In-Licensing Strategies by Public-Sector Institutions in Developing Countries

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ABSTRACT

In the past, it was possible for some countries to ignore IP (intellectual property) management while pursuing economic development and improved public health. Globalization, however, has brought the world closer and closer together, and with the advent of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), no country can afford to be isolated from the global IP system. This chapter explains how developing countries can use this new system to their advantage through in-licensing technologies (that is, bringing technology into the public sector through patent license agreements). Offering an overview of the usual requirements of a license agreement, the chapter also considers issues that are uniquely relevant to public-sector institutions in developing countries as they negotiate such licenses.

1. INTRODUCTION

Thanks to globalization, the rules governing intellectual property (IP) are changing rapidly. Many countries, such as India, that formerly stood outside the patent system have become fully compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). For developing nations with strong science and technology bases, established pharmaceutical industries, and emerging biotechnology industries, adherence to TRIPS compliance and the ensuing changes have created both challenges and opportunities. Developing countries can produce health products in two ways: first, by licensing technologies developed by public-sector research and development (R&D) institutions to the pharmaceutical industry (including the biotechnology industry in general, which encompasses agricultural applications); and second, by in-licensing technologies from the pharmaceutical industry. While the public sector wants to introduce affordable health products to the marketplace, the biotechnology industry is primarily interested in optimizing its investment returns. But compromises can be made. For example, IP developed by the biotechnology industry can be transferred to the public sector for further development.

In-licensing is a well-recognized strategy for transferring technologies from companies to the public sector. In-licensing allows many parties to manufacture products, thereby creating enough competition to bring down the costs of public health products (like drugs, diagnostics, vaccines and other biologicals) and crops in agriculture. IP licensing is often complex because the parties concerned have conflicting objectives. Furthermore, the biotechnology industry, at least in developing countries, usually is not very eager to work with often-times inefficient and incompetent government officials. In any case, all parties involved in IP licensing need:

- the skill to negotiate a deal
- a strategy for negotiation

Satyanarayana K. 2007. In-Licensing Strategies by Public-Sector Institutions in Developing Countries. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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- practices that protect the interests of the public sector

2. TYPES OF AGREEMENTS

2.1 *General Requirements*

IP transfer agreements must address a number of aspects: confidentiality, material transfer, development (the licensee assumes all responsibility for further development), co-development (two parties collaborate on continued development), and distribution.

Such agreements are at least two-way because more than one public-sector institution can be involved in developing a product. For example, if the Indian Council of Medical Research, New Delhi, (ICMR) were to in-license a technology for developing a vaccine from a private company, there could be at least three parties involved in the agreement: the ICMR, which is the licensee and a public-sector institution; the licensor, which is a private company; and the Ministry of Health & Family Welfare, Government of India, which will fully or partly fund the project, conduct clinical trials, and make the vaccine available to the public. Usually, either the public-sector agency or the private company will provide the first draft of a negotiation agreement.[1] It is important that all the parties, especially the licensee, clearly understand the basic philosophy behind the deal: to provide a product to people who would not have access to it without government support. A good agreement is one that benefits all parties.

Well-drafted agreements should allow government officials to negotiate quickly, get approval from the bureaucracy, as appropriate, and come to a consensus. Since it takes several years to bring a product from the laboratory bench to the patient's bedside, mutual trust is very important during the negotiations and implementation of the project, especially if some renegotiation is needed partway through. Court battles are messy, expensive, and generally unwelcome, especially if they involve a foreign party.

Parties intending to enter a long-term working relationship with each other may either sign a series of agreements, one omnibus comprehensive agreement (with smaller specific agreements attached), or one broad, general agreement with two or more related, but separate, specific agreements. The following sections describe the kinds of agreements that can be signed by two parties engaged in jointly developing a product. The appendices provide examples of agreements that might be used by public-sector organizations.

2.2 *Confidentiality agreements*

The development of a proprietary health product usually involves the use of confidential information: research data, sources of materials, methods of production, designs of specialized proprietary equipment, and other nonscientific business information. The involved parties should therefore enter into a confidentiality/nondisclosure agreement. Such an agreement not only protects commercially useful information but also indicates the value of that information. Such agreements allow all parties to exchange sensitive information confidently.

2.3 *Materials transfer agreement*

A materials transfer agreement is drawn up whenever a potential licensee wants to evaluate a new product or process. The licensor should be willing to provide samples or information but, naturally, will want to assure that the other party does not misuse them (such as by passing on a portion of a sample to some third party or using it to generate additional material for unlicensed use). The Center for the Management of Intellectual Property in Health Research and Development (MIHR) recommends that public sector research organizations use the Uniform Biological Materials Transfer Agreement and the implementing-letter format developed by the U.S. National Institutes of Health (NIH). The wording of the agreement is uniform for all IP transfers, with only the Implementing Letter specifically tailored to each transfer.

2.4 *Co-development through collaboration*

Even after acquiring new IP from a private company, it is not always possible or feasible for a

single public sector agency to carry out all stages of production and marketing. The agency may, for example, need to collaborate with other public sector laboratories in order to complete product evaluation (preclinical toxicity tests, clinical trials, and so on). Also, high-quality, good manufacturing practice (GMP) production facilities, which most public sector research organizations lack, are needed to develop products for the market. The licensee can either pay other agencies to perform some of the tasks, or, preferably, form partnerships with them. Collaborating agencies may request a share of the IP rights or a portion of the revenue generated by product sales. It is possible that the final stages of product development will require new IP.

Requests for collaboration often take the form of open tenders. In the absence of established procedures (since technology commercialization by the public sector is still an emerging area), various means have been adopted by the public sector—primarily to "protect" the public sector institution from the unlikely event of a commercial blunder—most government departments resort to what is called a "committee approach" through which a group of officials, including tech transfer professionals, administrators, finance people, and so forth, work in a transparent manner to negotiate a deal. Public communication is important because the government that is funding the initiative will expect the deal to be performed with complete transparency. Furthermore, transparency reassures partners and investors.

2.5 *Technology licensing agreement*

Technology licensing agreements allow one party to use the proprietary materials or know-how of other parties. Standard technology licensing agreements clearly define the period of time for which the license is valid, the kind of license (exclusive or nonexclusive), the territory in which the license is valid, the market in which the product will be released (public sector or open market), whether or not the product can be sublicensed, the amount of money to be paid up front, and the royalties that the licensor will receive.

2.6 *Standard elements of typical agreements*

2.6.1 *Confidentiality*

A confidentiality agreement requires all information to be carefully protected. Access to confidential information should be given only to the proven trustworthy, as improper use of confidential material can seriously erode mutual confidence between partners and even lead to litigation. Scientists, especially those in the public sector, should be especially careful because they, in other contexts, discuss science openly.

2.6.2 *Territorial exclusivity*

In a licensing agreement, the territory is the geographic region in which the licensee is permitted to sell the product. The territory could be part of a country, part of a subcontinent, several countries, or the whole world;[2] or, alternately, territory can refer to a segment of the market in a single company like public sector or private sale. Sometimes, nonexclusive licenses are awarded to licensees in order to promote competition between them. Or an exclusive license may be granted to market an expensive product within a limited market—unless such market exclusivity is guaranteed, no one may be willing to manufacture it. Commissioning a professional agency to carry out market research in order to make sure that the product is correctly priced and appropriate for the intended territory is always advisable. (Commissioning such surveys is slowly becoming routine practice due to a lack of in-house expertise and the system of government regulations.) The guiding principle for deciding whether to grant exclusive licenses of nonexclusive licenses should be that while it is most important to bring new products to market at affordable prices.

2.6.3 *Product liability*

Health-related products can lead to liabilities; especially susceptible products, such as vaccines, are tested on healthy volunteers. Often, companies are unwilling to market a product because of potential liabilities. The licensing agreement for a health-related technology must define the cases in which the investigators will, and will not, be held responsible (for example, such cases might

involve bad or inferior product, improper storage and use, administration of the wrong dosage) and the licensee must take out an appropriate amount of insurance before starting trials. The clinical trial agreement should also describe how, and how much, an individual who is harmed by a health product should be compensated.

2.6.4 *Up-front fees and royalties*

Ultimately, marketability and price decide a product's fate. The licensor must decide the kind and number of licenses, how much market access, and so on, it will grant. The parties must agree on how much money the licensor will receive both up front and via royalties. These decisions will be influenced by the amount of revenue the product is expected to generate. A committee of experts, administrators, and financial advisors usually negotiates on behalf of public-sector institutions. A balance must be struck between the desires of the licensee (to pay less up front and more through royalties) and those of the licensor (to receive as much money as possible at the beginning). Factors that affect the price of the license include the expected life of the product, the duration of IP rights, the existence of a competing product, purchasing capacity, and whether or not there is a committed market (in other words, governments offering purchase commitments), and so on.

2.6.5 *Arbitration*

The licensing agreement must stipulate the terms of arbitration in case something goes wrong and there is disagreement between parties. Arbitration procedures can be relatively simple if the parties are in the same country. If governments are involved in such arbitration proceedings, such governments will often dictate the outcome. Arbitration becomes very complex when parties from different countries are involved, especially if the arbitration is conducted in a third country. Of course, all efforts should be made to settle issues amicably.

3. CONCLUSIONS AND RECOMMENDATIONS

In developing countries, it is important for the pharmaceutical industry, in general, and the biotechnology industry, in particular, to develop products (drugs, diagnostics, and vaccines) with a potential global market. This reorientation from an exclusive concentration on markets in developed countries to a product development plan that includes developing countries can be achieved through partnerships between the public and private sectors in both developed and developing countries.

Most developing countries do not have the expertise to deal with complex IP licensing issues. Public officials in developing countries often postpone making decisions in order to cover up their ignorance and lack of expertise, thereby discouraging private companies that might be interested in collaboration with them. Professional help in all areas, from product valuation to drafting IP agreements, would be useful. The following drivers are needed for developing countries to optimize their success:

- **a business strategy** that aims to balance the objectives of the public sector (to bring affordable health products to market) with those of the private sector (making profits)
- **a marketing strategy** that prices products realistically, using up-to-date marketing information (any existing products, their price structure, potential customers, the size of the potential market in private and public sectors, and so on)
- **the proper legal expertise** is usually already locally available, as many legal firms in developing countries are familiar with basic licensing procedures. Marketing and scientific experts could assist in valuating patents

Perhaps the ideal solution to the lack of know-how in developing countries is two fold: first, the establishment of a national technology transfer office; and second, the development of core team of experts drawn from diverse disciplines devoted to helping to negotiate product in-licensing. ■

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1 Some argue that in general, the public sector organization should offer the first draft of a licensing agreement. (See for example, in this *Handbook*, chapter 12.1 by RT Mahoney.) This approach is generally much easier than trying to work from a draft prepared by the private sector organization, because the draft needs to cover a number of topics of particular concern to public sector organizations, and these topics probably would not be addressed in a private sector organization's draft.

2 In India, as perhaps in other poor countries, there are states, or equivalent entities, that are rich, and politically stable, with promising markets, while other states—often those with unstable governments—have uncertain market potential. Currently, each state in India has its own drug regulator. These officials have varying expertise and, along with other factors, can determine the marketability of products in their states. Additionally, while a price can be the same over the entire country, each state has its own rates for sales tax and other taxes.