Questions raised about whether compulsory licenses get best prices

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Negotiating costs: Groups such as UNICEF help facilitate voluntary discounts.

The use of so-called 'compulsory licenses' by developing countries to obtain cheaper drugs for HIV and AIDS by circumventing patents has not been the best strategy for achieving the lowest prices over the past decade, a new study claims. Instead, the best prices were often obtained by countries that procured their drugs through voluntary negotiations, often facilitated by third parties such as UNICEF or the Global Fund to Fight AIDS, Tuberculosis and Malaria.

A compulsory license allows a government to license the use of a patented invention to itself or a third party without the consent of the patent holder. They have been used by many low-income countries to enable the domestic production or importation of generic medicines at lower prices, particularly for antiretrovirals. Drug companies, unsurprisingly, are not fond of the mechanism, and they argue that it should only be used as a last resort in a health emergency. The World Trade Organization, however, says that countries are free to determine the grounds on which they will grant licenses.

Amir Attaran, who studies law and population health at the University of Ottawa in Canada, compared the prices of antiretroviral medications obtained through compulsory licenses in several countries with the median price achieved by peer countries for the same drugs through international procurements in the same year. Compulsory licensing did result in lower drug prices compared with the price on offer before the license was issued, but of the 30 cases of compulsory licensing from 2003 to 2012 for which reliable data was available, the median price achieved through international procurement was lower for 19 of them—in the majority of cases by more than 25% (*Health Aff.*, **34**, 493–501, 2015). The effect was strongest in the poorest countries, where in six out of seven cases the procurement price was more than 25% lower than the compulsory license price.

Attaran says the results suggest that countries should not rush into using compulsory licenses until they have exhausted all other options. "Countries can save money using compulsory licenses, but they can save more by negotiating and using international procurement channels," he says. "If saving money is paramount, then compulsory licenses may not be the optimal strategy."

The price differential was highest when countries issued a compulsory license to manufacture the drug locally. The largest disparity was seen in 2012, when Ecuador licensed the production of a combination treatment of the drugs abacavir and lamivudine. The median price achieved by other countries for that drug combination was ten times cheaper. This is because to produce the drug locally a country may need to build up a manufacturing base from scratch, and economies of scale are lost. Attaran says there are valid reasons a country may want to do this, for example to ensure a secure supply or to address concerns about manufacturing processes, but then price can no longer be the driving force for the decision. "If they want local production, it's going to cost them," he says.

Alternative explanations

Daniel Cahoy, who studies intellectual property law at Pennsylvania State University, cautions against extending the results too far. "This is just for one kind of drug, and antiretrovirals are a very special case," he says. "They get a lot of attention, and there are initiatives that exist for getting them to poor countries that don't apply in other compulsory license cases."

He is not surprised, though, that international procurement strategies generated lower prices than compulsory licenses. "It makes sense that if you have a lot of NGOs putting pressure on pharmaceutical companies and developing group pricing power that it would drive down prices," he says.

Sivaramjani Thambisetty, a patent law expert from the London School of Economics, says the lack of alternative explanations in the paper for the price differential is "problematic." For example, the poorest countries may not be able to benefit from bulk pricing, which may drive down international procurement prices. "The bargaining power may not be available to poorer countries that do not have public health systems, and so cannot take advantage of bulk procurement prices," she says.

The grant of a compulsory license is often a signal of problems with the validity of a patent, she adds, which can strengthen the negotiating power of those seeking a bulk procurement.

And compulsory licenses do not negate a patent holder's rights completely, she points out. They are still entitled to "adequate or reasonable remuneration," which will be reflected in the price. "A compulsory license is never a guarantor of an absolute baseline price," says Thambisetty. The licenses also provide an incentive for companies to negotiate lower prices, she adds. "I do not see the results of this study as making international procurement preferable or comparable to a compulsory license, the threat of which remains an important tool in the repertoire of less-well-off countries."

Attaran agrees that the existence of the mechanism and countries' willingness to use it has provided them with a stronger negotiating position, as companies sacrifice some profits in order to protect their market share. "It's the same reason that we have labor laws and unions, because it is conducive to the negotiation process," he says. "It's the same for compulsory licenses: they provide a safety valve in case negotiations do not proceed properly."

Attaran also stresses that he is not opposed to compulsory licenses, which have become something of an ideological battleground. "This is not an indictment of compulsory licenses, but a question of judgment," he says. "It's not in anyone's interest to advocate for something that is not supported by evidence."

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