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HARRIS-LUX CONSULTING

29 August 2014

MEMORANDUM THRU Michael Kelly, Acting Chief Financial Officer

FOR Robert A. Bradway, Chairman and Chief Executive Officer

SUBJECT: Rivalry in the Biopharmaceutical Market

- 1. Harris-Lux Consulting is pleased to deliver the fifth of five papers analyzing Amgen's current position within the biopharmaceutical industry, using Michael Porter's five economic forces as a basis of analysis (Porter, 1979). In this memorandum, HL Consulting will analyze the impact that rivalry has on the biopharmaceutical industry.
- 2. <u>Background.</u> In the 1980s, the pharmaceutical market was fragmented and no single company could claim more than 5% of the market share. This fact resulted from two factors: 1) different pharmaceutical companies focused on specific classes of medications. Based on profits, these companies had no compelling reason to pursue other classes of medications. 2) The rapid growth of the pharmaceutical industry (due to new medications and the demands for them) allowed each company to grow without significantly impacting the market shares of other companies. The opportunities for uncontested growth in each class of medication made interest in penetrating other classes unattractive due to legal complexity, cost of entry and existing competition resulting in de facto monopolies (Mullins, 2007).

This rapidly growing market attracted genetic and molecular biologists into pharmacology and thus biopharmaceuticals were born. When first introduced in the forms of Genetech's clot busters and Amgen's own erythropoietin medication, Epogen, biopharmaceuticals fared exceptionally well in the marketplace and the industry became even more attractive (Mullins, 2007).

The market changed rapidly in the twenty-first century. Decreased federal constraints made it easier to enter the market. Buyer power, in the form of managed care organizations, rose exponentially. And, in recent years we have seen the introduction of new legislation to limit patents of biopharmaceuticals, allowing the introduction of biosimilar competitors in just 12years. Rivalry increased throughout the 1990s due to the attractiveness of the market. The market also saw a rise in science-focused drug discovery firms using rational drug design to discover new therapies quickly and with little overhead. Initially, these firms sold discoveries to the pharmaceutical companies; however, many companies began to develop and market their own medications increasing the rivalry within the field. With the increase in rivalry, many small niche market firms found it attractive to merge or consolidate to take advantage of economies of scale. These larger firms then bought out or merged with many of the discovery firms to increase their competitiveness in the market (Mullins, 2007).

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- 3. <u>Industry Rivalry.</u> Rivalry in a market is based on: 1) the concentration of the market; 2) price, quantity, quality, or service competition; 3) switching costs; 4) information; 5) degree of differentiation, and 6) government constraints (Baye & Prince, 2014). Many of these ideas overlap between the Porter's five forces (1979); we will again highlight: market concentration, competition, and government constraints. The effects of switching costs, differentiation, and information are discussed in depth in the 'The power of substitutes' and 'The power of buyers' already submitted to Amgen.
- 4. <u>Market Concentration Today.</u> As we have previously discussed, in 2013 Amgen's revenues increased 8% to \$18.7 billion (Amgen, 2013). This increase exceeds the current biopharmaceutical market increase of 6% (Roth, 2013). The biopharmaceutical market is expected to grow between \$190 and \$200 billion by 2015 (Amgen, 2013). Amgen ranked second in biopharmaceutical earnings in 2013. The four largest biopharmaceutical firms account for 79% of the market (a four-firm concentration ratio of 0.79), with Amgen accounting for approximately 18% of the market in biopharmaceuticals (Roth, 2013). Figure 1 highlights the top 10 companies' revenues and research and development expenditures.
- 5. <u>Competition.</u> Amgen faces direct producer-producer rivalry in the market as customers are limited to those who need the medication (Baye & Prince, 2014). Due to patent laws, Amgen will be protected from direct competition for new biopharmaceuticals for several years (discussed below), but the competition to between producers is constant as all companies strive to produce the best, new medication the fastest. Novel medications result in little direct competition, essentially a monopoly. However, once a medication is introduced the doors open for additional, similar-but-new medications. Sometimes, this will create price wars and impact Amgen's profits (Baye & Prince, 2014).

Consumer-producer rivalry can also be seen in the biopharmaceutical market through the bargaining power of managed care organizations and Medicare. Managed care organizations want to pay the least amount possible for medications and will aggressively negotiate with producers. Managed care organizations can significantly impact Amgen's profitability and market share if they choose not to add one of Amgen's products to their formularies (Pollack, 2013).

At this time there is no consumer-consumer rivalry seen in the industry because Amgen and its competitors are all producing adequate supplies of their biopharmaceuticals (Baye & Prince, 2014). Consumer-consumer rivalry will occur if producers cannot meet demand.

6. <u>Government Regulations</u>. The introduction of The Biologics Price Competition and Innovation Act (BPCI Act), part of the Patient Protection and Affordability Act (Affordable Care Act) of 2010, reduces the period of time a pharmaceutical corporation has to recoup research and development costs, Amgen will see increased rivalry for its biopharmaceuticals. Rivals will be able to introduce biosimilar products using the Food and Drug Administration's fast track approval process in 12-years. Biosimilars, will total between \$2 and \$2.5 billion in sales, impacting revenues (Amgen, 2014). This new legislature creates a new market dynamic, both a concern and an opportunity for Amgen. As individual states enact biosimilar substitution laws, Amgen could see a decrease in usage as the cheaper biosimilars are utilized (Mazer, 2014). This does, however, create opportunities for Amgen to compete with its own biosimilars.

- 7. <u>Amgen's Current Status.</u> Amgen is currently positioned well in the market. Amgen grew through acquisitions and mergers in past years. Specifically, the acquisitions of Onyx Pharmaceuticals, Inc. in 2013 added to its strong oncology section of research, development, and production (Amgen, 2013). The acquisition of KAI Pharmaceuticals in 2012 brought many newly developing products to Amgen's line and the acquisition of deCODE Genetics stock in December 2013 added significantly to the research and development potential (Marketline, 2014). In 2013, Amgen also bought the rights to several other, developed medications increasing both profits and market share (Amgen, 2013). Amgen began advancing its global footprint through acquisitions of medication rights in several countries this year and expects to have a foothold in more than 75 markets by the end of 2014 (Amgen, 2014). See figure 2, for Amgen's current market sales by geography.
- 8. <u>Conclusion.</u> As HL consulting has previously stated, the impact of new governmental regulations regarding biosimilars to Amgen's marke share will need to be assessed as new medications come to market. However, Amgen is well placed, both financially and geographically, to continue to be a force in the biopharmaceutical market. Amgen continues, through effective and profitable research and development, to provide new and innovative medication to the market. Amgen must explore the market of biosimilars to remain competitive as well as continue to investigate acquisitions and mergers with other companies to reduce overhead, encourage economies of scope, and unify research.

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1	Roche/Genentech	\$37,582
2	Amgen	\$17,265
3	Novo Nordisk	\$13,475
4	Merck Serono	\$8,234
5	Baxter	\$6,237
6	Biogen Idec	\$5,304
7	<u>CSL</u>	\$4,550
8	Allergan	\$1,766
9	Alexion	\$1,134
10	Regeneron	\$858

2012 R&D Expenditures

1	Roche	\$8,031
2	Amgen	\$3,380
3	Novo Nordisk	\$1,882
4	Merck Serono	\$1,526
5	Biogen Idec	\$1,335
6	Baxter	\$1,156
7	Allergan	\$986
8	Dendreon	\$626
9	CSL	\$364
19	Alexion	\$223

Figure 1. Top 10 Biopharmaceutical Companies Based on 2012 Revenues Note: In all top company profiles, dollar amounts are in millions. (Roth, 2013)

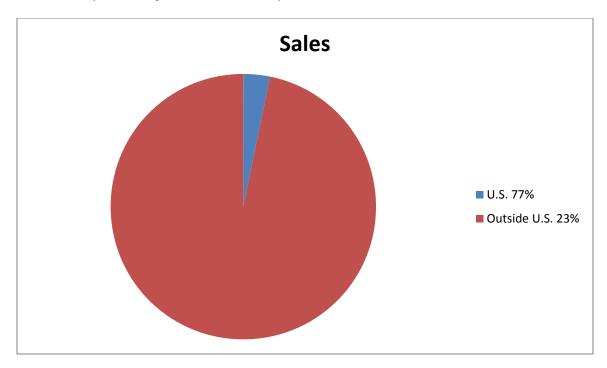


Figure 2. Amgen's sales by geography, 2013 (Amgen, 2013).