, animal model development, and equipment IQ/OQ/PV. The technology department also assists with MIS systems, information technology resources, document back up

⁸⁹ Bleicher, “Tools Are Just the Beginning”, 2005.

⁹⁰ Charles B. Stabell and Øystein D. Fjeldstad, “Configuring Value for Competitive Advantage: On Chains, Shops, and Networks”, *Strategic Management Journal*, Vol. 19. (1998): 417.

and information security. Integrity of these activities facilitates regulatory approval of INDs and BLAs.

6.1.2.3 Intellectual Property Management

Intellectual property management is an important supporting activity. Intellectual property management affects the value chain and latter primary activities. This supporting activity can directly affect value if at any point along the value chain strategic alliances, joint ventures or licensing of patent rights occur. For example, a strategic alliance with a globally respected organization can increase corporate image and product value.

6.1.2.4 Human Resource Management

This activity is responsible for recruiting, hiring, training, integrating and developing the team. Inter- and intra- team coordination is important for efficiency and progress.

6.1.2.5 Financial Management

Obtaining funds for successive levels in the value chain is an on-going process. Funds come from a variety of sources because of the high capital required.

6.1.2.6 Infrastructure

Included in this category are the services or Regulatory Affairs, Quality Control, Quality Assurance, and Materials Management. These services are required to demonstrate to regulatory bodies that the integrity of the document and the vaccine development trials are of the highest standard.

6.2 Summary of Value Creation Through Internal Characteristics

This chapter looked at areas where the new entrant can create value in order to obtain a sustainable competitive advantage. A value chain analysis of a typical biopharmaceutical

organization showed R&D and clinical trial phases as key primary activities. The linkages between primary activities are points where outsourcing or forming strategic alliances can create value through cost leadership; or, moving forward with lean operations can create value through differentiation and/or cost leadership. This information is useful for the new entrant in assessing strategic alternatives.

7 AXS*VAX'S CURRENT STRATEGY

This chapter reviews AXS*Vax's current strategy and strategic direction. Following this, the chapter will forecast its expected performance.

7.1 Current Strategy Situation

The general strategies to consider are product differentiation, cost leadership or a focused/mixed niche strategy⁹¹. AXS*Vax aims to differentiate itself from current low cost alternative treatments. A mixed strategy of product differentiation and low cost is congruent with Dr. Brunham's statement; the chlamydia vaccine will be "safe, affordable, and effective".

The full immunization treatment against *C. trachomatis* includes a series of two or three booster shots. The target factory-gate price for each shot in the immunization series is approximately \$10. The ultimate decision to enter the market depends on the results from clinical trials and the cost of manufacturing the vaccine.

The United States and Canada will be the initial target markets. This large market size will provide revenues that will 1) reduce capital liabilities from product development and 2) subsidize sales to developing countries. Under Canada's Regime, the biopharmaceutical enterprise may export the chlamydia vaccine to developing countries at a reduced price.

There are three levels of strategy articulated by AXS*Vax. They are the corporate level, positioning, and competitive strategies. The current corporate strategy is to develop and launch a vaccine product business. The positioning strategy is a focused/mixed strategy. An affordable single vaccine product in a global niche STD market is the target. Its competitive strategy is to

⁹¹ Porter, *Competitive Strategy*, 34-46.

provide R&D for a prophylactic and therapeutic vaccine treatment against *C. trachomatis*. Table 9 lists the functional strategies sought by AXS*Vax.

Table 9: AXS*Vax's Current Functional Strategies

Strategy	AXS*Vax Inc.
Market strategy	Public health and UN agencies
Pricing strategy	Tiered pricing
Production strategy	To be determined: outsource or in-house To be determined: local or foreign sites
Intellectual Property Strategy	Outsource to law firm(s)
Financial strategy	Grants, philanthropic gifts and government loans
R&D strategy	First to market Product and process R&D
Clinical strategy	To be determined but considering outsourcing to not-for-profit clinical organizations

Source: author

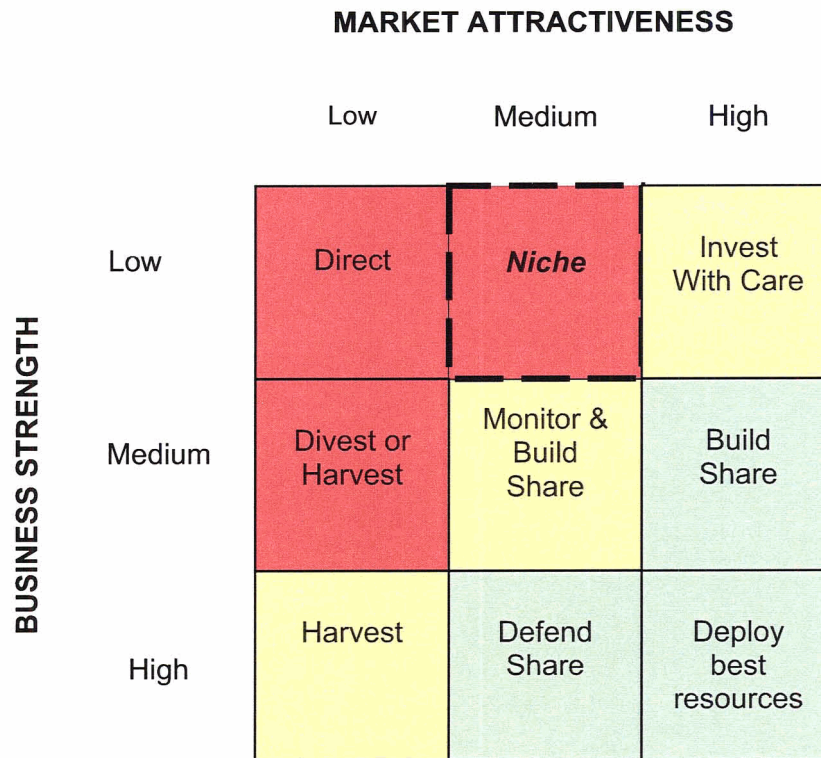
To date, the inventors have not formulated an exit strategy. It is their intention to maintain control of product development as far down the value chain as possible. This way, if for public health benefits they must sell the IP, the higher value created will result in higher return on their investments.

7.2 Expected Performance Given Current Strategy

Using the General Electric (GE) McKinsey Matrix, AXS*Vax's current business strength is mapped against industry attractiveness⁹². Figure 7 looks at this matrix and maps AXS*Vax's position.

⁹² David A. Aaker, *Developing Business Strategies*, (Toronto: John Wiley & Sons, 2001): 124.

Figure 7: AXS*Vax's Current Position



Compiled from John Peters, "On Product and Service Management", Management Decision 31,6, (1993), ABI/INFORM Global; and, David A. Aaker, Developing Business Strategies. (Wiley & Sons, Inc., 2001): 124.

Market Attractiveness. The global market's attractiveness is medium. Seven attributes led to this assessment. These attributes are as follows.

- i. *Market size (large):* The North American segment represents 50% of market sales potential.
- ii. *Market growth (moderate):* The chlamydia vaccine will initially enter the market primarily as a therapeutic but later placement will be as a prophylactic in immunization programs. Market growth is further expected due to access to new international markets.

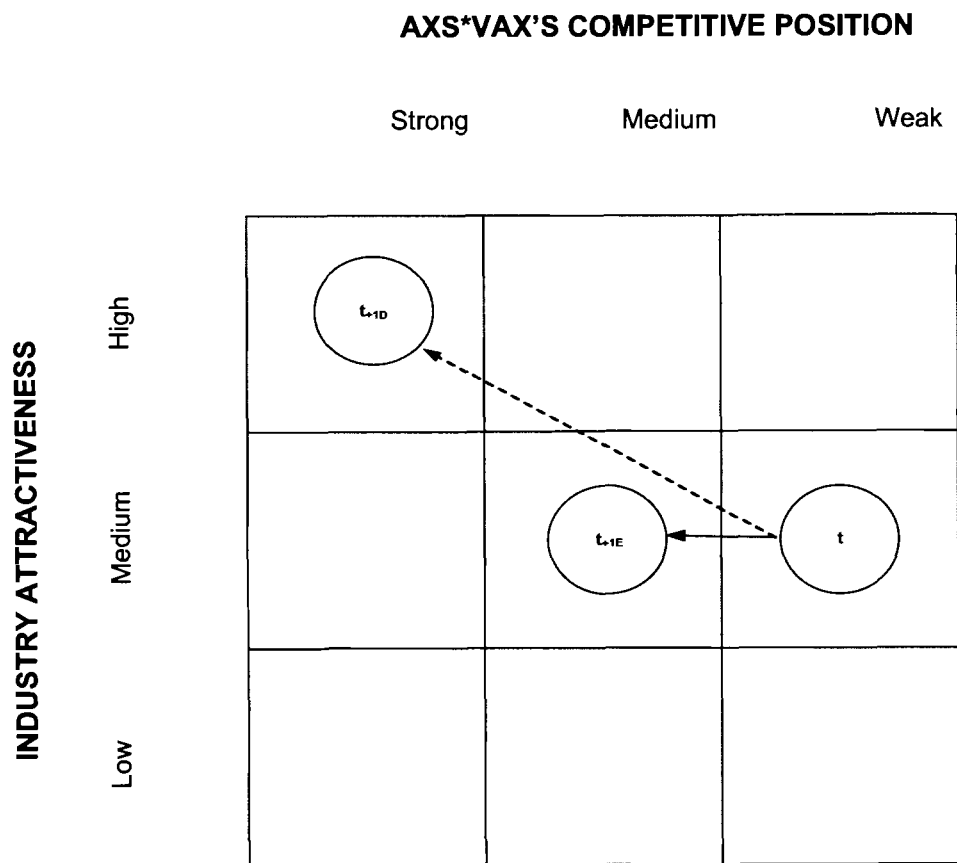
- iii. *Competitor number (low)*: Four vaccine competitors, one antibiotic competitor and only a few PPPs in the market
- iv. *Expected retaliation from competitors (high)*: Pfizer and GSK are likely to retaliate.
- v. *Customer loyalty to competitors (high to moderate)*: Corporate brand loyalty to GSK and Pfizer is high and is unlikely to change.
- vi. *Government regulations (high)*: Regulatory bodies manage the right to administer the vaccine product to humans, to commercialize the product, and to export/import products.
- vii. *Buyer power is (moderate)*: Distributors have moderate power but customers (i.e. UN agencies, public health agencies) have high power.

Business Strength. The business strength is low. Six attributes from the internal analysis led to this assessment. These attributes are as follows.

- i. *Organization (low)*: Enterprise not yet formed.
- ii. *Customer loyalty (low)*: No customers yet.
- iii. *Financial assets (low)*: Unsecured financing.
- iv. *Flexibility (medium)*: Many options available along value chain.
- v. *Patent protection (high)*: Legal firm manages IP in Canada and the US.
- vi. *Technology skills (high)*: Highly skilled scientific resources (human resources and equipment) available.

The matrix evaluation advises selective investment for AXS*Vax. External factors affect market attractiveness. Internal factors affect business position and/or strength. Business strength rated low because the selection of the management and scientific teams has not yet occurred. A practical evaluation of their strengths, weaknesses, and operational stewardship is not possible at this time. With the right management and scientific team, AXS*Vax will build business strength. It will move from a 'Niche' position to a 'Monitor & Build Share' position. Figure 8 outlines AXS*Vax's current, expected and desired positions. With the right influences, the competitive position can become stronger.

Figure 8: AXS*Vax's Performance Matrix



Based on conceptual diagram from Boardman and Vining, "A Framework", 42.

Demonstration of the vaccine's technological superiority and greater public health benefits will create a stronger competitive position against rivals. As regulatory agencies increase the rate of product approval, and as TRIPS opens access to patented medicines in developing countries, the industry attractiveness will increase. This takes many years, as infrastructure changes do not occur swiftly.

8 COMPARISON AND EVALUATION OF STRATEGIC ALTERNATIVES

Based on the external and internal analyses in the previous chapters, four alternative proposals emerge. The four strategic alternatives are as follows.

Alternative 1: Develop a ‘fully integrated’ not-for-profit biopharmaceutical firm

Alternative 2: Develop a ‘virtual’ not-for-profit biopharmaceutical firm

Alternative 3: Develop a ‘tiered-pricing’ biopharmaceutical firm

Alternative 4: Create a vaccine development business unit within the BCCDC

This chapter begins with a description of the four strategic alternatives. The following section described the inventors’ goals for AXS*Vax. The chapter concludes with an evaluation and multi-goal comparison of the strategic alternatives⁹³.

8.1 Strategic Alternatives for AXS*Vax

Alternative 1: Develop a ‘fully-integrated’ not-for-profit biopharmaceutical firm. This alternative describes a firm with limited outsourcing. It would mirror IOWH’s business model. This alternative would rely heavily on philanthropic donations and grants. The firm would control all primary activities. AXS*Vax would conduct R&D and manage its clinical trials in-house. It would also maintain control of the IP rights. The corporate focus would be on vertically integrating.

⁹³ Boardman and Vining, “A Framework”, 21-25.

This alternative would lead to some large obstacles. One obstacle would be retaliation from large pharmaceutical companies. This would be the greatest obstacle in this alternative because any type of strategic alliance is undesirable to the new enterprise. Another obstacle would be that obtaining funding would be very difficult firstly, because of the high sunk costs required to implement in-house production of primary activities; and secondly, because there is only one product in development without any plans for developing a product portfolio to diversify risk.

Alternative 2: Develop a 'virtual' not-for-profit biopharmaceutical firm. This alternative describes a firm that would outsource most of its activities. It would engage in PPPs. Each firm in the PPPs network would provide unique core competencies. The network would create synergy in product development and commercialization. Products would move quickly through the pipeline. AXS*Vax would provide R&D services and maintain control of the IP rights. This alternative would rely on grants and government assistance. The corporate focus would be on managing a mixed differentiation//low cost strategy.

This alternative would most likely lead to some competitive advantages for two reasons. The first reason would be that the risk of retaliation would be less within PPPs. The second reason would be that the funding opportunities would be greater with this alternative because there is generally a reduction in annual production costs.

Alternative 3: Develop a 'tiered-pricing' biopharmaceutical firm. This alternative describes a firm that would be looking to earn rents and make a profit. The difference is that it would use a tiered-pricing system for different income markets. For example, in the industrialized nations it would provide the same market pricing and services as GSK currently does with its influenza vaccines. However, in developing nations, the firm would provide the chlamydia vaccine at minimal or no cost. AXS*Vax would control IP rights. Strategic alliances and joint

ventures would be at management's discretion. This alternative would rely on the same financing sources as any other for-profit biopharmaceutical firm. The corporate focus would be on differentiation.

Alternative 4: Create a vaccine development business unit within the BCCDC. This alternative describes a business unit that would exist within the CDC. Much like the UBC CDC is a business unit within CDC, so would be AXS*Vax. Funding would come from the same sources as the BCCDC currently receives. UBC CDC would provide the R&D support. The BCCDC would conduct quality assurance, quality control, and relevant regulatory affairs functions. Clinical trials would be outsourced. Additional funding would provide the BCCDC with a cGMP certified wing. A cGMP contract vaccine manufacturing business would support UBC CDC R&D and earn rents from external customers. This is possible just as the BC Cancer Agency has a for-profit business unit within a not-for-profit organization. The for-profit business unit within the BC Cancer Agency provides contract GLP animal studies for cancer research. Similarly, AXS*Vax would manufacture vaccine test articles for pre-clinical and clinical trials in the BCCDC's cGMP wing.

8.2 Goals for Analysis

There are six goals presented for analysis. Dr. Brunham and the project manager were out of the country and unavailable for discussion. Personal communication with a BCCDC GE³LS member on November 03, 2006 resulted in the selection of these six goals.

Goal 1: Impact on access to capital funding. At this stage of development, multi-year funding is a high priority. A multi-year deal is preferred over short-term financing to allow, no less than, pre-clinical studies to be completed. Capital funding comes from many sources and with just as many unique conditions. Despite the transaction costs associated with the terms of agreement, further research and product development is not possible without access to capital.

Goal 2: Impact on the degree of Gates Foundation support. The realization of this goal would help financing and create competitive gains based on power by association. Just as profits are a signal to resource holders and investors, so is the Gates Foundation brand a signal. It signals that the technology is a viable, breakthrough vaccine for the improvement of global health. The more the Gates Foundation lends its support to the chlamydia vaccine development, through grants or other means of collaboration, the more value is associated to AXS*Vax.

Goal 3: Impact on the incidence rate in Canada. The rise of the incidence rate in Canada since 1997 is alarming. Ideally, an immunization program would reduce the incidence rate to insignificant levels.

Goal 4: Impact on the incidence rate globally. Ideally, an immunization program would reduce the incidence rate to insignificant levels.

Goal 5: Impact on the elimination *C. trachomatis* as a disease of public health concern by 2020. This is the goal stated by the WHO. This goal places a time element and a sense of urgency.

Goal 6: Impact on the market price of the vaccine. This is the potential to provide the vaccine to all end-users, domestically and internationally, at an affordable price.

Dr. Burnham's overarching purpose is to commercialize a chlamydia vaccine that is safe, effective, and affordable. His primary purpose is not to make profits. Nor is he aiming to create a dominant biopharmaceutical firm within the industry. These aforementioned six goals reflect Dr. Brunham's personal intentions and goals. Dr. Brunham's goals are appropriate for the evaluation because an enterprise for commercializing the vaccine has not formed yet. This strategic analysis assumes that Dr. Brunham would be the founder and leader of the chlamydia vaccine enterprise. In this role, his capacity to influence the direction and culture of the enterprise would be strong.

8.3 Analysis of Possible Future Scenarios

Environmental uncertainty offers opportunities and risks. Forecasting future events is not always possible. Cornelius et al. write, “An important risk companies face is that major shifts in the business environment... can make whole investment strategies obsolete”⁹⁴. In the biopharmaceutical industry, an example of this phenomenon is the thalidomide case. Thalidomide is a drug that caused thousands of birth defects and resulted in many regulatory changes. Public safety concerns led US Congress to pass the Kefauver-Harris Drug Amendments in October 1962. For the first time, FDA inspectors had access to additional company records. Drug companies now had to prove the effectiveness for intended use, not just the safety, of investigational and commercial drugs. GMPs were enforced and the FDA now had to approve a marketing license for drugs⁹⁵. This exemplifies how one unforeseen event can lead to major changes in the biopharmaceutical business environment. Scenarios lay out plausible alternative futures⁹⁶. This section presents three such plausible futures. These three scenarios will focus on key variables that would have a direct impact the biopharmaceutical business environment⁹⁷. Each of these scenarios is useful to evaluate strategic alternatives. The scenarios are best-case, worst-case, and most-probable case.

Best-Case Scenario for the Future: This scenario assumes that the future environment would be more favourable than present environment. In a best-case scenario, vaccines are the preferred drug formulation over solid-dosage form tablets by health agencies. The benefits outweigh the concerns about product stability and robustness in harsh environment. Concerns about adverse effects, as seen with traditional vaccines, are in the past. Furthermore, regulatory

⁹⁴ Peter Cornelius, Alexander Van de Putte and Mattia Romani, “Three Decades of Scenario Planning,” *California Management Review* Vol. 48, No. 1 (2005): 92.

⁹⁵ US Food and Drug Administration, “Promoting Safe and Effective Drugs for 100 Years”, *FDA Consumer Magazine*, (2006), http://www.fda.gov/fdac/features/2006/106_cder.html, (accessed on November 15, 2006).

⁹⁶ Boardman, Shapiro and Vining, “A Framework for Comprehensive Strategic Analysis”, 28.

⁹⁷ Cornelius, Van de Putte and Romani, “Three Decades of Scenario Planning”: 95.

bodies such as the FDA would “fast-track” vaccine. Fast-track status would allow vaccines to enter the market in 5-7 years. Implementation of international (ICH) regulations worldwide would eliminate the need to seek market approval and commercial licenses in each national jurisdiction. Under TRIPS, the WTO would protect IP rights in global trade and prohibit parallel trading. This best-case scenario has a low probability of happening in the near future. Policy changes are unlikely to occur swiftly. Therefore, for simplicity, the evaluation of the strategic alternatives will not use this scenario.

Worst-Case Scenario for the Future: This scenario assumes that the future environment will be least favourable than the present environment. In a worst-case scenario, concerns about adverse effects related to vaccinations plague the regulatory environment. Regulatory bodies such as the FDA require longer clinical trials and further safety, efficacy and immunogenicity tests. New vaccines, such as the chlamydia vaccine, would require 10-15 years to enter the market. Vaccine manufacturers in Asia gain power and sell generic versions of the chlamydia vaccine to developed nations. Amendments to TRIPS would permit parallel trading and no longer be able to protect IP rights in global trade. This worst-case scenario is unlikely in the near future. Policy changes are unlikely to occur so swiftly. Therefore, for simplicity, the evaluation of the strategic alternatives will not use this scenario.

Most-Probable Case Scenario for the Future: This scenario assumes that the future environment will be similar to the present environment. As such, health agencies would consider vaccines as safe and promising drugs. The uptake of the vaccine by health agencies will be similar to those in other immunization programs, such as the tetanus/diphtheria/polio (TdP), hepatitis, or influenza immunization programs⁹⁸. The time to market a new vaccine, such as the

⁹⁸ The chlamydia vaccine uptake will most likely reflect the HPV vaccine uptake but at this time, the HPV vaccine is too new on the market to provide a comparison.

chlamydia vaccine, would require 7-10 years to market approval⁹⁹. Partnerships with large pharmaceutical or local independent manufacturer would be conducive to supply vaccines to developing countries. Parallel trading remains restricted, but legal, in most places worldwide. This most-probable case scenario is likely in the foreseeable future. Therefore, the evaluation of the strategic alternatives will use this scenario as the background business environment.

8.4 Multi-Goal Analysis for AXS*Vax

A multi-goal analysis evaluates the impact of each strategic alternative on each goal¹⁰⁰. This method provides explicit quantitative and qualitative reasoning to improve strategic choice¹⁰¹. This method improves strategic choice by assisting in the determination of which strategic alternative is the most favourable and conversely, which is the least favourable.

8.4.1 Impact of Strategic Alternatives

The impact of strategic alternatives describes the degree of each strategic alternative's effect on each goal. The degree of impact is "high", "medium", or "low". To translate this into quantitative terms, "high" equals a value of three, "medium" equals a value of two, and "low" equals a value of one. To measure the perceived utility function, each goal has a weight attached to it. The weights are assigned percentage values between zero and one hundred. The summation of values, from impacts and weighted-goals, results in a score for each strategic alternative (Table 10).

It is apparent that one strategic alternative is most favourable and one strategic alternative is least favourable. Developing a not-for-profit biopharmaceutical firm using the IOWH model ranked the lowest score in terms of these goals. This is surprising because the inventors expected this strategic alternative to be the most favourable strategy. On the other hand, developing a

⁹⁹ This is based on the current average time to develop a new vaccine and obtain a BLA with the FDA.

¹⁰⁰ Boardman, Shapiro, and Vining, "A Framework for Comprehensive Strategic Analysis", 29.

¹⁰¹ Aidan Vining and Lindsay Meredith, "Metachoice for Strategic Analysis," *European Management Journal* Vol. 18, No. 6 (2000): 605-618.

‘virtual’ not-for profit biopharmaceutical through outsourcing and PPPs, ranked the highest. This strategic alternative had a favourable impact on four of the six goals.

Table 10: Multi-Goal Valuation Matrix for New Chlamydia Enterprise

GOAL	Weight	ALTERNATIVE											
		Develop 'fully integrated' NPO (1)		Develop 'virtual' NPO (2)		Develop 'tiered-pricing' PO (3)		Develop new business unit within BCCDC (4)					
		Impact	Valuation	Impact	Valuation	Impact	Valuation	Impact	Valuation				
Impact on access to capital funding	7%	Low	0.07	High	0.21	Medium	0.14	Medium	0.14	Medium	0.14		
Impact on the degree of Gates Foundation support	13%	Low	0.13	Medium	0.26	Low	0.13	Low	0.13	Low	0.13		
Impact on the incidence rate in Canada	25%	Medium	0.50	High	0.75	Medium	0.50	Medium	0.50	Medium	0.50		
Impact on the incidence rate globally	20%	Low	0.20	High	0.60	Medium	0.40	Medium	0.40	Medium	0.40		
Impact on the elimination of <i>C. trachomatis</i> as a disease of public health concern by 2020	10%	Low	0.10	Medium	0.20	Medium	0.20	Medium	0.20	Medium	0.20		
Impact on the market price of the vaccine	25%	Medium	0.50	High	0.75	Medium	0.50	Medium	0.50	High	0.75		
TOTAL	100%		1.50		2.77		1.87		1.87		2.12		

Impact (Low= 1, Medium= 2, High= 3); Valuation= Weight * Impact
 Based on conceptual framework from Boardman, Shapiro, and Vining (2004)

8.4.2 Summary of the Analysis for AXS*Vax

The multi-goal evaluation of the strategic alternatives revealed an interesting ranking. The two for-profit alternatives obtained mediocre weighted scores. The two not-for-profit alternatives ranked at opposite poles. The alternative to “develop a ‘virtual’ not-for-profit biopharmaceutical firm” ranked the highest with a weighted score of 2.77. The alternative to “develop a ‘fully-integrated’ not-for-profit biopharmaceutical firm” ranked the lowest with a weighted score of 1.50. This section looks at these two not-for-profit alternatives in more detail.

Develop A ‘Virtual’ Not-For-Profit Biopharmaceutical Firm (Highest Ranked): Should this strategic alternative be implemented, AXS*Vax would produce a ‘virtual’ not-for-profit biopharmaceutical firm. Profits typically signal to resource holders where society most values resources. However, PPPs mitigate risk, which increases the attractiveness of the benefits. As a result, they more readily obtain needed capital from grants, foundations, and private investors. Vaccine research and development would be its core competency. PPPs would contribute their unique competencies in activities along the value chain such as clinical studies, manufacturing, and distribution. The pharmaceutical competitors may provide their expertise through alliances. Leaner operations, less overhead expenses, and less rivalry would minimize costs. Less costs and greater access to capital would lead to increased economic profits. The result would be a high impact on the affordability of the vaccine and a great impact on the incidence rate of chlamydia domestically and globally. The risks involved with this alternative would be high bargaining costs and potentially some opportunism or hold-up¹⁰². Another risk involved with using a differentiation and cost leadership niche strategy would be that AXS*Vax may find itself “stuck in the middle”¹⁰³. Resources and corporate style required to differentiate and maintain cost leadership would conflict with each other. Extra care would need to be administered.

¹⁰² Aidan Vining and Steven Globerman, “A Conceptual Framework for Understanding the Outsourcing Decision”, *European Management Journal* Vol. 17, No. 6 (1999): 645-652.

¹⁰³ Porter, *Competitive Strategy*, 41.

Develop A ‘Fully-Integrated’ Not-For-Profit Biopharmaceutical Firm (Lowest

Ranked): Should this strategic alternative be implemented, AXS*Vax would produce a ‘fully-integrated’ not-for-profit biopharmaceutical firm. Most biopharmaceuticals organizations mitigate risk by having a product portfolio. If AXS*Vax considered expanding its portfolio (i.e. more bacterial STD vaccines), this would help procure more financing. Another difficulty is producing an affordably priced vaccine with this strategic alternative. While this alternative aims to reduce transaction costs and opportunism, the trade-off is that there are higher sunk costs and higher probability of retaliation from competitors. Furthermore, AXS*Vax would no longer specialize in doing what it does best. It risks diseconomies of scope in managing multiple activities¹⁰⁴. This often leads to losing a sustainable competitive advantage by not focusing on its core competencies. The risk with being a ‘fully-integrated’ new entrant is that it would raise the production costs resulting in a higher market price for the vaccine. This strategic alternative is an unlikely choice as the outsourcing decision is become common practice. Outsourcing helps to maintain costs and increase efficiency thereby bringing the product to market more quickly and at a lower market price.

¹⁰⁴ Vining and Globerman, “A Conceptual Framework”, 647.

9 RECOMMENDATION: DEVELOP A ‘VIRTUAL’ NOT-FOR-PROFIT BIOPHARMACEUTICAL FIRM

The recommendation is a derivative of the external competitive analysis, the internal analysis, and the multi-goal analysis. AXS*Vax should not consider the recommendation to be the only option. It is the most favourable option based on the strategic analysis for its current position. Once the proof-of-concept studies are complete and successful, developing a ‘virtual’ biotechnology not-for-profit firm is the recommended strategy. This strategy will provide the most flexibility and the inventors will be able to maintain control of the IP. The strength of PPPs is growing in this biopharmaceutical industry. The TRIPS amendments will help increase AXS*Vax’s bargaining power in international trade. Canada’s Access to Medicine Regime will enable AXS*Vax to supply the vaccine at low or no cost to income-suppressed nations. At the same time AXS*Vax can earn rents in high-income nations to offset the access to medicines subsidies. Within this strategic model, collaborating with IOWH, GAVI, DNDi are possible. Partnering with Pfizer or GSK or other large pharmaceutical companies for defined geographical areas or market segments is always a choice within this strategic alternative. PPPs can provide a barrier to hostile competition from these rivals. Cooperation from these competitors is more likely than retaliation. As public confidence in vaccine treatments increases, so will financing options. Developing a ‘virtual’ not-for-profit biopharmaceutical firm, using a niche strategy, will lead to the commercialization of a chlamydia vaccine that is safe, effective, and affordable.

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