
Sustainable Innovation for Public Health

by Michael A. Gollin

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It is a central dogma of intellectual property law that patents improve public health by promoting innovation in medicine, but this view has been challenged and tested repeatedly this year. Four times -- in South Africa and Brazil over AIDS drugs, and in the United States and Canada over Bayer's Cipro as a treatment for bio-terrorist anthrax -- a national government facing a public health crisis threatened to override a foreign company's drug patent by using a compulsory license to make or buy a generic version of the patented drug. In response, the patent holders took legal action, or threatened to, but then made concessions to convince the government to stick with the patented product. Now, drug patents have taken center stage at the WTO meeting in Doha, Qatar in November 2001, pitting poor against rich countries, and populists like Doctors Without Borders against pharmaceutical industry associations.

The Desire For Health, Today and Tomorrow

Two fundamental human desires are at the heart of the conflict over whether governments should override drug patents to meet public health needs. The first -- sick people want the best medicine they can get, now. This urge finds expression in the populist argument that patents keep the cost of medicine too high for poor patients, and should be weakened. As the four cases this year show, drug companies have found it hard to win an argument of 'patients vs. patents' particularly when dealing with a single patented drug in the face of a public health crisis. The populist goal is to expand governments' right to avoid patents by granting compulsory licenses and importing generic drugs in order to protect public health.

The second fundamental desire is that people want new and better medicines in the future. The drug industry argues that weakening patents will reduce research, development, and improvements in health care, in effect robbing improvements from future patients, and will postpone the promise of genomics and proteomics. This is a fundamentally economic argument, which is lost on people who tend to discount future interests when balanced against urgent current needs. Those of us who work with drug patents know

anecdotally that patents do inspire innovation and investment in many cases. However, the theoretical and empirical evidence assembled by scholars such as Keith Maskus, Carlos Prima Braga, Carlos Correa, and Jayashree Watal sheds little light on the central practical issue -- what is the **optimum** strength of drug patents? Further, industry's pro-innovation argument has become hostage to larger North-South power politics over distribution of wealth and technology, making it hard to forge a productive resolution of the populist-industry standoff.

Sustainable Innovation

A good beginning toward resolving this conflict would be to shift the discussion to address issues of intergenerational and international equity: The intergenerational issue: how do we balance the needs of today's patients for today's medicine with the needs of future patients to have new medicine? This balance may be referred to as "sustainable innovation," borrowing from the concept of sustainable development.

The international issue: how can we balance the needs of patients in rich countries with those of poor countries? Patients in poor countries are at a terrible disadvantage because of low purchasing power for current drugs, lack of incentive for development of drugs for their worst public health problems (e.g. malaria, tuberculosis, leishmaniasis), and the absence of intellectual property expertise, which is concentrated almost entirely in the rich countries.

The legalities, politics, and economics of sustainable innovation and international equity are far too complex to address in this brief space. However, the many compulsory licensing disputes this year suggest a practical approach that may help address the fundamental needs and equities of all. In these disputes, government actors invoked legal provisions allowing them to override specific patents they saw as obstacles to obtaining adequate supplies of drugs at acceptable prices. A mutually acceptable resolution was reached in each case, working within existing legal frameworks to achieve the goal of public health.

One lesson from these cases is that, whether or not intellectual property treaties, laws, and economics are biased toward rich over poor countries, and whether and however they may be reformed, governments facing a public health crisis should be empowered to make the best of the situation -- today, as laws exist, and tomorrow, as they may be reformed. That is, good intellectual property management skills and understanding of how to apply the laws should universally be viewed in a positive light, even if the laws are perceived as "negative" within poor countries, and even if the outcomes pressure patent holders against their wishes.

How IP management can promote sustainable innovation

How can intellectual property management help find the right balance between access to existing medicines today and development of new medicines in the future, between access in rich countries and poor countries, and between patent holders and generic companies around the world? The first step is to develop an understanding of intellectual property management in health and expand it to the poorer nations and those struggling to improve access to medicines. Second, patent holders, generic companies, and public agencies, in rich and poor countries, need to deploy such expertise in practical, creative ways to maximize access today while ensuring creative advances continue into the future.

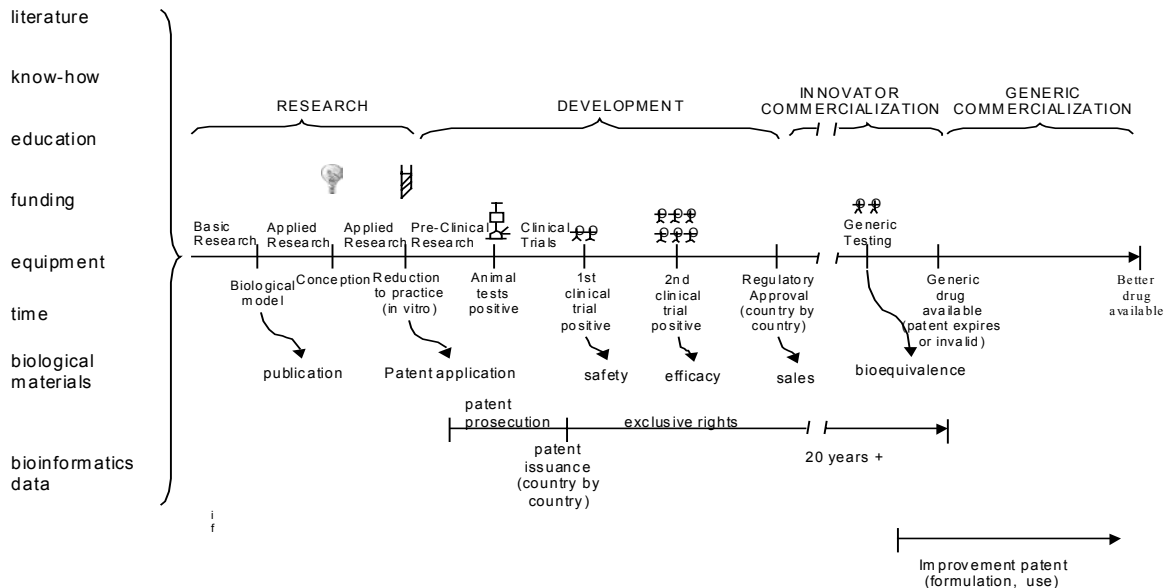
Figure 1 shows the inputs and four basic phases of the life cycle for a drug. Intellectual property management issues permeate each phase and define the relationships between the many players. Many inputs (left side) are necessary for the basic research that leads to a new drug. Rich countries are more successful in discovering new drugs largely because they have better inputs.

In the past decade, poor countries, especially in the tropics, have increasingly asserted that their plant extracts, genetic material, and traditional knowledge are critical inputs into the research enterprise, and deserve reward. While biologists, economists, anthropologists, and environmentalists debate the significance of such contributions, there is no doubt that in some cases the contributions are significant and justify a share of the resulting benefits, as in biodiversity prospecting agreements by companies such as Diversa Corporation.

During the research phase, a public or private research institution or corporation makes an invention and a patent application is filed to preserve rights. The patent issues several years later and gives exclusive rights for 20 years more or less. Improvement patents may follow (lower right). Meanwhile, in the development phase, a corporation conducts pre-clinical and clinical testing, under license if needed.

The innovator commercialization phase begins when the patent holder (or licensee) receives market approval in at least one country. This is the moment investors count on, when one out of many investments becomes profitable, and the investor

INNOVATION LIFE CYCLE OF A DRUG



is able to recoup a return on the investment that supported the research and development. Doctors, hospitals, patients, public health agencies, and insurers become involved in the pricing and commercialization of the product.

The generic commercialization phase begins when the innovator's patent expires in any given country, and generic companies step in and sell at dramatically lower prices. In a country where the drug is not patented, generic commercialisation can begin immediately, even before commercialisation by the patent holder. For example, many AIDS drugs are not patented in many African countries. A growing international generic drug industry can supply such drugs.

Mobilizing IP expertise for developing countries

Intellectual property is a thread running from research to delivery of drugs to patients. Without patents, research and development would be reduced. Without the generic transition, access to medicine would be impaired. The international patchwork of patent laws defines the balance between these interests, and professionals are accustomed to applying these laws in a methodical fashion to determine whether a client can legally make, sell, or use an approved drug in a given country, and how to pursue or block such actions.

Intellectual property professionals include patent lawyers and agents, and technology transfer specialists

such as scientists, doctors, and business people who have become literate with the basic concepts and strategies of intellectual property. Unfortunately there are very few such professionals in developing countries. This imbalance could be corrected by mobilizing IP professionals from developed countries to address issues of access to medicine for the poor, by training new professionals in poor countries, and by providing resources and referral services.

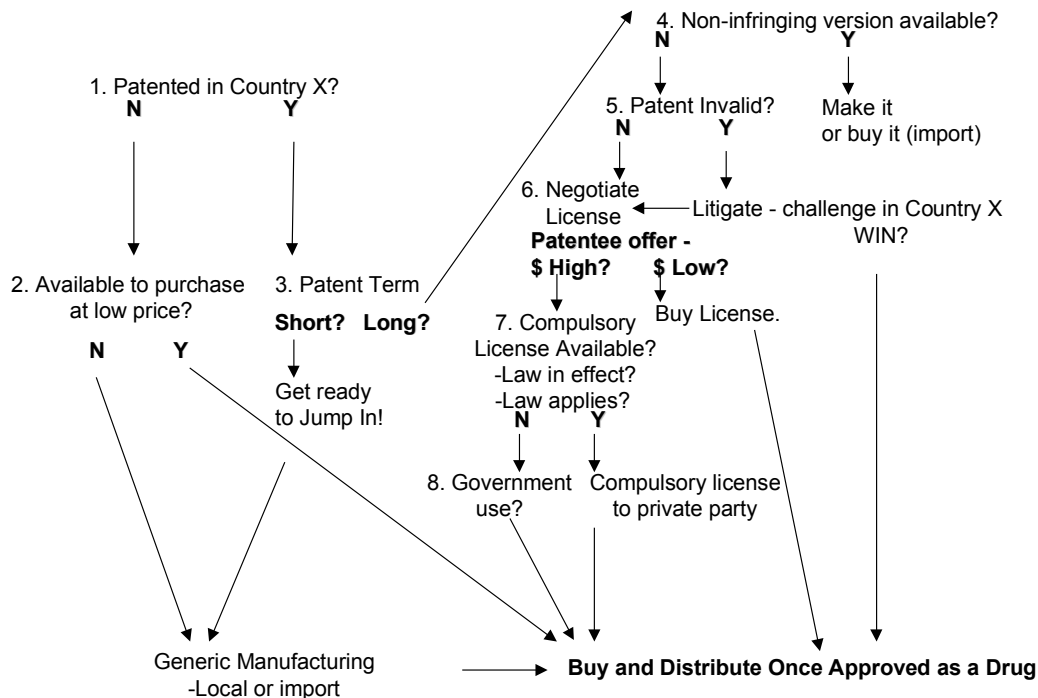
IP professionals can follow the decision tree of Figure 2, which identifies the questions to be asked to be able to produce and/or market a particular drug in country X, consistent with law, via principled negotiation, and minimizing the need for dispute resolution in national or international courts.

The questions:

Is the drug patented in country X? If not, then the country can support domestic generic manufacturing, or import the drug from a foreign generic company (consistent with parallel import restrictions).

Will the patent owner sell the drug for an acceptably low price? If so, purchasing from the innovator ends the analysis. Many of the following steps can result in leverage that can be brought back to a price negotiation.

IP DECISION TREE FOR ACCESS TO ESSENTIAL DRUGS



Will the patent expire soon (e.g. within one year)? If so, it may be best to wait for patent expiration and then proceed with the generic route as above.

If the patent has years to go, how narrow is it, that is, are non-infringing alternatives available? For example, penicillin and doxycycline may substitute for Cipro.

If no alternatives are available, is the patent invalid, i.e. the patent office erred in granting it? If so, one can challenge the patent in court, as with generic companies seeking to sell ciprofloxacin in the US.

Will the patentee agree to license a generic manufacturer at a reasonable royalty?

If no voluntary license is available, does the country permit compulsory licensing, and have the conditions for a compulsory license been satisfied?

If no compulsory license is available, can the country simply purchase or manufacture the product itself under its sovereign immunity from suit by private parties?

Looking from the innovator's perspective, that of avoiding competition and maximizing profit, parallel questions arise.

What patents cover the drug? These may include the active compound, the formulation, the use of the drug, methods of manufacture, and so on.

In what countries are the patents in effect?

1. Are the patents strong, or might they be ruled invalid?

Is there any benefit to licensing a competitor?

What leverage does the competitor have, e.g. via compulsory licenses?

Is there social or other benefit in waiving enforcement of the patents?

The possible outcomes from this decision-making process include: a) the patent holder sells the medicine at reduced price; (b) the patentee grants a non-exclusive license to an enterprise in the country, for free or in exchange for negotiated royalties, (c) the patentee is required to grant a compulsory license by the country in exchange for established royalties; (d) the patentee waives its rights; (e) there is no patent or the patent expires, leaving the field open for generic production. In all the possible outcomes, different options are explored in a logical fashion to reach a desirable result - the drug reaches patients in country X.

Although a pessimist might believe patent holders would oppose better advice to developing countries, to the contrary, industry representatives are aware that in general disputes are more easily resolved and deals are more easily reached when both sides have competent counsel.

Creative management of intellectual property may satisfy public health urgencies while protecting profit and permitting continued innovation. For example, with good counsel on all sides, the drug industry can increase support for research and development of medicines for neglected diseases, increase technology transfer to the growing number of public-private partnerships for

public health, support local manufacturing, and develop new effective distribution relationships in poorer countries. Such measures would promote the goals of sustainable innovation and international equity.

Compulsory Licensing is Here to Stay

Most countries have compulsory licensing laws. (In the United States, see 28 U.S.C. § 1498.) These laws are typically complex, and rarely invoked, but their mere presence on the law books provides bargaining power for governments negotiating with a drug manufacturer, and may provide the only path to having a drug on the market. And whatever the outcome of the current WTO meetings, compulsory licensing is here to stay as a tool of intellectual property management for public health.

The Trade Related Aspects of Intellectual Property (TRIPS) Agreement expressly permits compulsory licensing. TRIPS Article 30 allows member countries to provide limited exceptions to patent exclusivity. Examples in the United States include Bolar amendment use for purposes of regulatory approval, and surgical methods.

TRIPS Article 31 sets forth certain prerequisites for compulsory licensing: case-by-case evaluation; a prior request to the patentee for a voluntary license; reasonable payment to the patentee; non-exclusivity, non-assignability; and predominant manufacture for the domestic market (not for export). Some circumstances when compulsory licenses might be granted include a national emergency, national security, requirements of public health, and public non-commercial use. All these circumstances arguably apply both to treating AIDS patients in poor countries, and in responding to bio-terrorism in the US.

Conclusion

Once countries gain practical experience, today, with specific matters, they will be able to decide what their interests really are in legal/political reform, and one can hope that seemingly intractable disputes will dissolve into practical resolutions. So providing case-by-case assistance in practical skills and legal analysis could reach reasonable outcomes today, and have a positive impact on political/legal reform. A key obstacle to achieving this goal is the availability of expertise in intellectual property management in most poor countries. This obstacle can be removed by mobilizing the expertise needed to help poor countries use available legal tools to work within the patent system to promote public health, today and in the future.

The key to achieving sustainable innovation is to provide fair access to medicine without destroying the advantages of intellectual property in promoting innovation and diffusion of technology. Achieving and maintaining such a balance -- between access now and innovation later, between the needs of poor patients today and all patients tomorrow -- is critical to improving global public health.