



Bird Flu Prompts Calls For Compulsory Licensing

IP Law Bulletin (Thursday, October 13, 2005)--Fear of a deadly outbreak of avian flu is putting pressure on Roche Pharmaceuticals to lower the cost of the only available treatment or face the specter of compulsory licensing.

The calls for drastic action are coming against the backdrop of mounting concerns about a possible pandemic, although so far, the risk of a worldwide outbreak remains muted. Only 117 cases of human infection, all in Asia, have been reported, with 60 fatalities.

The United States has begun stockpiling the drug, according to the Center for Disease Control, with current reserves at 2.3 million regimens and another 2 million on order.

The heightened demand for the drug, Tamiflu, has caused unprecedented sales. In 2001, sales of the drug totaled \$76 million, climbing to \$134 million in 2002. In the first half of this year, sales of Tamiflu garnered \$456 million.

But governments are worried that the drug will be in short supply—and far too expensive—if a global pandemic does strike.

In remarks made last week at the headquarters of the World Health Organization in Geneva, U.N. Secretary General Kofi Annan said that intellectual property rights should not get in the way emergency production of vaccines and treatments.

"So we should be clear that in this situation, we will take the measures to make sure poor and rich have access to the medication and the vaccine required," Annan said. "And the decision should be taken ahead of time so that we don't have to quibble about it when the critical and the crisis moments arrive."

Roche counters that a compulsory license for the drug wouldn't make sense, since other drug makers don't have the facilities to produce Tamiflu on short notice.

Manufacturing Tamiflu involves 10 steps and can take up to 12 months to implement, according to the company. Roche says that it would take about three years before a generic company could produce the drug.

Compulsory licensing allows a government to temporarily override a patent. This allows generic copies of a patented product to be produced domestically, with compensation paid to the patent holder. For example, a government may issue a compulsory license to a company to produce generics when faced with a public health problem.

The TRIPS Agreement lays out certain procedural requirements that governments must follow when using compulsory licensing, including an expedited procedure for times when a government faces a public health "emergency" and must respond quickly.

Roche, and other pharmaceutical companies that have faced compulsory licensing issues, argue that permitting the production of generic versions drains profits from pharmaceutical companies and inhibits the production of future generations of the drugs.

Although compulsory licensing might seem an alluring proposition to governments faced with health scare, it's rarely the right solution, said George F. Wheeler of McAndrews, Held & Malloy, a legal expert with extensive experience in the pharmaceutical industry.

"The only reason people will invest in costly and risky vaccines is if they can recover their costs," Wheeler said. "Certainly this is an urgent problem, but compulsory licensing is not the way to solve it. If companies see a situation like this and realize they can't keep supply in the market, they can license others to produce the drug, but it should be voluntary."

The Pharmaceutical Researchers and Manufacturers of America, a group that represents pharmaceutical companies, including Roche, has issued a statement opposing compulsory licensing of the drug.

"Public health officials should not consider imposing compulsory licenses on avian flu medicines, a step that would take away incentives for other companies to undertake the difficult and costly work of searching for new antivirals and vaccines for this possible health crisis," Billy Tauzin, Pharma president, said.

The last major compulsory licensing agreement dispute in the United States came after the anthrax scare of 2001.

Bayer, producer of Anthrax treatment Cipro, said it would not be able to produce the 10 million doses asked for by Department of Health and Human Services Secretary Tommy Thompson. New York Senator Chuck Schumer asked Thompson to issue compulsory licenses to generic manufacturers for the drug. In the end, Bayer and the government negotiated a lower price for the drug, avoiding a compulsory license.

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