On October 15, 2003, health officials in the central African country of Mubanda reported the outbreak of a new flu-like illness resistant to conventional antibiotics. Rural clinics reported a number of deaths attributable to the new illness.

In the four weeks preceding the announcement, 45 cases of the unknown illness, which was being called SALS (severe acute liver syndrome), had been reported to the national health authorities. Ten of these cases had resulted in death. The disease seemed to be transmitted easily and therefore to be spreading rapidly. While the victims of the new disease were poor and were less likely to travel than urban victims, there were indications that the disease might spread to urban areas and might have already spread across the border to a neighboring country. The modern political border split the historical homeland of one of Mubanda's tribes and was irrelevant to most tribal members who freely crossed it daily as their ancestors had for centuries.

Mubanda, one of south central Africa's poorest countries, was uniquely unprepared to cope with a new health crisis. The country was already coping with the effects of the AIDS pandemic and had few health resources or funds to cope with another outbreak.

A Possible Cure
The Mubanda health minister, a British-trained physician, was encouraged by preliminary word from one of her health bureaus that the disease seemed to respond to a new drug, Holizan, recently marketed for other indications by a small American biotech/pharmaceutical firm, Rosendahl Meds, Inc.

Rosendahl, a 10-year-old firm, had only two pharmaceuticals on the market. Its prospects were heavily tied to Holizan, which represented a development investment of approximately $500 million. In its 10 year history, Rosendahl had successfully raised several rounds of venture financing and then, as its first product had shown evidence of a promising technology platform, had attracted substantial investments from two larger pharmaceutical firms. Representatives of both the venture investors and the large pharmaceutical firms served on the board, as did two university scientists who had advised Rosendahl closely over its short life. Rosendahl's CEO was Craig Elliott, who had earlier worked for two other San Francisco Bay Area biotechnology firms.

Mubanda's Options
As the Mubanda health minister evaluated the situation, she and the country had several options:
1. Divert what resources she could from HIV/AIDS programs to buy supplies of Holizan at the current global price to try to stem the outbreak. A treatment regimen would cost approximately $450 per treated individual. Given this cost, she thought it unlikely that she could free up enough cash to stem the rapidly progressing outbreak in time to prevent its spread to the urban areas.
2. Ask Rosendahl to make supplies of Holizan available free or perhaps at production cost, rumored be approximately $22 per regimen.
3. Arrange with a generic drug firm in South Africa to produce a Holizan equivalent without permission from or payment to Rosendahl. A recently passed Mubanda law allowed the health minister to abrogate patent rights in time of national emergency, which this might be—or at least could become if untreated. It was less clear whether the health minister had the right in this case...
to arrange with a drug company in a third country for this production, although the World Trade Organization had recently adopted exceptions that indicated such a step would be permissible under WTO rules under certain specific conditions.

4. Wait and see how the crisis developed. The health minister was acutely aware, however, that the Chinese government had been severely criticized in 2002 for its slowness in the SARS outbreak. She also knew that the Chinese health minister had been fired in response to international criticism.

Rosendahl's Dilemma

For Rosendahl, the news that its drug Holizan might stem the tide of the new Mubanda disease was mixed, to put it mildly. To make the fledgling company a success and to support the level of its stock price, CEO Elliott believed the company had to make Holizan a blockbuster.

Elliott worried that Mubanda's health minister would not be sympathetic in any way to the impact of her decision on Rosendahl's prospects or its stockholders. He specifically feared that Mubanda would move unilaterally to violate its patents and have a generic Holizan manufactured somewhere in Africa. Elliott doubted that a generic manufacturer would limit the sale of generic Holizan just to Mubanda or that it would stop production once the crisis had passed. Would the black market forever be flooded with generic Holizan, thereby destroying the market for the drug, not just in Africa but also possibly in Asia and even in Europe?

Elliott knew that Rosendahl's plight was not unique. Large and small pharmaceutical firms had faced a similar dilemma due to the HIV/AIDS epidemic in Africa. Faced with local emergency laws permitting the violation of patent rights, the WTO, under pressure from the United States, had permitted countries to produce the emergency generics in the country where they would be used. Many African countries protested that they did not have a generic drug industry and that these measures blocked their access to drugs needed in emergencies. In early September 2003, the United States gave in to world opinion and cooperated in the development of new WTO exceptions which permitted arranging for generic production elsewhere in times of genuine crisis. The exception prohibited a generic manufacturer from exporting such drugs to any other country and tightened up the definition of a genuine health crisis. Whether the Mubanda situation fulfilled the WTO crisis conditions was not clear.

Despite the American change of heart over the WTO rules, critics in non-governmental organizations argued the rules did not go far enough. Stating that the WTO rules "will not make a significant difference to the millions of sick people who die unnecessarily in the third world every year," Celine Charveriat of OXFAM told the New York Times that the rules requiring a health crisis were too strict. She implied that poverty alone in the third world ought to justify violating patent rights on a very broad set of drugs.

Elliott was also aware that the U.S. government had become worried about just the kind of situation Rosendahl was facing. While the United States had finally supported the new WTO policies, the head of the Food and Drug Administration had given a major address in late September 2003, stating that recent pressures on drug pricing and patents worldwide had forced the U.S. health care consumer to shoulder much of the cost of drug development through higher domestic prices. "New drugs are truly global products," the FDA commissioner stated. "They must be paid for by all countries and their citizens."

The Longer Term

While facing this particular dilemma regarding Holizan, Elliott wondered what the threat of this type of dilemma might mean for the long-term profitability and survival of his firm. He knew Bristol-Myers Squibb had recently given in to pressure from the scientific community to relax its patents over two AIDS drugs, allowing manufacturers in South Africa to produce cheaper copies
for local use. And another Bay Area firm, Maxygen, had garnered considerable favorable press for its decision to partner with non-governmental organizations to make its malaria drug available at reduced cost around the world. Maxygen was obviously accepting a smaller return on its investment than it might otherwise receive.

Rosendahl had recently been asked by BIO, the Biotechnology Industry Organization, one of the trade associations to which Rosendahl belonged, to consider a partnership with universities, research institutes, and the Gates Foundation, to develop new drugs for third world diseases off its current technologies. Such arrangements usually required the bio or pharmaceutical firm to license the resulting drugs to a non-profit international health initiative.

As Elliott thought about the situation, several questions ran through his mind including:
1. What long-term strategies regarding the availability of its drugs in the third world would serve the interests of his investors and the company itself?
2. Would the possibility that its property rights might be abrogated reduce the value of its stock?
3. Would it be better to get out front and win some good will by doing some cooperative deals on third world disease?