Companies Weigh Offer of Royalties For AIDS Drugs Aimed at Africa
By Daniel Pearl

Two U.S. drug companies appear to be weighing an Indian generic-drug maker's offer to pay them 5% royalties in exchange for permission to sell knockoff versions of their patented anti-AIDS drugs in developing countries.

Bristol-Myers Squibb Co. and Pfizer Ltd. have both promised to respond soon to the offer from Bombay-based Cipla Ltd., according to letters made available by Cipla. The Indian drug company produces its own version of anti-retroviral drugs used to fight AIDS, and recently jolted pharmaceutical companies by offering to sell an AIDS "cocktail" to an international aid organization at a much lower price than the multinational pharmaceutical companies had offered poor countries.

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Cipla says it hasn't received responses from two other companies -- GlaxoSmithKline PLC of the U.K. and Boehringer Ingelheim Ltd. of Germany -- to its proposal, made in a Dec. 19 letter that requested a "timely response." Glaxo told The Wall Street Journal it was considering Cipla's offer but had reservations about it.

The idea of a 5% royalty is unlikely, by itself, to resolve the current quandary over how to protect patent rights while making drugs available to poor countries hit hard by the AIDS pandemic. Glaxo, after all, has already rebuffed Cipla's bid to sell AIDS drugs in Ghana, where Glaxo claims patent protection. Still, it is risky for drug companies to brush off Cipla's royalty offer, because doing so could hand Cipla a weapon to enter those markets anyway, through a maneuver called "compulsory licensing."

Under compulsory licensing, a government can force patent holders to grant licenses to generic drug makers. Unless there is a "national emergency," though, the generic company first has to establish that it tried to get a license on "reasonable commercial terms" but was rebuffed.

Patent holders "don't want to issue licenses," says James Love, a Washington-based activist who has been involved in talks between Cipla and international aid groups that are hoping to distribute AIDS drugs free of charge. Mr. Love, of the Ralph Nader group Consumer Project on Technology, says that with compulsory licensing, it is "up to the governments" to decide who gets a license. He says citizens groups are starting to put pressure on African governments to try to get low-priced AIDS drugs even if it means going generic.

Pfizer expects to respond to Cipla's proposal later this month, a spokesman said Thursday. "We think it unlikely that an agreement could be reached with Cipla," the spokesman, Bob Huber,
said. But Pfizer will ask for additional information about Cipla, including its roster of board members and manufacturing processes. Pfizer advocates donation programs as the best way to expand patient access to vital medicines in Africa and elsewhere. "It makes little difference if a medication is priced at $5,000 a year or $500 a year in many developing nations," Mr. Huber said. "Both are beyond the reach of most patients."

Bristol-Myers didn't respond to a request for comment on Cipla's offer. A spokesman for Boehringer Ingelheim said that he was unaware of Cipla's letter but that "any kind of offer would have to be discussed."

Glaxo spokesman Phil Thomson said, "The best thing we can say is we have received [Cipla's offer] and it's under consideration." But he cautioned that "we need to look at the royalties" and said he couldn't say when the company would respond to Cipla's offer. Right now, Glaxo said, it is focused on selling the two products Cipla referred to in its letter, lamivudine and zidovudine, through a United Nations program in which drug companies negotiate with developing countries to sell their AIDS drugs at a discount.

From Cipla's point of view, a compulsory license would be an easier way to get its AIDS drugs into sub-Saharan Africa than selling to aid groups. Cipla is expected to meet in coming days with the group Doctors Without Borders to try to iron out an agreement to sell the group an AIDS cocktail at a price of $350 per patient per year. But even if a deal is reached, Doctors Without Borders could face problems distributing the drugs in countries with strong patent protections.

Cipla's strategy is to "somehow persuade the governments to recognize compulsory licensing," says Jesal Shah, a research associate with SG Asia Securities, based in Bombay. He adds, "Cipla has been trying to break into the sub-Saharan region with its AIDS drugs for quite some time now."

Cipla officials say winning a compulsory license wasn't necessarily the intent of the December letter to the AIDS-drug patent holders. "We don't have a definite plan of action" if the drug companies turn down the offer, says Amar Lulla, Cipla's joint managing director, who signed the letters. "I don't think we would be able to afford litigation or to pressure governments."

The World Trade Organization, by 2005, will require members to have laws in place to protect pharmaceuticals from copycat manufacturers such as Cipla. But countries can include compulsory licensing in their laws. The licenses would require an adequate payment to the patent holder, though determining what's adequate could be sticky. Cipla is offering up to 5% of sales, depending on how strong a patent claim the other company has in a particular country. Cipla says it drew the figure from a year-old submission by a U.S. pharmaceutical trade group that cited 5% as the average pharmaceutical royalty rate. But a spokesman for the group, Pharmaceutical Research and Manufacturers of America, says the 5% is a "low-end, conservative estimate."
Although some developed countries such as Canada have used compulsory licensing in the past to keep drug costs low, poor countries haven't been jumping on the idea. Even in India, some pharmaceutical companies have mixed feelings about a strong compulsory-license measure being considered in their country. After all, it could come back to haunt them if they develop their own drugs. Government officials worry that foreign aid could dry up if they push for compulsory licenses, says Anand Grover, a Bombay public-interest lawyer specializing in AIDS issues.

U.N. officials are cheering the idea of royalties, but from the sidelines. Jonathan Quick, director of the World Health Organization's department of essential drugs, notes that royalties are a "business arrangement," and that U.N. officials decided this week that "it's not our role to get in the middle of commercial patent discussions."

Geeta Anand, Jesse Pesta and Vanessa Fuhrmans contributed to this article.