Case Study

Great Science Comes From Challenging the Status Quo

Over the second half of the 20th century, scientists and medical researchers made great leaps in molecular understanding by unraveling the chemistry and biology behind two fundamental biopolymers: DNA and proteins. However, characterization of the so-called “third biopolymer”, carbohydrates, was thought by many scientists to be impossible, given their profound complexity, though it was clear that being able to recapitulate carbohydrate-based compounds would be scientifically and medically beneficial.

In the early 2000s, a group of scientists conducting research at the Massachusetts Institute of Technology (MIT) refused to accept the view that carbohydrates, or complex sugars, were too complex to characterize. They set out to solve that mystery, knowing that drugs based on the biology of complex sugars held tremendous potential that could not be fully realized until this challenge was met. They brought together knowledge and skill from a number of scientific disciplines with the idea that complex problems could be solved by breaking apart the question and applying the most appropriate technology to each piece of the puzzle. Momenta was incorporated in 2001 to support this mission.

The Impossible Drug

Momenta focused its initial efforts on creating a therapeutically equivalent, generic version of LOVENOX® (enoxaparin sodium for injection), a highly complex, low-molecular weight heparin product and a leading hospital-based medication in the US. The inherent complexities of this mixture were thought to be too subtle for anyone to ever decipher.

However, Momenta remained confident that the team could meet the scientific challenge. The market had demand for a generic LOVENOX as there was no equivalent generic version. Our scientists saw an opportunity to not only solve a scientific puzzle, but also provide an important alternative for patients and reduce the financial burden on the U.S. healthcare system.

To the scientists at Momenta, the logic required to solve the problem seemed straightforward. While most researchers will typically break apart a complex mixture into pieces and analyze it with a single tool to reduce the daunting scope of the task, Momenta scientists believed that this approach would limit what one type of analysis can say about many parts. They realized that with a mixture as complicated as enoxaparin, separating the pieces would actually increase the scope of the problem requiring an impractical investment in time, effort and money. Momenta’s approach was to analyze the mixture as a whole, using multiple types of analysis to learn about one complex mixture.

A key to Momenta’s success was in understanding that no one tool is able to completely solve the structure of a complex mixture: it is the unique integration of orthogonal approaches utilizing the many tools available. Momenta assembled a cooperative team of experts in disparate, advanced scientific techniques and recruited highly skilled scientists to analyze the data and bring the entire picture into perfect resolution.

Question Problems to Find the Answer

The characterization of enoxaparin turned out to be just one of many challenges Momenta faced. Company scientists applied the same approach to each new challenge: complex analysis combined with unconventional, insightful problem solving.

Momenta sought human and financial resources to scale up the manufacturing of a complex mixture drug and finance the anticipated lengthy regulatory review by the FDA and a potential drug launch. **In 2003**, Momenta entered into a collaboration with Sandoz, a leading global generic pharmaceutical company and division of Novartis, for the development, manufacturing and commercialization of a generic LOVENOX.

In 2005, based on Momenta's data package, Sandoz filed an ANDA for enoxaparin sodium injection with the FDA. Many skeptics doubted that the FDA would approve an interchangeable generic version of a complex drug such as LOVENOX without clinical studies to establish safety and efficacy. Momenta approached this challenge in a characteristic manner, addressing regulatory questions by using multiple different complementary methods to support the ANDA, and continuing to draw on innovative and rigorous science to build a robust data package. After over two years of review, the regulators continued to refine their approval criteria and determine what data would be necessary to complete their review. At that point, Momenta was asked to submit additional data that would confirm that its generic enoxaparin had the same immunogenicity profile as LOVENOX. Through their knowledge of the biology of low molecular weight heparins, Momenta's scientists assembled a compelling and convincing data package that fully addressed the regulators' concerns regarding the product's sameness with regard to its immunogenicity potential.

Through the ANDA submission and review process, the Momenta team created a rigorous scientific framework to provide comprehensive, robust data to meet the FDA's multiple-point criteria for the approval of an enoxaparin ANDA.

On July 23, 2010, Momenta and Sandoz were the first to receive regulatory approval for their generic form of LOVENOX. We estimate that this generic drug has already saved the U.S. health care system hundreds of millions of dollars while providing the same level of therapy for patients as branded LOVENOX.