Sanofi & Genzyme

“The link between how we make money and our values is extremely strong. Approach the world globally, recognize your responsibilities, and that drives your profits.”

Sanofi, the world’s fifth largest pharmaceutical company, develops and manufactures pharmaceuticals, vaccines, and animal health products. Genzyme, a subsidiary of Sanofi, is a US-based biotechnology company that develops and delivers therapies for rare diseases. Patients remain at the heart of the sustainable and inclusive business activities for both healthcare companies. The goal of their inclusive business activities is to ensure the availability of treatment via drug development and access to treatment via fostering the growth of sustainable healthcare systems. Endeavoring to ensure that as many patients as possible have access to essential medicines, vaccines, and a full continuum of care is their stated responsibility but also their greatest challenge. Inclusive business activities are centered around two strategies: (1) partnering with nonprofit organizations and local governments to circumvent financial, geographic, or logistical barriers to treatment; and (2) building an internal business case that justifies research and development (R&D) for patient populations in emerging markets. Genzyme, specifically, does not focus on return on investment (ROI) when evaluating inclusive business; instead it considers factors such as reputation, customer expectations, and global responsibility.

COMPANY OVERVIEW

Sanofi is a French multinational pharmaceutical company that engages in the research and development, manufacturing, and marketing of pharmaceutical drugs. There are three business segments: pharmaceuticals (82% of sales, 2014), vaccines (12% of sales), and animal health (6% of sales). The company covers seven major therapeutic areas: cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis, and vaccines. Sanofi is the world’s largest producer of vaccines through its subsidiary Sanofi Pasteur.

As of 2014, Sanofi operated in 107 sites in 40 countries and employed more than 110,000 people. The company has reported a slight decrease in net income due to competition from generic drugs, with reported revenues of 37.8 billion USD (2014). About 32% of these revenues were generated in emerging markets, the company’s largest geographic market.

Founded in 1981 in Boston, Massachusetts, Genzyme evolved from a start-up to one of the world’s leading biotechnology companies that develops and delivers therapies for rare diseases, thyroid cancer, and multiple sclerosis. Genzyme was acquired by Sanofi in 2011 and remains headquartered in Cambridge, Massachusetts. Genzyme employees work in over 65 countries, with patients in over 100 countries. It has developed an expertise in rare genetic diseases known as lysosomal storage disorders (LSDs).

A rare disease, often difficult to diagnose and treat, means that a relatively small number of people are affected by it. Rare disease drugs may have greater R&D costs, fewer competitor drugs on the market, and longer patent protection, so Genzyme has a high-margin, low-volume business model due to the high price point and potential profitability. Given the infrequency and often severity of rare diseases, once a treatment has been developed, Genzyme aims to fulfill any unmet need by delivering treatment to patients affected with the condition. Genzyme’s business model is different from its parent, Sanofi. Treatment for large patient populations, such as drugs for diabetes or cardiovascular drugs, are high-volume and typically lower margin, but Sanofi’s challenge is in disparate genetic profiles of these conditions across the world.

SANOFI & GENZYME’S INCLUSIVE BUSINESS EDGE

Inclusive business at Genzyme and Sanofi means being responsible to all stakeholders by running a
sustainable business that can continue to invest in important research and innovative new therapies, while improving access to treatment through healthcare solutions. Genzyme predicates its values and orientation on the recognition of health as a universal right. David Meeker, the CEO of Genzyme, notes, "...it’s highly personal. There’s a huge emotional piece here and people are very attentive to values and approach." Genzyme and Sanofi are engaging in partnerships with local entities to ensure treatment delivery and product affordability for patients. Even with free drug programs or other forms of funding, patients’ access to treatment can still be impeded by political or logistical challenges, inadequate healthcare facilities, or lack of awareness of the disease or treatment. So, in addition to donating products, Genzyme works to “build and maintain the many avenues necessary for medical care.”

Even in countries with established health systems, patients can face delayed or limited coverage, reimbursement difficulties, or other barriers to care. For such cases, Genzyme Humanitarian Programs provides therapies free of charge, while simultaneously working with governments and other local entities to help identify sustainable, long-term financial resources for treatment. Genzyme relies on organizational partners, including Project HOPE, ANERA, Direct Relief, and others, for their local expertise and relationships, which help Genzyme support patients and navigate the challenges of access. More than 1,700 patients in 70 countries have received free therapy since these programs were introduced.

A major success for Genzyme has been finding ways to subsidize the cost of treatment for patients. Partners, including The Gates Foundation, remain vital to this initiative. Although the Foundation focuses mostly on infectious diseases, it also works to bring health interventions to vulnerable populations. A second major partner is local government. After the drug has been delivered to patients in a certain country at low or no cost through its Humanitarian Program, the next step for Genzyme is to partner with the local government to build a functioning healthcare infrastructure. According to Meeker, “It’s not until a government, no matter how poor, how big, or how small, makes a commitment to these areas that you begin to move to sustainability. They begin to pay attention, the disease gets championed, and the right things begin to happen.”

Sanofi has the responsibility, and the concern, to improve access to these treatments, regardless of a patient’s location, finances, or other circumstances. In India, diabetes afflicts over 65 million people, with another 77 million pre-diabetic. Sanofi has engaged in many initiatives to improve the quality of life of diabetes patients in India. It has partnered with Apollo hospitals to support the Apollo Sugar Clinics facilities throughout India. This partnership is designed to provide better care to diabetes patients in different regions in India and improve outcomes. To increase its diabetes-related presence in India, Sanofi will build its second foreign production facility in Telangana, India, by 2019. The facility will be equipped to manufacture insulin cartridges, making insulin more affordable and accessible throughout the country.

**THE BUSINESS CASE FOR SANOFI & GENZYME**

In emerging markets, there has been a marked increase in chronic diseases like diabetes and cardiovascular or inflammatory diseases, but these diseases differ biologically. The genetic profiles of patient populations in emerging markets differ from those of Western patient populations, whom are the intended recipients of many drugs and vaccinations. For example, diabetes in India...
“When you get it right, the overall business will be better, the bottom line will improve.”

is not the same type of diabetes as the obesity-driven diabetes in the US. According to Sridaran Natesan, Vice President of Strategic Initiatives and Scientific Relations (North America) at Sanofi, “Lean type 2 diabetes patients in India present distinct disease phenotype and carry higher risk of coronary heart diseases. Current glucose-lowering medications are not effective in mitigating the risk of cardiovascular complications in these patients. We need to put more effort into understanding the molecular mechanisms responsible for high coronary heart disease in this patient population and develop new medicines that really mitigate this risk.”

More research must be done to understand the molecular basis behind the Indian variety of diabetes. A diagnostic understanding for every condition for every part of the world requires extensive R&D, and a business case must justify Sanofi’s direction of expansion. Targeting new products is also viewed as a great opportunity for Sanofi, but the company struggles to justify this type of market entry without a robust business case. Though the company wants to capture more market share in emerging markets, it recognizes the mechanisms and manifestations of disease can vary by geography and ethnicity. Natesan believes that “to develop drugs that are effective in specific populations, we must understand precisely the molecular mechanisms of the disease in that population. This effort should be led by the national and regional policies and targeted investment initiatives. Pharma investment will certainly follow once we have a reasonable understanding of the science behind the disease.”

Drug pricing is a complex process. In the pharmaceutical world, the rarer the disease, the higher the price point. Therefore, Genzyme must balance the costs of drug development with the provision of treatment in a way that is sustainable for the business. While Meeker notes that there are continual profit and loss (P&L) reviews for the activities and investments made, Genzyme does not rely on a specific ROI to green-light investments. Additional considerations that influence the benefits of the investment play a role in deciding which sustainability efforts to undertake.

These considerations include reputation, customer expectations, and political concerns. Meeker believes that Genzyme can “do the right thing and the money will follow,” noting that collective action is the more sustainable approach, rather than treating a particular case to improve the bottom line.

Genzyme is challenged by others’ perceptions and the expectations of helping patients who cannot afford or access the treatment. Both developing and developed countries perceive patients in dire situations as a global responsibility and look to companies like Genzyme to take action. Working against the backdrop of a challenging political environment hasn’t stopped Genzyme from delivering care. As Meeker explained, “We are still supplying drugs to rare disease patients to war zones in Libya and Iraq... There is no government, no healthcare system, and no supply chain that allows you to get in and get things done but there is an expectation that you know the patients are still there, they still need help.”

Sanofi and Genzyme have continued to expand their presence into new regions based on identified patient needs; first to Europe, then Asia-Pacific and Latin America, and now the Middle East and emerging markets such as China and India. Current treatments are typically based on the genetic profile of Western patients, making growth more challenging. As a result, developing drugs for emerging market populations is limited by the R&D resources and requires a strong business rationale. Further, the profitability based on drug reimbursement in an emerging country may not exist upfront. For example, Genzyme has provided treatment to rare disease patients in China free of charge through the company’s humanitarian program. Given China’s improving healthcare system and increasing presence of payers, Genzyme must look for ways to build compensation mechanisms into the healthcare infrastructure of the country by partnering with the local government, among other possible solutions. The strategies that drive inclusive business activities at Genzyme are creating a sustainable business model while best reaching patients through partnering with local healthcare systems.


