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How To Charge \$1.6 Million For a New Drug And Get Away With It

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Call it a warning shot: last week an Indian patent court shocked the \$600 billion global pharmaceutical business by ordering Bayer, the German health care giant, to allow a tiny Indian generic drug company to sell cheap copies of the blockbuster cancer drug Nexavar – even though everyone agrees that the drug is protected by a patent. Instead, the court decided that Bayer had an obligation to make Nexavar available to people in India who needed it.



The Indian decision is “arbitrary,” says Sapna Palla, a lawyer at Kaye Scholer who represents pharmaceutical firms in patent litigation. Why Nexavar, and not any other high-priced drug? She says it “undermines the innovative pharmaceutical industry in India in the long run” and predicts the decision will “stymie foreign investment in India” because it will add to doubts about the Indian patent system. (Bayer contests the decision, too.)

It’s a basic tenet of the pharmaceutical business that companies have a right to charge high prices for new, innovative medicines. Because more than 90% of experimental drugs fail to be proven safe or effective, it’s necessary for medicines to generate billions of dollars in sales in order to entice investors and companies to sink money into research. Patent protection is not the ideal way to fund medical research, but nobody has found anything better.

But in this case, the Indian patent court and Natco Pharmaceuticals, which brought the case, have a point. The many thousands of Indian patients suffering from kidney or liver cancer could not get their hands on Nexavar. Only a few percent of them took it.

Knowledge Ecology International, a group that campaigns for people in developing world to have better access to new medicines, says Nexavar was priced at \$69,000 for a year of

treatment, 41 times the per capita income in India. For comparison, a drug that cost 41 times the U.S. per capita income would cost \$1.6 million. The Natco price? \$177.

In the U.S., Nexavar actually costs even more in real dollars. The average liver cancer patient would pay \$80,000 for a ten-month course if he were paying the wholesale acquisition cost of Nexavar; kidney cancer patients pay \$96,000 a year. Except, of course, that they don't pay. Insurers cover much of the cost. Bayer and partner Onyx Pharmaceutical, which split sales duties in the U.S., have a program to make sure that eligible patients aren't responsible for more than \$100 of copayment. They also have programs to make sure that uninsured patients have access to the drug.

Even for mass-market drugs, it is increasingly the reality in the U.S. that the patient doesn't pay. Insured patients can get \$160 worth of branded Lipitor for \$4, with maker Pfizer picking up the rest of the co-payment. Meanwhile, Pfizer is negotiating with health plans to convince them to buy its Lipitor over the \$120-a-month generic version.

This is even more true for the specialty medicines, like cancer drugs, that are the drug industry's stock-in-trade these days. The customer is not the patient but the insurance company or government picking up the check. That's why drug companies refer to governments and insurers as "the payors."

As a result drug companies can price new medicines at a cost that no individual person could pay. I count ten medicines that have an average per patient cost of more than \$200,000 per patient per year, including the treatments made by Sanofi's Genzyme unit, Biomarin, Alexion Pharmaceuticals, and now Vertex's new cystic fibrosis drug, Kalydeco — the first medicine ever to work on the genetic defect that causes that lung disease, but only for a select few that have a particular mutation.

It's an open question, but it's possible that it's better to have \$300,000 drugs that are highly effective than \$3,000 drugs that aren't. All these medicines are priced as they are because the Payors will pay. Alexion, whose Soliris treats rare and lethal disorders that destroy blood cells or damage the kidneys. "Even at a \$400,000+ per year price point, they manage to justify the value of their medicine for the small patient populations with the relevant diseases," writes Sanford C. Bernstein analyst Geoffrey Porges. Proof? Alexion's stock has been outperforming Apple's. That will get a lot more companies interested in rare diseases. We're still not at \$1.6 million per patient per year, the per capita equivalent of Bayer's price in India, but there is no reason to think we can't get there.

But moving these drugs into other countries often means giving even more away. One executive once told me his emerging markets strategy for these ultra-rare disease drugs was to get any patient who needed the medicine on it, and then to try to convince governments or

insurers to pay full price for one patient, then another, then another. The key is that the medicines be worth the money.

Even at Nexavar's comparatively low price point of "just" \$80,000 a year, this same strategy can work. Assuming Bayer can make Nexavar for about the same price as Natco, it could break even getting paid for one out of four hundred prescriptions. It needs to do better than that, financially, but it also needs to find ways to make the drug available to patients who need it worldwide. The new pharma compact may well be that companies can charge what they will, but that they must in the meantime make sure patients get their medicines. How long this system will be sustainable is, of course, anybody's guess.