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Generic Drugs, Compulsory Licensing, and other Intellectual Property
Tools for Improving Access to Medicine

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Generic Drugs, Compulsory Licensing, and other Intellectual Property Tools for Improving Access to Medicine

Introduction

This presentation suggests how intellectual property laws and practices can help improve access to medicine for people in developing countries. The intent is to provide a pragmatic context and concrete steps for achieving this important goal.

Three requirements for success become apparent from this analysis, all supporting negotiated approaches. First, improved access requires input from intellectual property professionals (lawyers, patent agents, and technology transfer specialists) who can determine the extent to which patents and other intellectual property rights pose a legal obstacle to obtaining access to the medicines, for particular drugs, on a case-by-case basis, in individual countries and for enterprises within such countries. Such IP professionals can find ways of removing IP obstacles, including negotiating patent licenses.

Second, developing countries need to make available national-level intellectual property tools such as compulsory licensing to help provide leverage in negotiations over patents and trademarks affecting important drugs. Such IP tools are consistent with TRIPS but are the subject of debate in the WTO, and further in many cases still need to be implemented through national legislation and establishment of a regulatory framework.

Finally, to actually make any particular medicine available in a given country, the drug must be supplied by a manufacturer, who may be either (a) an original innovator, (b) a foreign generic manufacturer (e.g. through parallel imports), or (c) a domestic manufacturer. Developing countries should consider the latter approach as a desirable way to achieve technology transfer and capacity building in the country, because the experience gained in the local generic manufacturing and distribution may in turn support the growth of relevant technologies in the country, with the many benefits that domestic production brings.

Common goals

To provide a pragmatic context, we need to detail the subsidiary, specific goals that fall within the larger objective of improving access to medicine for poor people. These specific goals include:

- Expand access to drugs for all who need them
- Promote basic research, applied research, and development, with exclusive rights as incentives
- Facilitate commercialization
- Provide a framework for deal-making
- Ensure safety and efficacy
- Hasten transition for generic competition for each drug at end of patent term

Most of these goals have been voiced by the WTO and the WHO. Some of the goals are more controversial than others. WTO Director General Mike Moore believes the TRIPS Agreement can serve such goals by finding an appropriate balance between promoting disclosure, providing incentives for R&D through exclusive rights, setting out limitations and exceptions to such rights, and allowing transition provisions for implementation.¹ Also, a joint report from the WHO and WTO on the Workshop on Differential Pricing and Financing of Essential Drugs, April 8-11, Høsbjør, Norway (available at www.wto.org) refers to discussions about the role of voluntary and where necessary compulsory licensing, and the need to stimulate research into neglected diseases of the poor.

The practical approach

The most effective approach to achieving these goals has the following characteristics. First, it must be pragmatic. There are many theories and political positions in discussion, but this author believes that the most satisfactory results may be achieved by focusing on specific situations and problems and trying to find specific steps to solve them. Successes in turn can inform the theoretical and political debates.

Second, an effective approach should use available strategies for managing and dealing with IP, and patents in particular, including implementing legislation and regulation about IP, and evaluating, protecting, attacking, and licensing patents. Third, pragmatism requires working within the existing international system (TRIPS, Paris

¹ Mike Moore, "Yes, Drugs for the Poor – and Patents as Well", International Herald Tribune, Feb. 22, 2001, available at www.wto.org/english/news_e/news01_e?tn_dg_iht_feb2001_e.htm.

Convention, WIPO), not rebuilding the system. That said, pragmatism does not negate the possibility of reform. But reform and development should look to existing national legislation and arrangements for examples.

Two areas of legislative and regulatory activity found in almost every country will be discussed below in more detail. These are IP (in particular subject to national Patent Offices and judiciary) and drug regulation (through a Food and Drug Administration or Ministry of Health). Although the author’s experiences are skewed toward the situation in the United States, a pragmatic approach will be just as effective using examples from other countries.

From idea to patient – the life cycle of a drug

Several figures help illustrate the context in which ideas, effort and money become drugs, and those drugs become available to patients. These figures can help the reader begin to identify paths for improving access to medicine in developing countries.

Figure 1 is a schematic flow chart showing how various actors (A, B, C, and D) add value to an initial biological resource or idea and bring it forward to market. “A” may for example be a collector of plant material. ”B” may be a researcher who extracts and identifies a compound having anti-cancer activity. “C” may be a company that discovers how to synthesize the compound and conducts clinical trials leading to marketing approval, and “D” is the end-consumer, the patient.

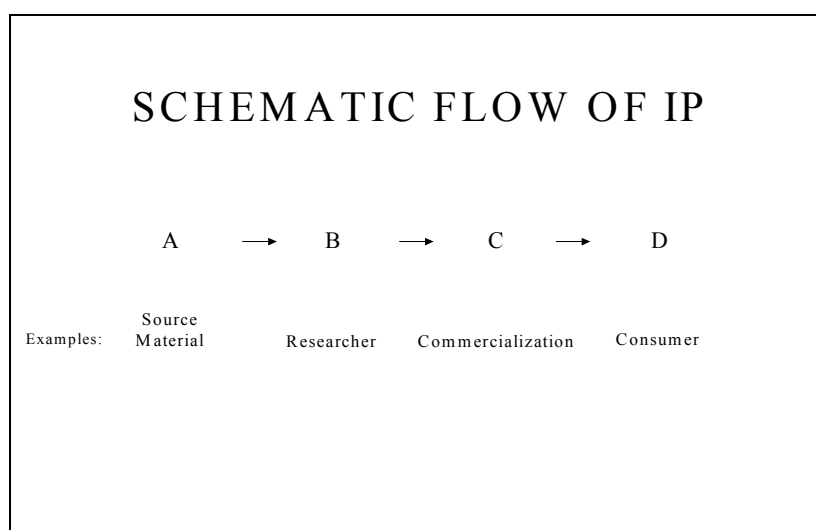


Figure 1

Figure 2 shows a more detailed flow chart of the life cycle for a particular drug. On the left side, many inputs are necessary for the basic research that supports the conception of a new drug. This explains why some countries are more successful than others in discovering new drugs. There are four basic phases to the life cycle: research, development, patentee commercialization, and generic commercialization. At any given time, all drugs under investigation or on the market may be categorized as falling within one of these categories in any given country.

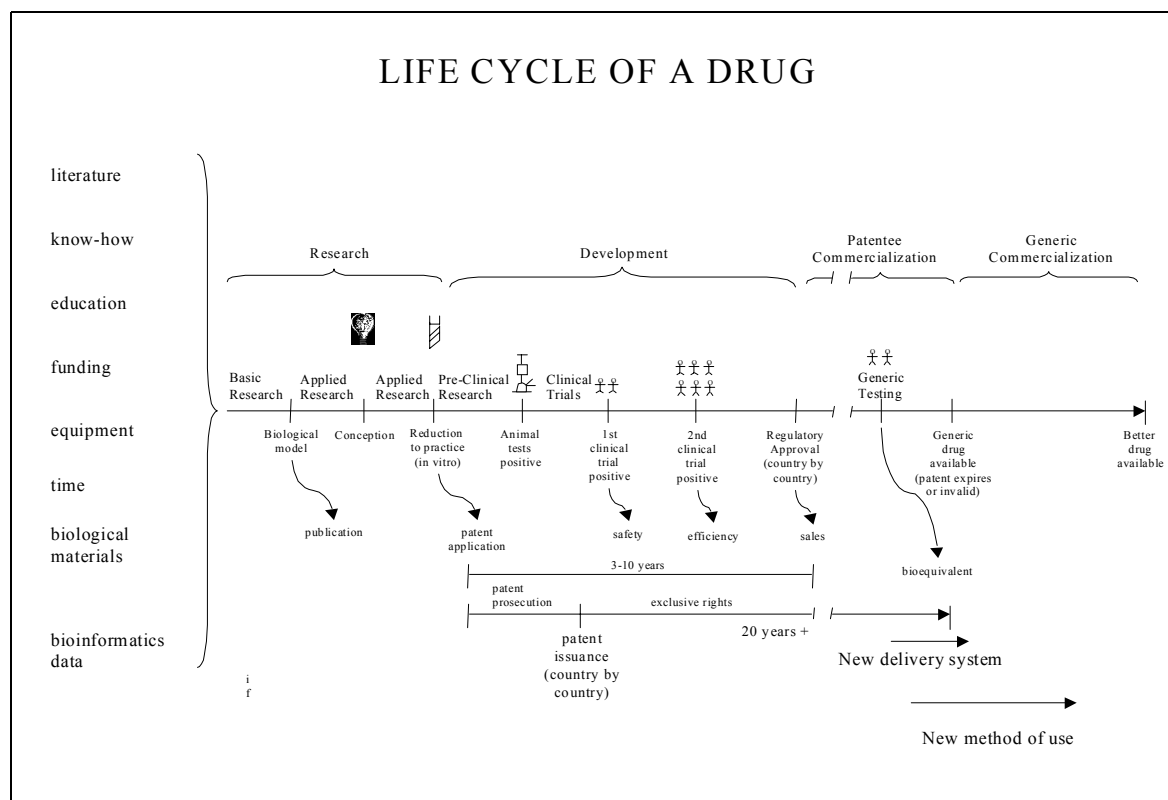


Figure 2

During the drug research phase, typically an invention is made and a patent application is filed, as shown beneath the main time line. At this point, we may refer to the development phase, typically involving pre-clinical and clinical trials with oversight of the Food and Drug Administration or equivalent in various countries.

Once market approval is given to the innovator (patentee) in any given country, the first commercialization phase begins. When the innovator’s patent expires in any given country, the generic companies may step in and begin generic commercialization at dramatically lower prices. To ensure that generic products are ready at the time the patent expires, during the patentee commercialization phase, generic companies may begin to test their own versions of the drug (under the so-called Bolar amendment provisions in the United States, Canada, and some other countries). This patentee-generic transition typifies the United States system. Other countries do not support the hand-off to generic companies as extensively as the US.

There are several meanings of the term “generic” in the context of drugs. A common definition is the sale of a drug without the brand name of the innovator, i.e. the first company to develop and market the drug. Here, “generic production” means manufacturing and distribution by a company that did not invent the drug, but has learned how to make it.

At the lower right of Figure 2, two arrows indicate strategies taken by innovators to extend the term of their commercialization under patent. For example, the innovator may provide a new delivery system (e.g. extended release capsule) or a new method of use (e.g. use of an antibiotic to control malaria). It is crucial to keep in mind that such improvement patents do NOT extend the life of the original patent. Thus, upon

expiration of the original patent, competitors may make the old product – just not the new extended release form, or the antibiotic packaged and targeted to malaria.

Finally, we can say the life cycle of a drug ends when a superior product enters the market. In reality, most old drugs (such as aspirin and sulfa drugs) remain on the market, but they may become more marginal as successor drugs supplant their dominant position.

Figure 3 illustrates the various groups that together constitute the pharmaceutical “ecosystem” and how these groups are positioned with respect to the life cycle of a drug. Figure 3 shows the actors grouped approximately in the order in which they interact with the development pathway of a drug from idea to patient. Some of these actors are:

- inventors
- research institutions
- corporations
- funders (investors, insurers, donors)
- regulators in various countries (PTO, FDA)
- doctors
- patients.

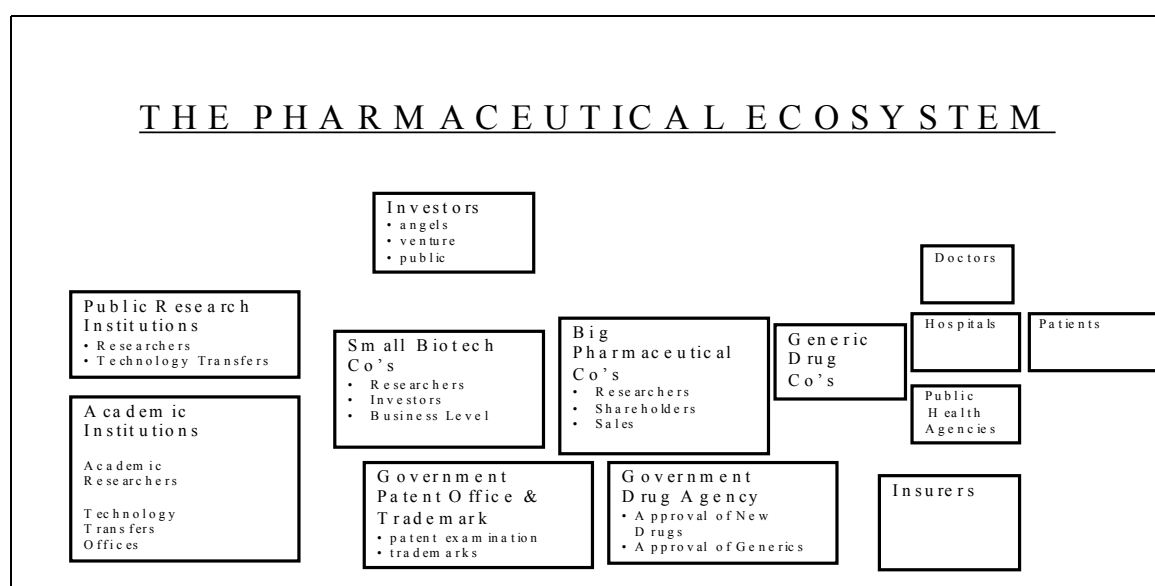


Figure 3

The IP decision tree for access to drugs

Intellectual property plays an important role in the path to delivery of drugs to patients in poor countries. This role may be depicted as a decision tree. See Figure 4. This IP decision tree identifies the individual decisions that should be made, and the order to make them, in the effort to produce and market a particular drug in a given country, consistent with law, to reach a reasonable negotiated arrangement, and to minimize the need for dispute resolution in the national courts.

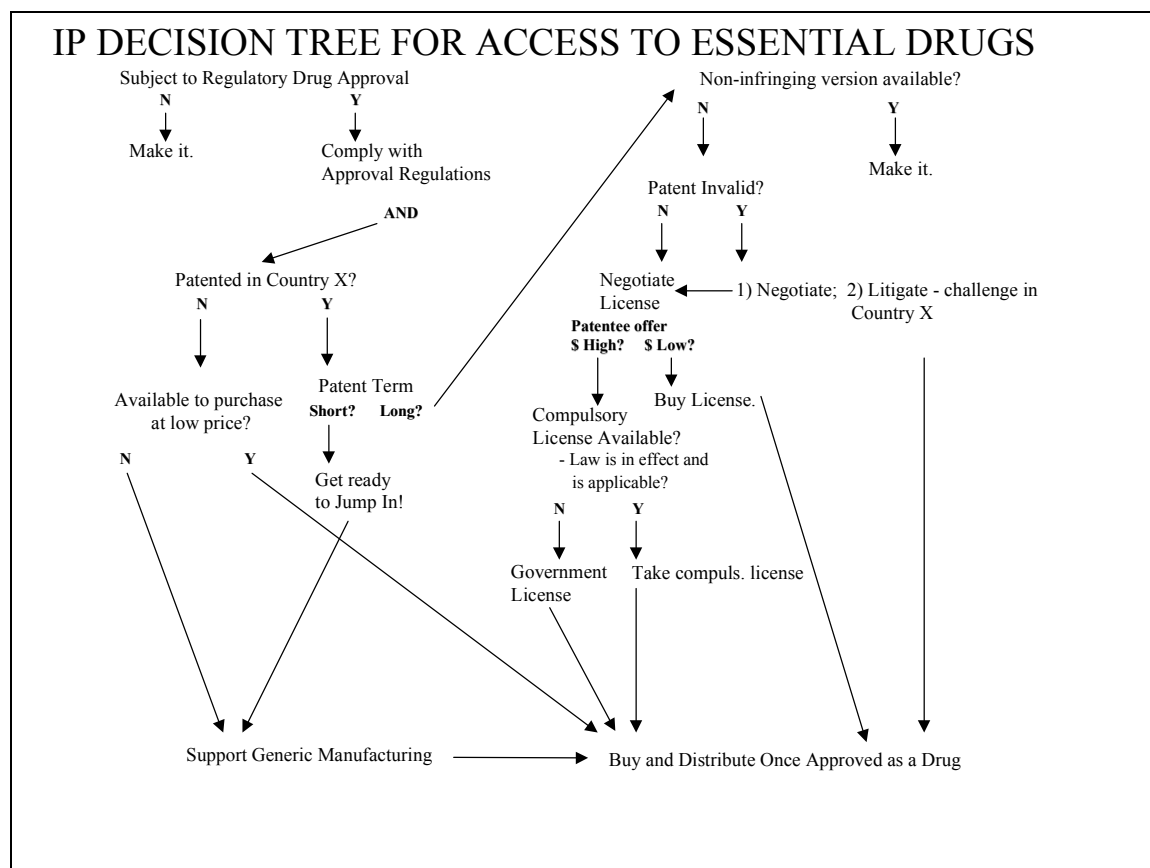


Figure 4

Many different scenarios can result from following through such a decision-making process. For example: a) the patent holder may sell the medicine at reduced price; (b) the patentee may agree to grant a non-exclusive license to an enterprise in the country, for free or in exchange for negotiated royalties, (c) the patentee may be required to grant a compulsory license by the country in exchange for established royalties; (d) the patentee may waive its rights.²

Other options arise where there is no relevant patent in the country, or the patent expires, leaving the field open for generic production. Figure 4 shows how these different options may be explored in a logical fashion to reach a desirable result – that the drug can be bought and distributed – in any given patent scenario.

Clearly it requires professional expertise to navigate this decision tree. Intellectual property professionals are those who are trained and experienced in evaluating patents and negotiations about them. These IP professionals include lawyers, patent agents, and technology transfer specialists. They can determine the extent to which a patent or other intellectual property rights block access to a particular important medicine, in a particular country, and they can find, on a case-by-case basis, ways of removing IP obstacles, including negotiating patent licenses. Perhaps even more importantly, they

² . “More equitable pricing for essential drugs: What do we mean and what are the issues?” Background paper of the WHO-WTO secretariat WTO on the Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, April 8-11, 2001, p. 21.

can determine whether, for a given drug in a given country, there is any patent to worry about at all. Clearly where the answer is “No” the path to market is easier. One should not underestimate the problems of bringing even non-patented drugs to market, however.³

Figure 4 also provides a practical context for discussions about the significance of compulsory licensing of private parties and government agencies, differential pricing, and parallel imports. That is, the existence of legislation in a country permitting compulsory licensing provides an important option and perhaps in some cases the only path to having a drug on the market. But more practically, the existence of legislation permitting compulsory licensing serves as leverage and provides bargaining power when negotiating a voluntary license with a drug manufacturer. Thus, developing countries need to make available national-level intellectual property tools such as compulsory licensing to help provide leverage in negotiations over patents and trademarks affecting important drugs. Such IP tools are consistent with TRIPS but are the subject of debate in the WTO, and further in many cases still need to be implemented through national legislation and establishment of a regulatory framework.

There are many pathways to market, but they are limited. That is, to actually make any particular medicine available in a given country, the drug must be supplied by a manufacturer. The manufacturer will be either (a) an original innovator, (b) a foreign generic manufacturer (e.g. through parallel imports), or (c) a domestic manufacturer. Developing countries should consider the latter approach as a desirable way to achieve technology transfer and capacity building in the country, because the experience gained in the local generic manufacturing and distribution may in turn support the growth of relevant technologies in the country, with the many benefits that brings.

Differential pricing

To address the problem of access to medicine in poor countries, it is clearly necessary to address the pricing of the medicines, and this has led to discussion of “differential pricing,” meaning that drugs are less expensive in poorer countries, and more expensive in richer ones. Many different approaches to bring prices down are currently underway, in connection with HIV/AIDS, malaria, tuberculosis, and vaccines. For example, a generic company (Cipla) offered to provide triple therapy to HIV/AIDS patients for less than \$600 per year, and an innovator company reduced its prices even lower than that.⁴

Extended discussion of differential pricing is beyond the scope of this note. However, it is clear that price is a highly negotiable and negotiated term in any transaction, whether between private enterprises or between a private company and a government regulator. As a negotiated term, pricing is subject to bargaining power, and the more bargaining power that poor countries have, the lower a price they will be able to negotiate. Accordingly, the suggestions made here (presence of IP advocates,

³ Ibid.

⁴ Further examples and summaries of case studies are provided in “More equitable pricing for essential drugs: What do we mean and what are the issues?” (Ibid).

availability of compulsory licensing, and expansion of generic manufacturing) can all help bring down the price of drugs in poor countries.

National legislation to implement compulsory licensing under TRIPS

A final topic to address is what exceptions to patent exclusivity are consistent with TRIPS, and what basic compulsory license provisions may be established in domestic law.

TRIPS Article 30 permits members to provide limited exceptions to patent exclusivity so long as they do not unreasonably conflict with normal exploitation of a patent. Carlos Correa recommends the following exceptions for implementation by developing countries:⁵

- experiments made for the purpose of seeking regulatory approval for marketing of a drug after the expiration of a patent;
- use of the invention by a third party that had used it before the patent application filing date.
- use of the invention for teaching purposes;
- use of the invention in non-commercial acts
- use of the invention for scientific research;
- experimentation on the invention for commercial purposes, for instance to test it or improve on it;
- preparation of medicines under individual prescriptions.

The first three exceptions are common and found in many countries. The remaining four suggestions are more controversial.

TRIPS Article 31 permits member states to provide compulsory patent licenses so long as certain criteria are met. In sum, compulsory license legislation must require:

- Case-by-case evaluation and decision
- Prior request to the patentee for a voluntary license
- Determination of scope and duration of the compulsory licence
- Non-exclusivity of the license
- Non-assignability
- Preference for the domestic market (may limit exports/parallel imports to other country)
- Remuneration to the patentee
- Possibility of requesting the revision of decisions (on validity and remuneration) and the revocation of the license.

Correa recommends the following particular examples of circumstances when compulsory licenses may be granted:

- when the patentee has rejected or not replied to, within 150 days, a request for a voluntary license under reasonable commercial terms and conditions;

⁵ Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed 2000), p. 241.

- in cases of emergency;
- when required by public health;
- when required for security reasons;
- when necessary for environmental reasons, such as to preserve plants or animals or avoid prejudice to the environment;
- as a remedy against anti-competitive practices such as abusive pricing;
- when required for a public non-commercial use;
- when required to use a dependent patent, provided that it involves an important technical advance of considerable economic significance;
- lack or insufficiency of local working of the patent when necessary to promote a sector or vital interest to socioeconomic or technological development.

(Correa, p. 241). Many countries have compulsory licensing laws, including the United States. As noted above, even though compulsory licensing laws are rarely invoked, their mere presence on the law books can exert leverage on behalf of the government of a developing country or enterprises within the country in their dealings with a multinational pharmaceutical company.

Conclusion

Developing countries and enterprises within them should look at several practical actions that will help them gain access to medicines. These actions (as outlined in Fig. 4) can ensure a successful pathway to putting a drug on the market. A common thread for these actions is that they require the services of IP professionals. Unfortunately there are very few IP professionals in developing countries. Therefore, there is a need for a non-profit organization or program to deliver IP services to organizations and agencies who need it in the public interest. Such an organization should provide training and resources to IP professionals around the world and serve as a referral service for clients seeking IP representation in the public interest.