A Brief Introduction to the EAL

You know about AIDS in Africa, and you've read about some of the recent talk about how prices for AIDS drugs are coming down, but you're wondering, "How do patents affect the pricing of drugs in the developing world?," and "Where do universities fit into the picture. And what is the EAL?" Here's a little background.

Say you just created a nifty dohicky that might save many lives and/or make you lots of money, you're going to need to patent it. A patent is essentially a government promise to protect your invention and give you the exclusive right to make, use, or sell your dohicky. (There are lots of different flavors of patents, but lets let the patent lawyers worry about those details for now). You won't get your patent automatically though. You have to apply to the government, pay some thousands of dollars and show that your new thingy meets three criteria: that it is novel (no one has publicized your idea before), non-obvious (duh), and useful (don't worry, they're lenient about this one). But you can't patent any and everything. You can't patent some natural processes like gravity or shooting stars (although, these days, you can patent genes, and you can patent living organisms if you engineer them).

When any new invention is patented, it guarantees the holder of the patent 20 years during which no one else is allowed to produce, sell, import, or do research on that product without their permission. Its kinda like a reward allowing the inventor some time to make back the money they invested in making the invention. But it is also a protection so that innovators don't spend loads of cash to produce a new kind of fishing lure that can catch gobs of fish, only to have someone steal the idea as soon as they put it on the market. If you have a patent and someone steals your dohicky idea from you (called "infringement"), you can sue them and collect damages.

The issue gets a little trickier when it involves things people need in order to live. Patented medical technologies have the nasty habit of being really expensive, for two reasons: first, it costs a lot of money to research and develop these products. A new pharmaceutical drug must go through three rounds of clinical trials, which take a long time and can be expensive. Second, since the patent owner has a monopoly on the product, *i.e.* no competitors, they can usually set the price at whatever level they want. The problem is that monopoly prices are usually way too expensive for people who live in developing countries. Sadly, they are often the people who need the technologies the most (check out http://www.accessmed-msf.org/ for more background on this).

The interesting thing is that if you ask the folks at the Securities & Exchange Commission, who keep the tax records for all sorts of industries, they'll tell you that the patent-based pharmaceutical industry is the most profitable industry in the world (making profits as a percentage of revenue about three times higher than the rest of the Fortune 500), and is spending on average 27% of its revenue on marketing and 11% on research and development (R&D) (Angell, 2004; Mahan, 2002; Light & Lexchin, 2004). Then the folks at the National Institute of Health (NIH) will tell you that that R&D number is also

inflated, because a lot of taxmoney goes to the R&D process, even at the clinical trials stage (85% of the key R&D, including clinical trial costs, happened to come from taxpayers for the five most important drugs on the market) (Angell, 2004; Goozner, 2004; Light & Lexchin, 2004; Mayan, 2002; Young & Surrosco, 2001). What patents seemed to have done is allowed some members of the pharmaceutical industry to get a two decade monopoly and the profits from enjoy uncompetitively high pricing, while taxpayers foot the bill twice (once at the R&D end, a second time at the pharmacy).

For the consumers in poor countries, it's true that patents aren't the only barriers to accessing essential medicines. If patents weren't in the picture at all, there could still be issues of lack of infrastructure (from transportation to the clinic, to clean water), lack of political will, or insufficient funding of treatment programs. But while coming up with some creative solutions around the patent problem is not sufficient to ensure poor people can get medicines, it is a necessary step to ensure that those medicines are affordable. Most poor people (except in Europe) do not have any medical insurance that will help pay for health care, so if medicines aren't cheap, then people can't buy them. Nor can the governments of poor countries, which often have economies a fraction of the size of drug companies' annual profits.

The approach to this problem, which we've called the "equitable access license", is aimed at promoting competition to keep the prices of drugs at reasonable levels (since it's generally accepted that competition is the best way to keep prices down in the case of medicine costs in poor countries; see Oxfam's Briefing Paper No. 26). We've noticed that universities play a large role in basic scientific research. While universities used to do this research purely for the public good (as part of their mission as non-profit institutions), they have started to try to seek a profit off of it. More universities are filing more patents than ever before: According to the Association of University Technology Transfer Managers, 216 institutions filed 7,741 patent applications in 2002, a jump of 13% from the year before (AUTM Licensing Survey, 2002). Universities have profited handsomely from pharmaceutical inventions such as Xalatan, a glaucoma drug invented at Columbia University, and some of the antiretroviral drugs used for HIV such as stavudine (also called d4T, Yale University), abacavir (University of Minnesota), lamivudine (Emory University), and enfuvirtide (Duke University).

But since universities don't develop pharmaceutical drugs, they must license their patents out to someone who does, like a pharmaceutical company. A license is essentially a contract between the owner of the patent and a party that wants to "exploit" it. This contract is flexible. We could put things in it, such as the exclusive right to the verb of your choice: to make, sell, import, export, develop, etc., in any country where this technology is patented. In exchange for these rights, universities get a share of profits from products that use their innovation, and possibly a little bit up front too. Universities can also put restrictions in the license that revoke the rights originally given if the licensee doesn't develop the technology at a reasonable speed and commercialize it (called a "due diligence" clause), or doesn't abide by other terms of the contract. Restrictions are pretty common in licenses, and because they can be potential deal-breakers, they're often haggled intensely by lawyers on both sides before the license is signed.

With universities patenting and licensing more than ever, it seems like a good idea to make sure that the fruit of their inventions reaches those whom it was designed to benefit. In the case of pharmaceutical drugs, this would mean the university does everything it can to make sure that people in poor countries have access to the drug. This doesn't mean the university should go into the development business, but it does mean that the university, as the patent holder, can exercise control over how a drug is priced in developing countries. It can be done: Yale and Bristol Meyers Squib singlehandedly reduced the price of stavudine (d4T) in South Africa by more than 95% by agreeing not to enforce the patent there.

But the d4T story is one of a retroactive reaction to a bad situation, and only one drug in a triple cocktail. It has taken years for prices on other AIDS drugs to come down. Millions have died in the meantime, and more will follow. There's no reason for us to be in this situation to begin with. We think it would be better if there were a *proactive* approach, one that encourages competition to ensure the cheapest price possible for the drug, therapy or diagnostic right after it hit the market. That's what the Equitable Access License (EAL) is designed to do. Would this harm the pharmaceutical industry's bottom line? Not really: turns out that only 1.3% of their market is in sub-Saharan Africa, for example, so as the former Eli Lilly CEO put it, even losing this market altogether (as opposed to competing in it, as we're proposing) would cost at most "about three days' fluctutation in exchange rates" (Gellman, 2000). Not really the kind of thing that'll hurt R&D. But will the EAL lower prices in America and European countries? Nope. We'll have to work on that in other ways; the EAL is intended for the poorest, and its unique structure (explained more below) is made to address the worst cases first.

The EAL is intended to be incorporated into the licenses that universities use when negotiating with biotech or pharmaceutical companies. It was designed to do a number of things those licenses typically don't do. Specifically, certain conditions in the license can be met (for example, a pharmaceutical company in a poor country can notify the university that a key medicine is overpriced there), and three things happen as a result. First, patent barriers are lifted, because the university deems its technology (and any related patents possessed by the licensee) to be "open licensed" in that country. "Open" licensing, as opposed to "exclusive" licensing, means that the intellectual property required to make that product is open to anyone that wants to use it. This means generic pharmaceutical companies who want to produce the technology in a poor country won't get sued for doing so as long as the conditions that trigger the license are met. (For an explanation on why we chose open licensing as opposed to seeking price restrictions, please see the 'Explanation of Model Licensing Provisions for an Equitable Access License', available online: http://www.essentialmedicines.org/Explanation.pdf).

Second, regulatory barriers are lifted because the open licensing structure also applies to regulatory data held by the university or licensee. Regulatory data is information such as clinical trial data that is used to seek drug approval from a regulatory body such as the Food & Drug Administration (FDA). This data is often used as a second line of patent protection because, while a generic company can produce a drug, unless it can have access to the marketing data, it will be forced to go through the multi-year drug safety and efficacy testing process all over again. The EAL avoids such redundancy by granting

an open license to that data, allowing the medical regulatory agency in a country that lacks access to the drug to rely upon the clinical trial and other data that was submitted in the US or Europe. For example, a Malawian official wouldn't have to require that a Malawian company prove that beta blockers help treat heart disease; the company would only have to prove that its drug is of good quality and has the same chemical structure as US or European beta blockers, then present the existing evidence that the beta blockers work well.

Third, production barriers are lifted because the license allows producers in any country to produce the product for the sole purpose of exporting to a poor country. In a nutshell, this means that access to medicines in developing countries is not dependent on there being a pharmaceutical industry in the target country. Once the license is triggered, a generic company in North America or Europe would be allowed to produce the product for export to poor countries as long as it did not sell it within North America or Europe itself. So an American philanthropist can still donate drugs to a poor Latin American. Essentially, the EAL is trying to wiggle its way around some international trade laws that have tried to offer the same remedy but have failed in practice.

In addition, the EAL is unique in that it can be used regardless of where the university or licensee holds patents. It also encourages research on neglected diseases through its royalty scheme, outlined below. Third, it requires minimal administrative overhead. Neither the university nor the original pharmaceutical company that contracted with the university needs to monitor what countries lack access, nor must either party “do something” to grant the open license (which helps because the American company isn't likely to be too proactive about helping poor countries get cheaper meds).

Now lets look at what triggers the EAL. It is set up so that in all low and middle income countries, if someone wishes to compete with the licensee to make the product, they must only write a letter to the university and the licensee notifying them that the EAL is being invoked. Once that is accomplished, the license is triggered, and the third party is deemed to have permission to make, sell, export, or import the product from the date the letter was sent until the relevant patents expire. Notice that the university and the licensee don’t have to do anything. They don’t have to say “yes”; they don’t have to monitor “access” in other countries; they don’t even have to talk to the third party invoking the license. By reducing the bureaucratic hurdles, the EAL should ensure low activation energy for third parties to enter into competition with the licensee.

There’s one catch: it is rare that only one patent goes into making a new drug or diagnostic. While developing the university’s drug, a company might find a cheaper way of making it, or a better formulation (like how to dose it once a day, or put it into liquid form for babies). All of these marginal little improvements, believe it or not, can usually be patented. So what about these other patents that are needed to make the wonder drug? The EAL anticipates this scenario by ensuring that when the university and licensee agree on a license, the licensee provides the university with a limited license (a.k.a. a “grant back”) to all “licensee improvements,” which are defined as technologies, data, etc. which “relate to the manufacture, use or sale of an End Product.”

Ok, maybe there's more than one catch. All this can't be for free, right? Someone else buys the rights to the university patent, develops the drug, then all some whippersnapper of a generic company has to do is write a letter and they get to come in and sell it for cheap in low and middle income countries? Won't that bankrupt research and make pharmaceutical companies stop producing new drugs? Well, actually, it ain't free, and it won't bankrupt anything. First, technology transfer officers, university presidents and pharmaceutical representatives will disagree. They'll tell you that any changes to the current patent structure will hurt innovation and investigations into new potential therapies. Is this true or is it just an excuse to keep high prices? Well, both. Research and development is indeed expensive, and an expected profit incentive is necessary to convince companies that a large investment now will pay off years down the road. However, to assume that opening access to developing countries equates to a loss of enough potential income to squelch innovation is a proven fallacy. Pharmaceutical sales in developing countries represent only a tiny fraction of the total (Kapczynski, et al., 2003). In reality, critics of open licensing are less worried about the money they will lose in Africa and more worried about the possibility of illegal importation back into their more lucrative developed world market. It turns out, fortunately, that new regulatory barriers and customs regulations have minimized the threat of this, so the idea is being used more as a political excuse than as a practical concern (Basu, 2004; Outtersson, 2004).

Just to prevent any other kinds of impropriety, the EAL requires the company triggering the license to pay back the licensee that paid for all the research and development (called "remuneration"). The royalty rate is on a sliding scale – the richer the country, the higher the royalty. (For full details on how this royalty rate is calculated, see the 'Explanation of Model Licensing Provisions for an Equitable Access License', available online: http://www.essentialmedicines.org/Explanation.pdf). So for every drug sold under this license, a share of the cash will be going back to the company that developed it in the first place. This ensures that we do not have to choose between access and R&D; access itself can stimulate more R&D. As an added bonus, the EAL is written so that the royalties generated from the open license are divided evenly between the university and the licensee. But if either party wanted to (and maybe they'll want to, if students protest enough), they could decide to place the royalties into a fund for research on neglected diseases.

Another aspect of the EAL will, however, protect generic producers from suits, to protect against Big Pharma's pesky habit of catapulting a herd of lawyers at anything that looks progressive: if DoughRollers accepts the royalty payments from EALPosterChild's sales in South Korea, then the EAL says this counts as an agreement not to sue. This will prevent Big Pharma companies from giving mixed messages and changing their minds after they initially decided not to pursue a suit.

As you probably guessed, not all technologies that improve people's lives were researched and patented at a university, so the EAL is not a panacea. But it is a first step that could help set a precedent for access-oriented drug development. At the very least, it should help erode high prices as barriers to access to essential medicines in poor countries.

Citations and Additional Resources

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Useful Websites:
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For a discussion on the role of university research in drug development & medicine access, see:

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