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The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries

Lita Nelsen*

Universities that attempt to use patents arising from academic research to make medical treatments available in developing countries are caught in a paradox of the patent system. Simply put, if all the medicines and vaccines needed in developing countries existed today, one would wish the patent system to disappear. The absence of patents on medicines and vaccines would presumably allow maximum competition and drive prices down, thereby maximizing affordability and availability.

In reality, adequate treatments and preventatives do not exist for many diseases common to the developing world. If one wishes to encourage industry to use its skills and resources in the discovery, development, testing, quality control, and distribution of new drugs and vaccines, patent protection may be necessary to provide the incentive for industrial participation. Few, if any, companies will start on the long trail of new drug discovery and development unless they can depend on patent protection from competition should a drug prove successful. Thus, we come to the conclusion that patents are neither inherently bad nor inherently good for this purpose. Like all tools, they must be used wisely.

Research institutions such as universities, medical schools, and other non-profits engaged in biological and medical research (collectively referred to as “universities” in this piece) have a special role to play in the use of patents for the development and distribution of drugs and vaccines for developing countries. These institutions are often the main source for the core technologies and lead compounds that are developed into drugs and vaccines. The primary ways in which universities disseminate their discoveries are through publication and the training of students. But since the passage of the Bayh-Dole Act in 1980,¹ U.S. research institutions have

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1. Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at

also used patents and licensing to transfer inventions arising from their research into the marketplace.

Again, it seems paradoxical that patents—which are legally a way to exclude others from appropriating one’s inventions—could be used by universities whose primary purpose is to disseminate knowledge. But this paradox is readily resolved. Knowledge itself is disseminated by universities via publication, but the commercial use of some of that knowledge is restricted by patents to companies to whom the universities grant licenses. The public purpose of this patenting and licensing activity is to encourage early investment in new university findings to translate these findings into products for public consumption. The incentive for investment is sometimes provided by “exclusive licensing”—that is, the restriction of the commercial use of the patent to only one company.

Why would a university choose to grant a single exclusive license rather than multiple non-exclusive licenses to multiple companies? University research is usually at so fundamental a level (“embryonic” is a common term) that investment in development involves substantial risk—neither the technical practicability nor the market acceptability of the invention is proven. More inventions will fail than will reach the market, particularly in the medical field. In order for a company to be willing to take on the risk of developing an early stage technology, it may demand protection from its potential competitors via the exclusive use of the patent. This is especially important in the medical field, where development and, in particular, clinical trials, require very large investments.

Naturally, universities also hope for some financial return from their patents, but, contrary to widely held beliefs, this return is seldom large. On average, American universities receive licensing royalties equivalent to approximately two-to-four percent of their research budgets.² Most universities believe that the primary purpose of their technology transfer activities is to induce investment in university technology by private firms to bring products based on the technology to the public. A second goal at many universities is to aid local economic development by encouraging the creation of startup companies based on licenses to use their technology.

Despite the avowed public-minded purposes of their technology transfer activities, universities have recently come under criticism for using patents in a way that does (or could) inhibit the distribution of medicines

35 U.S.C. §§ 200-211, 301-307 (1994)).

2. Summary of AUTM Licensing Survey FY 2001. *Available at*

<http://www.autm.net/surveys/01/01summarypublicversion.pdf> (last visited July 2, 2003).

to developing countries at accessible costs. Universities often grant exclusive licenses to first-world pharmaceutical companies in order to provide the incentive for these companies to invest in developing the products. However, by insisting on enforcing these patents in developing countries, the pharmaceutical companies may prevent local companies from producing and selling the drugs at affordable prices, thus effectively denying life-saving drugs to poor people in these countries.

In the context of non-profit research institutions, such cases are very rare (in part because the fraction of medically-related patents owned by such institutions is small). However, the visibility of such cases, coupled with the universities' consciousness of public responsibility, is causing university technology transfer offices to make changes in their licensing practices for patents relevant to health care in developing countries. Awareness of these issues is new, and techniques for addressing the problem are only emerging. As yet, there is no consensus concerning "best practices." The remainder of this piece addresses some potential solutions.

RAISING AWARENESS IN THE UNIVERSITY COMMUNITY

The first task is to raise awareness of these issues in the university community as a whole. Increasing technology transfer officers' consciousness of developing-country health care needs and their universities' responsibilities to the public should help prevent the inadvertent granting of exclusive licenses without building in protection for developing-country needs. Senior administrators and researchers will become more ready to accept licensing terms that, while somewhat less profitable, address the needs of developing countries. Finally, a consistent policy from universities on these issues will raise awareness in the companies with which they deal, making these companies more readily accepting of licensing terms that address these issues.

In North America, the Association of University Technology Managers ("AUTM") has begun publicizing this issue to its members. More than ninety percent of technology transfer professionals working at non-profit research institutions in the United States and Canada belong to AUTM, and there are more than 100 members from other countries. Their 2003 annual meeting included the first AUTM workshop on health care needs for developing countries. A Special Interest Group was formed and at next year's Annual Meeting an intensive educational program will be run. AUTM also intends to compile from its members a collection of "best practice" policies and licensing terms to distribute.

A new international organization, the Center for the Management of Intellectual Property in Health Research ("MIHR"), originally formed by

the Rockefeller Foundation and now based in London, is working to educate research institutions in developing countries about intellectual property in health research, and with AUTM to spread awareness to research institutions in first-world countries. Additionally, MIHR is also developing practice manuals and will eventually develop a collection of "best practices" with the intent to distribute them widely both in the United States and worldwide.

CREATING PATENTING AND LICENSING STRATEGIES WHICH ADDRESS THE NEEDS OF DEVELOPING COUNTRIES

1. Where to File Patents

Usually, when a research institution patents and licenses out a technology, it can—if it insists—continue to own the patent after licensing. (This is the practice in most American universities.) Universities can then contract with the licensee company to control in which countries the patent will be filed. The best strategy regarding where to file a patent, however, is not easy to determine.

a. Prohibition-on-Filing Strategy.

Where the drug or vaccine in question has a large first-world market, one strategy is to prohibit the patent from being filed in developing countries. Presumably, most of the licensee's profits, with or without developing country patents, will come from first-world markets. The loss of revenue from developing countries (which could not afford to purchase large quantities of the medicines at first-world prices anyway) would be negligible and the licensee would, presumably, not be substantially disadvantaged by the strategy.³ The absence of patents in the developing world would allow "generic" competitors to produce drugs in those countries at low prices.

This strategy will be effective only if:

- (i) The first-world market for the medicine is large. If the first-world market is only a specialty "travelers' market" and the

3. The proposition that the effect on incentives for R&D of patenting drugs in poor countries depends on the relative size of the market for the drug in poor versus rich countries is well supported in the literature. See J. O. Lanjouw, *A Patent Proposal for Global Diseases*, in 2001 ANNUAL WORLD BANK CONFERENCE ON DEVELOPMENT ECONOMICS 189 (Pleskovic et al. eds., 2002).

- primary demand for the medicine is in developing countries (malaria vaccines are a good example), this strategy will not be acceptable to the licensee company;
- (ii) The drug or vaccine is relatively easy to manufacture and does not rely on any special knowledge from the licensee company. This is more likely with simple chemical drugs than with biological drugs (including vaccines). If the techniques needed for production and purification of complex biological drugs are beyond the capabilities of developing countries, permitting them to appropriate the patented technology will be of little help;
 - (iii) The research institution owns the core patent for the drug or vaccine and other, "secondary," patents owned by the licensee are not critical to the development and manufacture of the medicine. If such secondary patents are critical and the licensee chooses to file them in developing countries, then attempts by the university to provide their own technology "freely" may be moot. If secondary patents prevent the distribution of a drug, then the only effect of not enforcing a primary patent is to shelter the university from criticism. Theoretically, it is possible for the university to demand in its licensing agreement that no such secondary patents be filed in developing countries. But it is doubtful that the university will have sufficient negotiating power to make that demand, particularly if the university's invention, at the time it is licensed, is still far from becoming a marketable product; and
 - (iv) Both the developing countries and first-world countries in which the licensee sells the product will take effective legal measures to prevent importation of the presumably cheaper generic drug back into the first-world markets of the licensee.

b. When Patent Filing in Developing Countries May Be Beneficial for Access.

When the demand for a drug or vaccine exists primarily in developing countries and products that meet the demand satisfactorily do not yet exist, the primary problem is one of developing a sufficiently profitable market to provide an incentive for the private sector to invest in the discovery and development of the medicine. Absent a profitable market, only governments or non-profit non-governmental organizations (NGOs) are likely to fund the research, manufacturing, development, and clinical testing required to create a new drug; and they have very limited resources to do so.

Patents may provide an incentive for the private sector to invest in drugs for the developing world by aggregating the developing world market into one single market large enough to warrant investment by an exclusive licensee. The success of this strategy relies upon:

- (i) The availability of sufficient resources to buy the product once it is developed: Governments and NGOs may have to step in to supply the money for purchase by the public sectors of the poorer developing countries, particularly if there is no private "travelers' market" from which higher prices can be extracted;
- (ii) Adequate systems for quality control and regulatory approval that assure consistent high-quality products in the absence of first-world regulatory control over the product;
- (iii) Belief that the legal systems of non-manufacturing countries will be strong and consistent enough to allow the supplier to enforce its patent rights; and
- (iv) The willingness of governments and NGOs to accept prices sufficiently high that suppliers can recoup research and development costs.

2. *Licensing Strategies*

Universities and other research institutions have the most control over the use of their inventions at the time of licensing. It is before each invention is licensed that a university can best ensure that the license will be used to advance—or at least not to hinder—efforts to meet the health care needs of developing countries.

The first decision for a university is what kind of license it will grant for the invention. A license may be fully exclusive, exclusive but limited by type of product, exclusive but limited by geographical territory, or nonexclusive. Two extreme cases are illustrative:

- Where the invention is a tool for discovery that does not need significant additional development to be useful, nonexclusive licensing is probably most appropriate for first-world use, while foregoing filing of patents on the same invention in developing countries.⁴
- Where the patent covers the core invention of a potential new drug or vaccine requiring years and tens, if not hundreds, of million

4. Many universities will require their patents not be asserted against other non-profit research institutions, thus allowing free access by such institutions in all countries. The purpose of this is to ensure that research in non-profit institutions is not inhibited.

dollars of investment, an exclusive license may be the best strategy.

The second case—exclusive licensing—puts a major responsibility on the university to negotiate license clauses that ensure both development of the product and its rapid distribution to developing countries at accessible prices. Consciousness of the need to do this is new to the university technology transfer community. Though “best practices” have not yet been established, strategies have evolved from experience (including a few situations that, in retrospect, were clearly mistakes and have become “learning experiences”). Some of these experimental strategies include:

- (i) *Development milestones*: A university may require, as a condition of the company maintaining a license, that the company devote at least a set minimum amount of resources to develop the technology. It may also require certain “success milestones,” e.g., performing clinical trials by a certain date, getting the product on the market by a certain later date, etc. However, success milestones are particularly difficult to negotiate for technology in very early stages, where both the company and the university are conscious of many unpredictable technical hurdles in the product’s development, making it difficult to demand set dates for success;
- (ii) *Requirement of delivery of products for developing countries*: A university may require that the company begin the testing and distribution of products in developing countries simultaneously, or at least within a very short time frame after, introducing them in first-world countries. This is particularly important for vaccines, where the “trickle down theory” has sometimes deprived developing countries of suitable products for decades;
- (iii) *Control over pricing in developing countries*: Prices can be set at a small percentage of cost; and
- (iv) *Compulsory sublicensing*: A university may require that, if the company cannot deliver a product or cannot deliver it at an acceptable price, then it must sublicense the patent to others. Where manufacture of the product is simple, this strategy may work, but where the product requires substantial company knowledge and background technology, the “victory” in forcing a sublicense of the patent alone may be pyrrhic. This is particularly true for complex biological drugs and many vaccines. Thus, the university must negotiate clauses that make sublicensing as attractive as possible to the company so that the company will cooperate fully in the venture. A recent article by

Friedman et al. in *The Lancet* describes such a strategy by the Pharmacia Company.⁵ The company enthusiastically sublicenses its patent, along with its know-how, and exerts a degree of control over the quality of the product. The benefits to the company are primarily reputational, with a justifiable pride in the good that is done. But it is also defensive—protecting the company from criticism it may receive for not meeting the needs of the poor in developing countries.

These are just a few of the strategies that universities and other research institutions may try in their quest to provide access to new medicines in developing countries. Each strategy has been tried to some extent in the past, but all are relatively new and will need refinement in the fire of negotiations between research institutions and companies—along with new approaches that will develop in the future. None will be effective unless both research institutions and companies become more aware of their obligations to help those in developing countries. And none will survive unless they meet the needs of both the research institutions and companies in developing new technologies for human health needs.

5. Michael A. Friedman et al., *Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 *THE LANCET* 341, 344 (2003).