Emergency Access to Patented Drugs

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Millions of birds have died from H5N1 bird flu. More than half of about 120 people reported to have contracted the flu directly from infected birds have also died. This has led to fears that this virulent disease will mutate into one transferable from person to person, rather than bird to person. A recent story on ABC Primetime, however, provided the welcome news that antiviral drug, Tamiflu, may reduce fatalities should that occur.

Since then, Tamiflu, manufactured by the Swiss company, Roche Holding AG, has received much attention. Although manufacturing capacity has been doubled and redoubled within the past two years, Roche remains unable to cope with global demand.

Inadequate supplies and Roche's reported refusal to license its Tamiflu patents to other firms have caused widespread concern. Now, Cipla, India's third-largest pharmaceutical manufacturer vows to produce a generic copy of Tamiflu despite substantial risk of patent infringement.

Within any given country, the owner of a patent can prevent others from making or importing its protected drug, but patents, of course, have no force outside of countries that grant them. Also, because patents are expensive to obtain and maintain, no company can afford to hold them in each of the 147 countries where pharmaceutical patents are, or soon will be, possible under the 1995 world-trade agreement known as TRIPS.

If Roche can enforce Tamiflu patents in India, it can stop Cipla from making a generic copy, much less exporting it. Barring that, Cipla's generic drug could then be shipped from India to any country that lacks patent protection.

But, as Cipla apparently hopes will occur in this instance, patent protection may sometimes be side stepped. In that regard, consider experience with HIV-AIDS.

About forty companies hold patents on drugs important for reducing or delaying AIDS fatalities. Yet, because millions have died and more are at risk, various measures may result in others being allowed to copy those patented drugs.

Political pressure, alone, may be enough. The website of the international HIV and AIDS charity, AVERT, reports that holders of South African patents backed down “following immense pressure from the South African government, the European Parliament and 300,000 people from over 130 countries.” Indeed, one company was induced to license a major South African generics firm to copy its drugs in return for “a promise to give 30 percent of their net sales [income] to one or more non-governmental organisations fighting HIV and AIDS in South Africa, which they continue to do to this day.”

Based on the 2001 Doha interpretation of TRIPS, companies may also be required to license others to copy patented drugs if necessary to protect public health. If applicable, that could permit Cipla and other firms to make, sell and export generic copies of Tamiflu despite patents that otherwise permit Roche to exclude would-be competitors. For that to happen, a public health risk must be evident, and alternatives must be inadequate. A quick search of the Internet, however, indicates that the first, if not also the second, condition is so far unmet.

Patents are critical to inducing firms to spend private capital in the hope of finding cures for diseases. Under eminent domain, however, all property may be taken if sufficient public need is demonstrated. Should Tamiflu ultimately be found to offer sufficient, otherwise unsatisfied, prospects for fighting something rivaling the Spanish flu pandemic that killed millions of people in 1918, Roche’s patents will not be allowed to interfere.

In such circumstances, companies are entitled to fair compensation, but that is not easily computed. Thus, the U.S. and other governments have agreed not to rely on the Doha interpretation to compel compulsory licenses lest they adversely affect

needed pharmaceutical risk capital.

This leaves a basic question, so far avoided. First is whether and, if so, when patent holders, themselves unable to satisfy public needs, should be limited to federal remedies under 28 U.S.C. § 1498 or possibly subject to state eminent domain proceedings. Put another way, when and why should drug firms fare better than homeowners required, following Kelo v. City of New London, Conn., 125 S.Ct. 2655 (2005), to sell *their* private property?

[I much appreciate reactions of my colleagues, William O. Hennessey and Craig S. Jepson, to earlier drafts of these comments.]

Added later:

The EU recently announced that Roche has agreed to license Tamiflu. For many, that will be welcome news. It should undercut, if not eliminate, the need for compulsory licenses under the Doha interpretation of TRIPS.

The sense of emergency may be reduced, but need to understand differences between licenses and compulsory licenses should not be. When firms license, they set the terms. In contrast, compulsory license terms are set by others.

Although 28 U.S.C. § 1498(a) is similar, it requires no demonstration of public need as a precondition of direct or indirect government infringement. We should consider why officials are nevertheless reluctant to take such measures when drugs are involved.

First, compensation for patent rights is far more difficult to compute than the fair market value of more fungible real estate. Of at least equal importance, officials also seem to understand that private investors who support pharmaceutical research have other possible uses for their money. Hence, despite similarities, we should not see the public use of pharmaceutical patents under eminent domain (more accurately, inverse condemnation) as essentially the same as seizing real estate for public purposes.

The focus on Tamiflu now, and on Cipro during the anthrax scare, should spark more attention to critical differences between real estate and drug patents. The need only increases in tandem with the seriousness of health threats.