SECTOR ANALYSIS

Biosimilar Pharmaceuticals

1. Context
2. Introduction to Biosimilar Drugs
3. Regulatory Environment
4. Post Sale Reporting & Significance
5. Growth Opportunities
6. Spotlight on Africa
7. Challenges for the Industry
8. Pricing
9. Government Benefits
10. Accommodating Generic Drugs
11. Profitability
12. Sources of Risk
13. SWOT
14. Porter's Five Forces Model

LEGACY PARTNERS

Strengths

• The predecessor, small-molecule generic, has been widely accepted by the industry and governments

• Significantly less expensive to develop

• Easier to gain approval than biologics

Weaknesses

• Regulatory situation is not well-defined in many countries

• Has not been adopted by medical professionals, many prefer brand-name

• Still a derivative of generics, not regarded as a standalone industry

Opportunities

• Is a low-cost alternative to existing products. Favorable for governments and insurance companies.

• Lots of opportunities in developing countries where pharmaceuticals are expensive

• Source of invention in an industry severely lacking innovation

• Emerging product that is proven to be useful and desirable

Threats

• Intellectual property conflicts create opportunities for risk

• Weak R&D spending in the original product market

• Foreign markets may not use the same regulations. Alternatively, rules may change unexpectedly

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Context

It is important to understand how biosimilar medicine came to fruition. The past few decades have seen massive growth in the pharmaceutical industry that has made it one of the largest, and most profitable sectors of the economy. Much of this increase attributes to the patenting of drugs designed to treat mankind's most chronic ailments. For many companies, their most profitable patents have either expired or are nearing expiration. Consequently, this has created the generic manufacturing industry.

A generic drug is the replica of a pre-existing small-molecule pharmaceutical. In simplest terms, a clone of a drug conceived in a lab by a group of chemists and pharmacists. The biosimilar is a derivative of these generic drugs. Starting in the 1970s, large pharmaceutical manufacturers began using sophisticated biological material, such as proteins, fats, and nucleic acids to create new drugs known as biologics. Being a relatively new variety of drug, they are extremely expensive to develop. Granted, they are highly effective and can treat hundreds of conditions regardless of severity.

The content of this report primarily focuses on biosimilar products, however, much of the statistical data presented is referring to small-molecule generics. As biosimilar products grow in popularity, they will be utilizing the same infrastructure as regular generics. Furthermore, much of the regulation and challenges facing this industry are remarkably similar to those faced by generics in years past. In closing, the biosimilar industry is largely dependent on generics.

Introduction to Biosimilar Pharmaceuticals

A biologically similar drug is a compound derived from a "reference" drug that is most commonly a brand-name medicine that has already proven its safety and efficacy in medical trials. They are created by taking biologic material such as protein, sugar, or nucleic acid, and slightly modifying the genetic structure to achieve one of three goals;

(1) To signal the body to initiate growth in a particular region.

(2) To conjoin two or more proteins that have qualities beneficial for treating a targeted condition.

(3) Replicate or modify a function of the immune system.

Most biologic drugs are modified genetically for a particular purpose and have shown to be effective in treating chronic diseases where "no other treatment is available" (U.S. Food and Drug Administration, n.d.).

Both the biosimilar industry and the pharmaceutical industry have many opportunities for expansion and growth. Governments are well aware of the benefits this technology can provide to both them and their people. Even the largest pharmaceutical manufacturers have shown a keen interest in developing the generics sector. However, there are some challenges facing companies looking to enter this market.

Declining research and development expenditures along with unclear regulations are two of the factors creating a barrier for new entrants. Furthermore, conflicts over patents and clinic testing processes are creating a volatile environment that is unpleasant for manufacturers and their investors. Nonetheless, the industry is evolving to overcome these challenges to create opportunities for profitability. The future of the industry is bright. However, success will be limited to those who possess and act according to a long-term horizon.

The Regulatory Environment

Since the 1970s, biologic drugs have been studied, and in spite of this, they have only been prominent since the 1990s. This was a time when the pharmaceutical industry was struggling with a perceived decline in innovation, and the expiration of key patents (Abou-Gharbia & Childers, 2015). Introductory regulatory framework for biosimilar drugs came to Europe in 2006 (European Medicines Agency, 2006). The United States and Canada later published their guidelines in 2010; Canada chose to use the term "Subsequent Entry Biologics" in place of "biosimilar" (Health Canada, 2010). Moreover, the World Health Organization (WHO) has published a guideline for its member nations to adopt (World Health Organization, 2009, p. 4).

In contrast to similar medicinal discoveries, notably medicinal marijuana, the consensus among regulators has been positive. Later sections will discuss how pricing and costs impact both governments and consumers.

As mentioned before, a biosimilar is effectively a clone of a pre-existing biologic drug. One of the most compelling advantages to a biosimilar medicine is the avoidance of staggering research costs borne by manufacturers. Significant cost savings make it possible for smaller enterprises to enter the market. In addition to not requiring extensive research, manufacturers are not obliged to complete the same degree of testing as a new drug. Health Canada along with virtually all nations who regulate biosimilars, need the duplicated drug to pass the "comparability exercise" (Canadian Generic Pharmaceutical Association, 2014). The purpose of this exercise is to determine whether the biosimilar has similar quality attributes to its original reference drug. If the drug is proven to yield the same safety and efficacy as the reference, it may move on to registration. The approval process is still demanding. However, it is miniscule compared to Health Canada's process for new medicines.

When the manufacturer completes the development process, they may apply to receive the Notice of Compliance (NOC) along with a Drug Registration Number. Thereby permitting the drug for sale in Canada (Health Canada, n.d.). After receiving the NOC, the manufacturer must follow

the same rules governing pharmaceutical companies to ensure safety and efficacy of the product. The importance of this regulation and relevance to an investor is in the following section.

The United States uses a similar system to that in Canada. A 2010 amendment to the Patient Protection and Affordable Care Act created an opportunity for "biological products that are demonstrated to be biosimilar or interchangeable with an FDA-licensed biological product" (U.S. Food and Drug Administration, 2010). Much like in Canada, manufacturers must be able to prove that their product has no clinically significant differences in terms of safety and efficacy. The goal of the FDA's regulation is to ensure that patients and health care professionals can use a generics just as they would the reference product.

International protocols, specifically those published by the WHO, tend to suggest that biosimilar products be tested enough to determine safety and efficacy (World Health Organization, 2009, p. 7). Overall, the regulatory environment is quite friendly to biosimilar products. Most countries have made the process relatively straightforward by allowing a corporation of any size to compete.

Although a regulatory framework has been developed, many companies have expressed concern and confusion over the new regulations. For example, some are unclear as to how much clinical testing is required before they can file for an NOC. Another example is the extent to which a biosimilar must be similar to its reference. When dealing with biologic material, it is impossible to replicate a compound with 100% accuracy, as the elements of the material are naturally inconsistent. Many of the regulatory faults are similar to the expressed concerns regarding generic drugs during the 1980s and 1990s (Dalgaard, Evers, & Jorge, 2012, p. 5).

Post-Sale Reporting Requirements and their Significance

It is important to note that biosimilar manufacturers must engage in the same monitoring practices as other producers. Health Canada requires all producers to complete a Pharmacovigilance Plan, which contains the benefit-risk analysis for the medicine. Investors should be cognizant of the subject matter within these reports as Health Canada continually monitors them. Severe consequences including termination of an NOC, or deregistration are possible for enterprises that fail to meet expectations (Health Canada, 2010).

Each Pharmacovigilance plan should contain the following two components: the Adverse Drug Reaction (ADR) report and the Periodic Safety Update Reports (PSURs). The ADR is designed to collect data on adverse reactions from patients and medical professionals and provide it to Health Canada. Moreover, this report requires the Director of Manufacturing to perform a critical analysis of all the adverse drug reactions on an annual basis. This allows both the manufacturer and government regulators to enhance the safety of the particular biosimilar, and all subsequent productions after that.

The second component are the Periodic Safety Update Reports (PSURs). These provide an up-to-date evaluation of the benefit-risk balance of a medicine. As new data is collected, it is the responsibility of the manufacturer to report if there are new risks identified and carry out an investigation if required. Although this information uses Canadian standards, it is applicable in all countries that have biosimilar regulations in place.

For an investor performing due-diligence, it is vital they inspect these documents. Their significance does not necessarily lay with the reported reactions, but with how the company has responded to these concerns. A passive response indicates a higher likelihood of legal risk, and also to regulatory risk through the loss of an NOC. A firm that reacts swiftly and efficiently likely exhibits that behavior elsewhere in its organization.

Growth Opportunities

Canada has the 9th largest pharmaceutical industry in the world in terms of production. Recent data recorded from 2001 to 2013 has shown Canada's drug exports to have risen 155%; current exports equate to over 50% of annual production (Canadian Life Sciences Industries, 2014). The pharmaceutical industry has proven to be very profitable for Canada, and regulations are favorable to manufacturers who have continued to expand domestic operations over the past 15 years. In dollar amounts, industry sales have been estimated around $22 billion in Canada, and roughly $380 billion in the United States (IBIS World, 2015). The United States represents the largest portion of global pharmaceutical sales, and advanced nations like Canada, the UK, Australia, and much of Europe represent a substantial portion as well. Interestingly, developing markets are beginning to experience major growth in their pharmaceutical sectors. However, this growth is not being driven by new pharmaceutical drugs, but by the generics industry. Estimates have pegged generic medicines as 30% of the developing world's GDP, and upwards of 70% of GDP growth from 2005 to 2010 (McKinsey&Company, 2013). To summarize, every region market is observing substantial increases in demand for pharmaceuticals. For a potential entrant or investor, this allows them to look globally for an opportunity to introduce, or fund, a biosimilar product. For example, a manufacturer that specializes in bio-generic vaccines may look towards a developing market where demand is greater for that type of drug. Alternatively, someone looking to invest in bio-generic cancer medication will look at opportunities in wealthy economies, where the drug is considered affordable.

Looking at the pharmaceutical industry on a broad scale, it is apparent the brand name drugs are still the dominant force in the market. Brand name sales accounted for 77 percent of the $22 billion pharmaceutical sales (Canadian Life Sciences Industries, 2014). Many doctors and customers are uncomfortable with generic products and feel that spending (20-80%) more for a brand-name product is worth the expense. Quebec has recently started banning doctors from requiring patients to use brand-name medicine to save money on provincial drug expenditures

(Derfel, 2015). This gives light to biosimilar products and their distinct price advantage over their original counterparts, which do not have to recoup the cost of research through price inflation.

Generic medicine is already being widely distributed in the United States, in fact, 80% of prescription fills are less expensive generics (Silverman, 2015). As more biosimilar products enter the market, they will be the more likely choice for customers who will trend towards the least expensive option. In Canada, retail pharmacies sell almost 90% of the pharmaceutical products sold in Canada through prescriptions and over-the-counter (OTC) sales (Canadian Life Sciences Industries, 2014). Producers can drive sales of biosimilars by focusing their marketing efforts directly on the consumer. Ensuring that customers are aware of the price advantage and assured quality level will encourage the client's propensity to consume the less costly merchandise.

Although Canada is a major manufacturer, 62% of pharmaceutical purchases are imported goods (Canadian Generic Pharmaceutical Association, 2014). Identifying the most highly demanded imports gives manufacturers ample opportunities to create generic versions intended for domestic sales. Moreover, the import drugs have already been approved for sale in a partnering country, and Health Canada has already cleared the drug for sale in Canada. Thereby helping to simplify the licensing and registration of the generic. The United States import restrictions are far more obstructive than Canada's as they concerned about impurities and poor quality products (Silverman, 2013). However, provided that manufacturers follow regulations, and they pay attention to pharmacovigilance, it is possible to export products to the United States. For example, the Indian company Ranbaxy1 has been exporting to the United States for years. India is a prime example of a developing economy that has benefitted from generic products. In fact, the nation is planning to open 5,000 "Jan Aushadi" pharmacies that will carry 500 essential medicines, most of which will be generic and biosimilar (Hindustan Times, 2015). The foremost advantage of a government distribution system is the fundamental inability to use exclusively domestic products. Government

[1] Ranbaxy Laboratories is a large pharmaceutical company in India. They were recently banned from exporting to the USA due to non-compliance with FDA regulation (IANS, 2015).

programs will be required to contract manufacturers to acquire the necessary medication, creating more opportunity for the biosimilar industry.

Spotlight on the African Continent

Africa is an exciting region that will either be extremely profitable or extremely costly. The market for generic drugs is expected to grow to $18 billion by 2020 (McKinsey&Company, 2013). While investors should consider the generics market to be medium to long-term, the African market is unlikely to turn a profit within the first five years. Also considering the instability of the region, the best strategy will be to establish operations in the most economically sound countries and rely on exporting to reach neighboring markets. Many nations will likely adopt the framework provided by the WHO, but non-member nations or particularly tenacious countries may resist the perceived foreign infiltration. Consequently, a lobbying force will probably be required, and it will be best to be dealing with as few governments as possible. A possible strategy would be to establish a manufacturing facility in one of the most stable countries and only use that factory to produce high demand products and to store and distribute imported products from other facilities.

Challenges facing the Biosimilar Industry

The most notable challenges facing biosimilars are the fault in regulations. Resolutions to these problems will arise as more competition enters the market and pressures the regulators. However, the solution to one challenge leads to another; a surge of new entrants has given rise to competition from small start-ups to large multinationals like Samsung and Fuji (Jack, 2012). Over the next ten years, the US market alone will increase by roughly $65 billion as a result of competition. When the market becomes more saturated, it will be more challenging for firms to find profitable opportunities. Furthermore, less experienced and less developed firms are likely to have difficulty competing against new entrants if the start-ups can deliver a superior competitive advantage.

Increasing costs to develop new medicines is a challenge that has faced pharmaceutical companies for the past two decades. Development costs for new drugs are often quoted to be around

$600 million over a span of 10 years. Generics are typically 3-$10 million over 2 or 3 years (Canadian Life Sciences Industries, 2014). These costs have been steadily rising as the "low hanging fruit" of pharmaceuticals has already been discovered and developed. The costs for a generic drug are significantly less in comparison, however, for a small company that is looking to produce generics, $10 million is a very substantial amount of money. No producer is immune to rising costs; total research expenditure has fallen 29% since 2001 (Graham, 2014). The cash flows that research provides no longer creates adequate incentives. A common trend is for large companies to contract small-to-medium sized enterprises (SME) to conduct research for them. Alternatively, some manufacturers will give colleges and universities education grants in exchange for access to their research. These efforts are a part of a grand scheme to lower costs wherever possible. When factoring the discounted opportunity cost of research on top of start-to-finish production costs, the real cost to a manufacturer is a staggering $2.6 billion (Peters & Lowry, 2014). On top of the expense, the internal rate of return for a project is falling (Graham, 2014). These factors combined make the R&D process increasingly undesirable. The consequence for biosimilar products will be a disruption in the product pipeline. No new products will equate to no new growth for generic manufacturers.

Antiquated patent laws are presenting a challenge to some of the larger players. Difficulties in R&D and employment falling 6.3% over the last five years has left many companies carrying a book of products too large for them to handle (Dalgaard, Evers, & Jorge, 2012). Pharmaceutical Research and Manufacturers of America estimate that 1 in 1,000 compounds make it to the preclinical testing phase (PRMA, 2007). Rather than allowing another company to work on one of the 999 unsuccessful compounds, producers tend to hold these patents for later research. Unfortunately, many of the failed compounds remain under patent, so competitors are unable to continue research that could perchance yield positive results. For generic producers, overlapping patents create legal complications when attempting to roll out a new product. A lawsuit is likely if the generic too closely resembles one of the original company's failed patents because the original manufacturer is trying to prevent any copies from negatively affecting their sales.

A challenge that is specific to biosimilar products is quality control. Rejection rates due to impurities or poor quality product are 1% higher than that of original producers (Dalgaard, Evers, & Jorge, 2012). Although one percent appears to be insignificant, producing a consumable medical product requires the utmost accuracy, for any impurities could have adverse effects.

The pharmaceutical industry is still a very profitable sector. Market penetration has been estimated as being over 80%, mostly captured by big pharma (Dalgaard, Evers, & Jorge, 2012). This leaves little room for smaller companies looking for a foothold in the market. For these firms, the challenge will be to devise a strategy that will allow them to overcome the large advertising budgets of the big pharma entities.

Corporations face many challenges, but customers and governments face problems as well. Pharmaceuticals in United States are almost twice the price of the rest of the world. Moreover, the nation's health care spending (18%) is the largest in the world (Dalgaard, Evers, & Jorge, 2012). It is important to remember that price is the fundamental reason generic technology is necessary.

Pricing

The chart provided in Appendix I shows the average change in price for brand-name and generic drugs. The numbers provided for costs are representing an average of both small-molecule generic and biosimilars. The actual costs for biosimilars are higher than generics. Nonetheless, the chart shows the gradual downward trending of generic medication in Canada and the subsequent increase in brand-name prices. The price of generics is falling due to competition and the combined impacts of the opportunities and challenges previously mentioned. Interestingly enough, the price of brand-names is rising, even though one would expect market pressure to push prices down. Remarkably, a brand-name manufacturer of any nationality will often increase their price to bring in more revenue from customers who refuse, or are unable, to purchase a generic alternative (Grootendorst, 2007). The high cost of brand-name drugs makes it increasingly harder for employers to provide reasonably priced health plans (Canadian Generic Pharmaceutical Association, 2014). The insurance companies backing corporate and personal health programs are

often hesitant to use generic alternatives for fear of adverse reactions and poor quality. For many unsupported customers, an inadvertent ignorance towards generic products leads to disproportionate spending on pharmaceuticals.

As mentioned earlier, Quebec, Canada has implemented a system to encourage the use of generic medicines. Australia plans to adopt a similar system that will allow them to redirect funds to pay for doctors, nurses, and facilities (Scott & Henderson, 2015). Quebec's new plan is expected to save upwards of $40 million per annum (Derfel, 2015). The cost savings provided by generics are phenomenal. However, many have argued that the odd Canadian pricing system has been detrimental to the healthcare system. Under the Canadian regulations, generic drugs are sold at 18% of their reference drug's price (Gallant, 2014). The system is unusual considering that other countries have adopted competition or negotiation models to establish a fair price. It is unlikely that this price ceiling will remain in place, especially as biosimilar drugs become more prevalent on the market. Given the higher production costs of biological products, the 18% rule will not be sustainable, or desirable, for manufacturers.

Government Benefits

The estimates for generic cost savings range from 70-90% depending on the compound and the resources required to develop it. On the other hand, biosimilar drugs are expected to yield a savings of 30% (Dalgaard, Evers, & Jorge, 2012). Moving customers over to generics offers substantial savings in government healthcare plans. The biosimilar supply chain has seen substantial growth and will be capable of providing large amounts of product in the very near future (Lucio, Stevenson, & Hoffman, 2013). The hope of many countries is to redirect the savings towards subsidies on expensive new treatments and drugs (Scott & Henderson, 2015). This will help to stimulate research and development growth to continue the production of new pharmaceuticals.

Accommodating Generic Drugs

The big pharma corporations like Merck and Pfizer are repositioning themselves to take advantage of both generics and biosimilar markets. Large entities are forming new operational

divisions to manage the pipeline of clients from their branded products. This is most common with companies that have recently lost patent coverage and are scrambling to maintain control over their customer base (Lucio, Stevenson, & Hoffman, 2013). Collaboration between firms is also starting to become more prevalent as generic drugs grow in popularity. As mentioned before, many companies will partner with SMEs to help develop or manufacture a particular product (Canadian Life Sciences Industries, 2014). A transformation within the pharmaceutical industry is inevitable, but the question is; will existing companies grow through M&A, or will they break into subsidiaries and strategic business units?

To help answer that question, we reference the corporate structures most prevalent in the United Kingdom. Nearly 90% of bio-pharma in the UK is small-to-medium sized enterprises (Taylor, 2011). The decline in research and development has resulted in smaller companies being better suited to service the demands of the market. Research into growth and innovation has suggested that 80% of new technology and methods have come from bio-pharma SMEs (Taylor, 2011). Moreover, many of these SMEs are solely focused on the R&D stage of development (Plewka, 2013). At first glance, the British system appears to yield positive results. However, the smaller companies are still unable to engage in the same degree of research as the large enterprises due to inadequate funds.

Profitability Going Forward

Much like the generics market that began to emerge over ten years ago, biosimilar sales started slow but have ramped up substantially. The graph in Appendix II illustrates sales growth among 5 EU nations. Europe has been one of the quickest adopters of biosimilar technology and has authorized more drug for sale than any other region. Over time, it is highly likely that similar growth in the US, Canada, and other advanced markets will occur.

Three key regions will be utilized to measure profitability (Rickwood & Iervolino, 2011). The United States is expected to be the most significant contributor due to their high healthcare spending and large population. The second will be other advanced economies who have already

established a framework for biosimilar drugs, but their uptake has been slow. The third region will be the developing nations where extraordinary demand exists for inexpensive pharmaceutical products.

According to data collected from Yahoo Finance (provided in Appendix III), the healthcare industry carries a net profit margin of 13.76%. The most profitable sectors are biotechnology and drug manufacturing with profit margins around 17%. On paper, the generics industry appear to be non-profitable with a net profit margin of -2.1%. However, when taking a closer look at the public companies listed under the industry (Appendix IV), it becomes evident that many of the enterprises in the industry are still in their start-up phase. Indicated by their small market capitalization and abnormally high debt to equity ratios. The data also shows that some of the top performing companies (30% net profit margin +) have market caps under $2 billion.

A conservative forecast estimates that the generic industry will reach a level of net profit similar to the average of the healthcare industry within ten years. The generic companies will be operating with a lower cost of production and favorable price position in the market. Many generic firms are already operating at a profit. However, the inflow of new entrants has led to an explosion in start-up companies. Some of which are well funded; development time for generics is still long enough that a young company without alternate revenue sources will have to record losses quarter to quarter. Many of the firms are still trying to cover the cost of the equipment required to give them biologic manufacturing capabilities that can cost tens of millions of dollars.

The annual growth rate for biosimilar products is 8% (Otto, Santagostino, & Schrader, 2014, p. 4). Annual revenues are expected to reach 200 billion by 2017 and almost 300 billion by 2021. These numbers could easily double if the United States fully integrates biosimilar products into its healthcare system.

Sources of Risk

Heavy competition in a market that is consistently taking on new entrants is a significant risk to manufacturers. There are many firms consolidating, which provides them with more resources to address the same market. Moreover, technological development by competitors could

render current technology or practices obsolete. The biosimilar industry in the UK is an excellent example of how competition, even from small enterprises, can drive innovation and create risk for larger firms. Finding ways to simplify the manufacturing process and reduce overall operating expenses can negatively affect a large company's ability to execute their strategy.

Product cycle risk is present if a business is unable to produce a new product promptly. Existing products are likely to be become undesirable or overtaken by competitors. This is relevant to the biosimilar market where being first to market is crucial for improving market penetration. Heightened product risk will adversely affect the availability of funds. For example, the inability to support R&D activities will adversely affect new products and will have a further effect on recovering sunk costs. Financing risk is present in this industry, maintaining a poor credit rating will complicate any efforts to acquire debt. This is more likely in smaller companies and start-ups that use debt to fund their research projects. The debt-equity ratios provided for the businesses in Appendix IV shows how smaller companies are more reliant on debt financing to stay afloat.

Some of the larger firms are using derivative instruments to hedge their exposure. While this is a beneficial strategy, it often covers just a portion of the company's net exposure. Derivative markets also pose the risk of volatility. Speculators looking to profit from the derivative product may have an adverse impact on the business's position.

Intellectual property is an important component of this business. Forms of patent law represent numerous risks on both the owner and manufacturer's side. It is very difficult to protect copyright, especially after it has expired. Future cash flows can be lost if another company can produce your compound. Moreover, when manufacturing biosimilar drugs, companies have to be mindful of competitors intellectual property. Infringing upon others will lead to legal action and possible sanctions. The time it takes for a country's patent office to process an application presents a risk to manufacturers who are scrambling to achieve "first-to-market" status. If a competitor were to complete the patent process faster; the losing firm would have to wait one year before it could sell its drug.

For companies participating in international trade, their strategies may not be able to generate a profit if economic conditions are poor. Global operations will always carry currency risk. An example is Russia; who fell under global sanctions in 2014. The decline in the ruble was catastrophic for Russian industry. Trade impediments further impacted domestic companies attempting to purchase Russian materials. Any dealings with developing countries expose a company or investor to political risks like civil war or government collapse. This is especially true in African countries, where many nations are in a state of civil war.

In terms of production, companies are engaged in a very complex manufacturing process that exposes them to a high likelihood of error. Proper quality control methods must be in place to ensure the final product is of top quality. Anything subpar will put the company at risk of reprimand by regulatory agencies. Even if the product passes quality control, there is no guarantee that it will gain market acceptance. Supply chain disruptions can in effect halt biosimilar manufacturers. There are very few suppliers of the biological material that these manufacturers need; a shortage of raw materials or laboratory equipment will negatively impact the speed at which manufacturers can release new products. Supply chain risk is intertwined with political and currency risk, especially in foreign markets. For companies operating or purchasing materials from the developing world; any of the previously mentioned risks could adversely impact organizations or groups that are essential to the firm's operation.

Lastly, manufacturers and their investors are subject to heavy regulations. Failure to comply leads to sanctions that will hurt the business. Increased spending on health care reform has been a goal of many governments. Change is guided by governments and health insurance companies. Both of these groups seek ways to reduce costs through cutting expenditures and coverages. This could adversely impact a producer who provides medicine for a potentially defunct program. The system in Quebec that restricted doctors from recommending brand name drugs, and similar systems to it, is a risk to brand-name manufacturers who charge a premium for their product.

Five Force Model

Threat of new Entrants

As previously mentioned, the threat of new entrants is high. Many of these entrants are generic and pharmaceutical manufacturers looking to expand their product lines. They are often the only companies capable of safely entering the market. Barriers to entry are quite high for new companies. Capital requirements are well into the eight-figure range, and production costs are in the low sevens. The regulatory environment is better established, but is still not at a point that will support future growth. Lastly, conflicts over patents are creating legal risks for those potentially in violation of another. Moreover, after licensing a generic product for sale, the manufacturer gets exclusive distribution for a year. Slower companies have to shelf their projects until a later date.

Threat of substitute products or services

The generic industry evolved from a desire for substitute products. Assuming product quality is the same (as per regulations) then the threat of substitution is very high. Whoever is capable of providing the lowest price product will be the most successful. **The first to market producers are protected from substitute products for one year.** Afterward, the market will open up. Switching costs between biosimilar products are tiny or zero, however switching to a brand-name product will be significantly more expensive. Overall, brand-name products will be less of a threat as customers grow more accustomed to generic products.

Bargaining Power of Customers

The customer base for pharmaceutical products has become increasingly concentrated. Drugstores, governments, and healthcare providers tend to be the most typical clientele for pharmaceutical manufacturers. The amount of product being purchased is increasing. However, the number of firms doing the purchasing is falling. Thus, bulk purchasers have a high degree of bargaining power because companies are unwilling to lose the business.

Bargaining Power of Suppliers

For small-molecule generics, suppliers have little bargaining power since there are many companies that can offer raw materials at a competitive price. On the other hand, biosimilar manufacturers do not have access to very many suppliers. Moreover, there are no substitutes for organic material, so producers are unable to source supplies through other markets. Changes in prices will impact the price of final products.

Intensity of competitive rivalry

As previously mentioned, the pharmaceuticals market has an estimated 80% penetration, making it difficult for biosimilar and generic producers to gain standing. Advertising efforts add further difficulty for competing firms, some estimates have pegged annual advertising expenditures over $30 billion. Overall, the intensity of competition is quite high.

SWOT Analysis

Strengths

- The predecessor, small-molecule generic, has been widely accepted by the industry and governments
- Significantly less expensive to develop
- Beneficial for many ailments (market penetration)
- Easier to gain approval than biologics

Weaknesses

- Regulatory situation is not well-defined in many countries
- A slow start in sales. Rate of growth is not desirable
- Has not been adopted by medical professionals, many prefer brand-name
- Still a derivative of generics, not regarded as a standalone industry

Opportunities

- Is a low-cost alternative to existing products. Favorable for governments and insurance companies
- Lots of opportunities in developing countries where pharmaceuticals are expensive
- Source of invention in an industry severely lacking innovation
- Emerging product that is proven to be useful and desirable

Threats

- Intellectual property conflicts create opportunities for risk
- Weak R&D spending in the original product market
- Rising production costs and the lowest hanging of the low hanging fruit is exhausted
- Foreign markets may not use the same regulations. Alternatively, rules may change unexpectedly

Summary

The biosimilar industry has strong ties to small-molecule generics. As the technology develops, investors should be cognizant of developments in both industries. Although the industry has challenges, especially on the regulatory front, the cost savings are undeniable. Generic products can vastly expand the consumer base of pharmaceutical products, improving accessibility and affordability. Investors should look for firms with well-organized strategic plans for the future and ethical staff who are eager to succeed in the biosimilar industry.

Appendix I

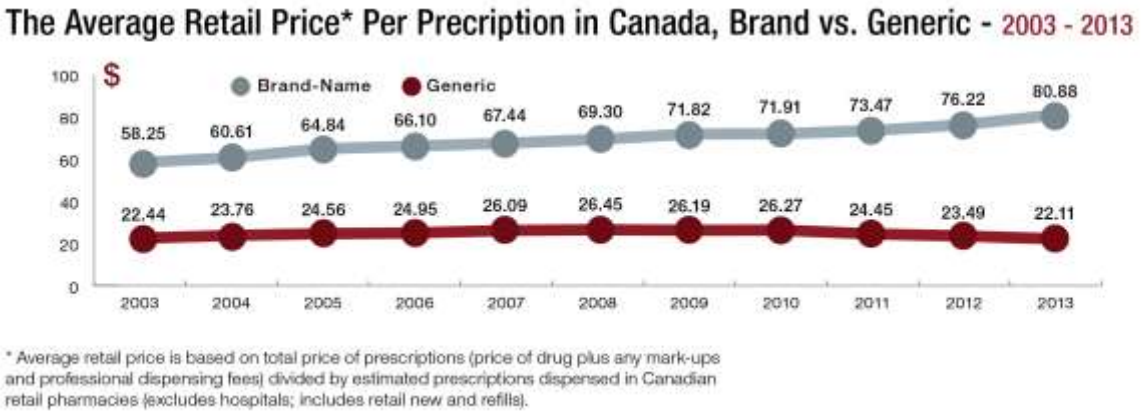

Figure 1 Average price of brand-name prescriptions (Canadian Generic Pharmaceutical Association, 2014)

Appendix II

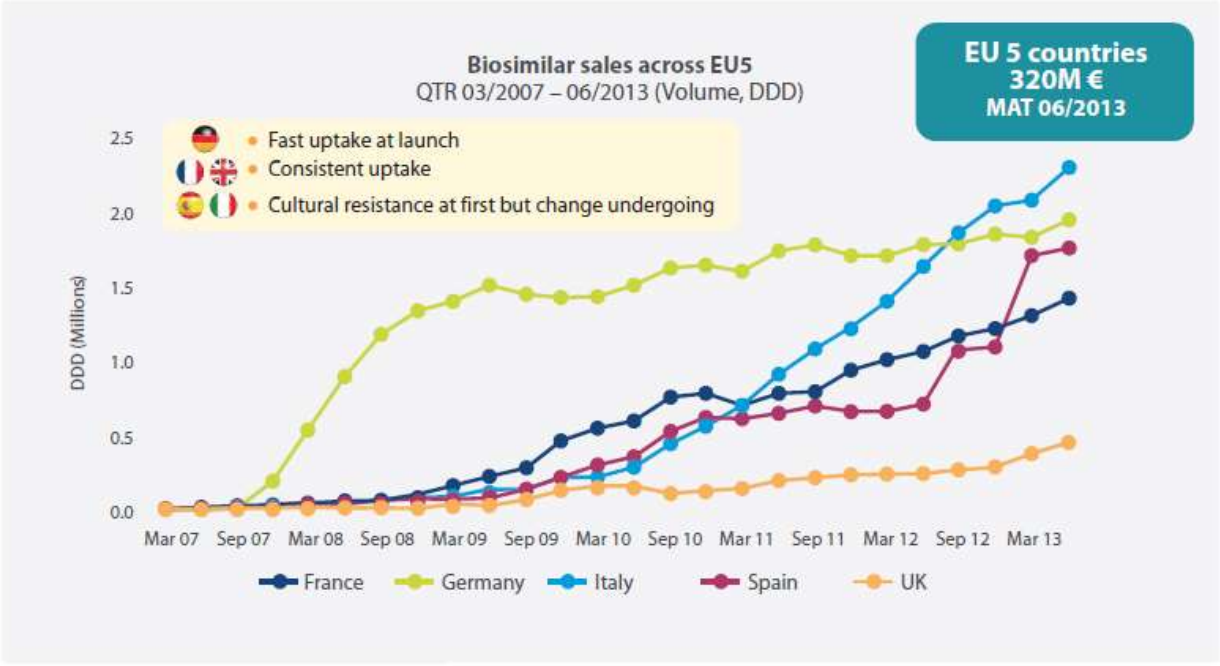

Figure 2 Growth of Biosimilar sales in 5 EU nations (Sheppard)

Appendix III

Industry	1-Day Price Chg %	Market Cap	P/E	ROE%	Div. Yield %	Debt to Equity	Price to Book	Net Profit Margin (mrq)	Price To Free Cash Flow (mrq)
Biotechnology	0.822	16603.52B	105.3	14.6	1.784	72.821	22.48	17.7	75.7
Drug Manufacturers - Other	0.143	342.69B	25.1	19.7	1.13	29.849	23.54	17.6	35.8
Drug Manufacturers - Major	-0.028	72364.43B	24	16.4	3.217	66.865	38.33	16.8	41.7
Medical Instruments & Supplies	0.503	517.59B	25.4	14.7	1.433	64.254	21.01	11.3	366.9
Diagnostic Substances	0.407	14.95B	0	12.1	3.378	1989.31	-10.79	9.9	-21.1
Medical Appliances & Equipment	-0.17	3509.36B	45.8	9.8	1.562	45.992	18.11	9.6	133.5
Drug Delivery	0.487	339.44B	157.1	9.1	0.09	152.602	-7.56	7.4	42.8
Specialized Health Services	-0.225	79.31B	25.2	13.7	1.208	123.998	-3.87	6.9	-15.4
Medical Laboratories & Research	0.631	821.34B	32.7	9.9	0.713	58.168	-8.7	6.9	-20.5
Drug Related Products	0.259	37.07B	107	2.8	0.3	64.578	-15.11	4.8	-18
Hospitals	0.992	1024.61B	28	70.7	0.145	79.647	-3.29	3.7	-39.2
Health Care Plans	-0.002	2296.31B	21.2	12.8	1.179	38.484	-59.44	3.2	21
Medical Practitioners	0.008	3.37B	0	0	22.3	45.153	4.1	-1.5	-15.6
Long-Term Care Facilities	-0.821	55.98B	0	0	0.628	262.208	12.85	-1.5	-138.5
Drugs - Generic	1.589	14266.38B	0	0	0.405	39.426	-7.02	-2.1	-14.8
Home Health Care	0.353	8.01B	0	0	1.212	61.801	-3.27	-5.4	-12.7

Appendix IV

Description	Market Cap	P/E	ROE %	Debt to Equity	Net Profit Margin (mrq)
Abbott Laboratories	7077.55B	1719.97	8.91	40.49	46.804
Actavis plc	80.34B	NA	-8.609	54.856	-18.066
Adamas Pharmaceuticals, Inc.	314.38M	33.623	8.926	0.113	32.114
Advik Laboratories Ltd	105.23M	40.06	NA	42.758	1.034
Agile Therapeutics, Inc.	257.21M	NA	-95.141	41.19	NA
Akorn, Inc.	4.65B	122.186	11.082	290.867	13.089
Alembic Ltd	10.04B	45.934	NA	0.154	-6.983
Alembic Pharmaceuticals Ltd	88.62B	31.312	36.268	26.96	14.015
Allergan Inc	NA	NA	21.537	27.791	28.288
Alliance Pharma PLC	10.98B	1299.47	12.381	32.033	17.801
Alpa Laboratories Ltd	315.69M	NA	NA	24.748	-11.397
Amarin Corp PLC	NA	NA	NA	NA	-119.278
Aquinox Pharmaceuticals Inc.	79.85M	NA	-106.52	NA	NA
Aspen Pharmacare Holdings Ltd	NA	NA	19.795	128.663	13.643
Aurobindo Pharma Ltd	NA	NA	NA	67.769	12.231
Bal Pharma Ltd	603.16M	16.382	NA	85.696	1.857
Benchmark Holdings PLC	10.27B	NA	-5.374	0.566	0.743
Benitec Biopharma Ltd	95.92M	NA	-46.731	NA	NA
Beryl Drugs Ltd	211.68M	71.754	NA	NA	0.053
Biofil Chemicals	63.96M	12.397	NA	33.577	11.381
Biomm SA	NA	NA	-11.769	58.272	NA
Bringwell International AB	333.11M	NA	-39.891	NA	-6.545
Cadila Healthcare Ltd	339.19B	32.642	NA	54.896	12.876
CannaVEST Corp.	62.52M	NA	-8.93	NA	NA
Carbylan Therapeutics, Inc.	142.33M	NA	-486.135	NA	NA
Catalent, Inc.	3.52B	36.018	217.969	398.096	7.053
Catalyst Pharmaceutical	NA	NA	-54.77	NA	NA
Catalyst Pharmaceutical Partne	277.73M	NA	-54.77	NA	NA
Celator Pharmaceuticals, Inc.	NA	NA	-74.512	46.205	NA

China Shineway	NA	NA	15.118	4.088	26.539
China Shineway Pharma.	10.71B	12.19	15.118	4.088	26.539
Cipher Pharmaceuticals Inc	NA	NA	40.693	NA	42.827
Comvita Ltd	131.89M	24.88	5.972	80.537	-5.262
Coral Laboratories Ltd	1.07B	12.172	NA	NA	21.766
Cumberland Pharmaceuticals Inc	NA	NA	2.952	NA	7.17
D Western Therapeutics	NA	NA	-8.757	NA	-60
Daito Pharmaceutical Co Ltd	NA	NA	11.139	43.924	5.124
Delcath Systems Inc	NA	NA	-67.678	NA	NA
DepoMed Inc	NA	NA	52.509	63.079	48.624
Diplomat Pharmacy, Inc.	2.06B	212.412	15.431	NA	-0.495
Divi's Laboratories Ltd	229.82B	29.719	28.307	0.603	26.274
Dr Reddy Laboratories Ltd	572.80B	26.346	22.92	37.729	14.949
Drugs - Generic	14266.38B	0	0	39.426	-2.1
Durect Corp	NA	NA	-103.513	128.226	-101.676
Eagle Pharmaceuticals Inc.	819.18M	NA	-141.046	NA	-98.321
Eisai Co Ltd	NA	NA	7.342	44.555	18.847
Evoke Pharma, Inc.	36.33M	NA	-87.236	47.797	NA
Evotec AG	509.98M	NA	-4.398	13.606	3.328
Fibrocell Science, Inc.	144.23M	NA	-64.065	NA	NA
Flexion Therapeutics, Inc.	398.88M	NA	NA	2.479	NA
Galectin Therapeutics, Inc.	63.58M	NA	-87.224	NA	NA
Galenica AG	5.24B	17.205	18.876	39.656	8.319
Gennex Laboratories Ltd	309.54M	330	NA	14.889	0.707
Genomma Lab Internacional	17.68B	12.388	14.734	68.692	4.985
Glenmark Pharmaceuticals Ltd	235.65B	46.412	NA	96.811	6.783
Grape King Bio Ltd	21.94B	23.403	39.971	NA	16.576
Guangzhou Pharmaceutical	39.16B	25.415	15.956	7.258	7.719
Gujarat Terce Laboratories Ltd	81.89M	33.125	NA	31.986	1.154
H Lundbeck A/S	NA	NA	-4.098	22.809	-2.273
HAEMATO AG	106.99M	15.324	11.906	48.341	2.375

Hangover Joe's Holding Corpora	0.33M	NA	NA	NA	NA
HC Berlin Pharma AG	37.62M	NA	-71.864	0.841	1.105
Healthcare	112284.37B	34.12	14.182	63.606	13.762
Hemo Organic Ltd	NA	NA	-29.83	5.192	-218.455
Hikma Pharmaceuticals PLC	407.91B	1477.7	25.067	46.217	14.514
Hiran Orgochem Ltd	43.39M	NA	NA	NA	-37.473
Hisamitsu Pharmaceutical	NA	NA	9.075	1.16	10.305
Horizon Pharma plc	4.37B	NA	-33.531	85.737	-17.282
Hospira Inc.	15.20B	44.492	10.437	51.184	6.435
Impax Laboratories Inc	NA	NA	6.755	NA	0.091
Indivior PLC	172.32B	477.689	NA	NA	30.677
Ind-Swift Ltd	306.19M	NA	NA	1623.23	-74.543
Innocoll AG	203.87M	NA	NA	NA	NA
Instituto Rosenbusch SA	166.10M	19.898	15.469	29.846	-11.87
Invion Ltd	12.00M	NA	-124.988	16.432	NA
Ipca Laboratories Ltd	81.15B	16.957	27.24	59.909	11.367
Ipsen SA	NA	NA	15.135	2.453	7.459
Ipsen SA	4.15B	27.114	15.135	2.453	7.459
Ironwood Pharmaceuticals, Inc.	1.99B	NA	-134.742	256.464	-114.828
Juniper Pharmaceuticals, Inc.	76.83M	26.117	7.631	8.528	-13.08
Karyopharm Therapeutics, Inc.	1.05B	NA	-41.897	NA	NA
Kissei Pharmaceutical	NA	NA	5.461	2.248	16.363
Knight Therapeutics Inc	681.14M	3.412	NA	NA	114026
Lactose (India) Ltd	211.70M	105.252	NA	NA	5.585
Lannett Co Inc	NA	NA	40.094	0.244	36.469
Lannett Company, Inc.	1.99B	14.572	40.094	0.244	36.469
Lansen Pharmaceutical	1.34B	12.263	12.413	74.003	10.874
Link Pharma Chem Ltd	54.35M	10.552	NA	94.121	-3.159
Lipocine Inc.	90.97M	NA	-57.24	NA	NA
Lupin Ltd	794.41B	33.121	NA	6.082	19.125
Mallinckrodt public limited co	14.42B	NA	-6.379	76.911	10.858

Maywufa Co Ltd	1.96B	24.583	4.725	11.609	4.858
Meda AB	48.86B	123.567	2.008	133.981	4.931
Medi-Caps Ltd	213.24M	NA	-2.016	6.918	12.268
Merck KGaA	43.27B	37.417	10.186	47.767	9.221
Merck Ltd	13.63B	31.577	8.024	NA	0.508
Mitsubishi Tanabe Pharma Corp	NA	NA	4.725	0.128	-9.221
Momenta Pharmaceuticals Inc.	1.13B	NA	-40.097	NA	-255.513
MPH Mittelstaendische	99.72M	14.934	9.244	41.64	3.869
Mylan N.V.	35.10B	33.582	14.214	94.929	3.024
MYOS Corp.	20.89M	NA	-88.507	NA	NA
Myrexis, Inc.	3.79M	NA	-25.672	NA	NA
Nature's Sunshine Products Inc	NA	NA	11.096	0.262	6.756
NephroGenex, Inc.	64.79M	NA	-653.839	34.84	NA
Neuland Laboratories Ltd	2.80B	10.437	23.846	287.738	NA
Neurocrine Biosciences Inc.	3.39B	NA	-13.636	NA	-6.03
NeutriSci International Inc	3.68M	NA	-53.394	93.184	NA
New Nordic Healthbrands AB	207.54M	15.466	61.815	30.794	4.251
Nutraplus India Ltd	967.13M	NA	NA	NA	9.809
Nuvo Research Inc	NA	NA	113.732	0.589	-179.253
Oculus Innovative Sciences, In	12.52M	9.333	13.452	0.077	-183.779
Orexigen Therapeutics Inc	NA	NA	-116.889	375.528	2.645
Orexo AB	3.38B	NA	-17.448	112.647	-10.403
Orion Oyj	NA	NA	56.538	57.417	25.279
Pacira Pharmaceuticals, Inc.	2.74B	NA	-0.891	56.589	2.161
Parabolic Drugs Ltd	728.47M	NA	-56.62	265.146	4.838
Parenteral Drugs (India) Ltd	611.47M	NA	NA	339.837	-9.863
Parnell Pharmaceuticals Holdin	52.21M	NA	NA	13.536	3.274
Pharco SA	1.00M	54.024	13.564	NA	NA
PNO Resources Ltd	NA	NA	-11.992	NA	NA
POZEN Inc	NA	NA	60.979	NA	70.99
Probiotec Ltd	8.20M	NA	-48.879	41.571	-83.106

pSivida Corp.	113.53M	11.156	46.071	NA	NA
QRxPharma Ltd	2.79M	NA	-125.634	NA	NA
Quantum Pharma PLC	16.00B	30.332	NA	NA	9.335
Ranbaxy Laboratories Ltd	NA	NA	NA	160.693	-39.32
Relmada Therapeutics, Inc.	107.36M	NA	NA	0.829	NA
Rigel Pharmaceuticals, Inc.	332.30M	NA	-57.774	NA	NA
RPG Life Sciences Ltd	2.46B	NA	NA	26.746	4.479
Sagent Pharmaceuticals, Inc.	738.05M	22.863	12.885	0.737	-2.292
Sandu Pharmaceuticals Ltd	195.46M	31.102	NA	53.407	2.017
Sci Pharmtech Inc	4.69B	19.627	12.335	28.162	14.207
SciClone Pharmaceuticals Inc	NA	NA	16.701	NA	8.495
Science in Sport PLC	1.75B	NA	NA	2.821	-13.417
SCYNEXIS, Inc.	81.29M	NA	-67.657	NA	-58.052
Senbo Industries Ltd	NA	NA	NA	NA	NA
Shilpa Medicare Ltd	33.72B	45.94	NA	32.773	10.958
Sihuan Pharmaceutical	45.71B	23.696	18.748	NA	41.506
Smruthi Organics Ltd	231.70M	NA	NA	145.452	-20.787
Sophiris Bio, Inc.	10.95M	NA	-111.747	40.448	NA
Source Natural Foods	NA	NA	NA	1.796	-5.043
STADA Arzneimittel AG	1.94B	38.708	5.59	93.362	4.362
SteadyMed Ltd.	108.81M	NA	-506.922	14.431	NA
Strides Arcolab Ltd	61.47B	4.32	NA	75.995	8.753
Sucampo Pharmaceuticals Inc	NA	NA	23.559	27.456	21.737
Sumitomo Dainippon Pharma Co.	NA	NA	4.654	19.765	7.174
Summit Corp PLC	8.55B	NA	NA	NA	NA
Sun Pharma Advanced	93.29B	NA	NA	2.56	-60.454
Sun Pharmaceuticals Indus	1988.70B	33.688	NA	1.289	33.3
Supernus Pharmaceuticals, Inc.	628.55M	20.659	58.789	12.378	3.26
Surya Pharmaceutical Ltd	34.47M	NA	-500.692	234.467	6.526
Suven Life Sciences Ltd	34.36B	27.59	NA	21.521	25.015
Takeda Pharmaceutical Co Ltd	NA	NA	3.082	35.481	3.747

Targeted Medical Pharma, Inc.	5.35M	NA	NA	NA	-104.749
Tetraphase Pharmaceuticals, In	1.51B	NA	-45.036	NA	NA
Teva Pharmaceutical	46.28B	17	12.016	48.582	8.952
The Canadian Bioceutical Corp	NA	NA	-113.87	66.631	NA
The Medicines Company	1.68B	NA	-2.344	56.195	3.979
Themis Medicare Ltd	1.10B	49.057	4.33	NA	NA
Tianjin Zhongxin Pharmace	1.02B	17.188	13.721	4.558	7.352
Tianyin Pharmaceutical Co Inc	NA	NA	-2.871	3.032	1.886
Tibet Pharmaceuticals, Inc.	NA	NA	32.146	NA	19.177
Toho Holdings Co., Ltd.	NA	NA	8.138	20.782	2.518
Trimurthi Drugs	66.15M	15.355	NA	NA	10.284
Valeant Pharmaceuticals	92.78B	92.398	17.099	395.74	3.364
Vansen Pharma Inc.	107.25M	NA	-267.233	169.929	NA
Veloxis Pharmaceuticals AS	NA	NA	-13.646	NA	NA
Venture Life Group PLC	3.01B	NA	-19.378	24.65	-24.314
Versartis, Inc.	422.43M	NA	-28.037	NA	NA
Vikram Thermo (India) Ltd	374.81M	10.173	NA	12.406	6.029
Vista Pharmaceuticals Ltd	269.28M	11.654	NA	NA	13.674
Weifa ASA	NA	NA	29.253	29.557	6.907
Wuyi International	NA	NA	-2.988	1.033	-12.925
Zoetis Inc.	23.04B	39.059	49.667	279.31	14.973

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