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## Patents and access to antiretroviral medicines in Vietnam after World Trade Organization accession

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## Patents and access to antiretroviral medicines in Vietnam after World Trade Organization accession

### Abstract

Antiretroviral (ARV) drugs, where they are accessible, have been shown to prolong the lives and increase the health and well-being of people living with human immunodeficiency virus/acquired immunodeficiency syndrome. In general terms, whether a country is able to provide affordable ARVs to people in need is determined by the pricing structure of the drugs, which is in turn based on the patent environment that regulates them. Increasing access in many developing countries, including Vietnam, requires a thorough understanding of the patent environment and of the legal options that will allow the production and/or importation of affordable treatments. This article provides an analysis of current patent law in Vietnam with regard to the production and importation of pharmaceuticals. It then reviews the current situation of supply of ARVs with regard to pharmaceutical patents and Vietnam's obligations and practices against international agreements. The study concludes by suggesting options for utilizing current law to improve access to ARVs and makes recommendations for the implementation of Vietnamese patent law.

### Keywords

Patents, access, antiretroviral, medicines, Vietnam, after, World, Trade, Organization, accession

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# Patents and Access to Antiretroviral Medicines in Vietnam after World Trade Organization Accession

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Antiretroviral (ARV) drugs, where they are accessible, have been shown to prolong the lives and increase the health and well-being of people living with human immunodeficiency virus/acquired immunodeficiency syndrome. In general terms, whether a country is able to provide affordable ARVs to people in need is determined by the pricing structure of the drugs, which is in turn based on the patent environment that regulates them. Increasing access in many developing countries, including Vietnam, requires a thorough understanding of the patent environment and of the legal options that will allow the production and/or importation of affordable treatments. This article provides an analysis of current patent law in Vietnam with regard to the production and importation of pharmaceuticals. It then reviews the current situation of supply of ARVs with regard to pharmaceutical patents and Vietnam's obligations and practices against international agreements. The study concludes by suggesting options for utilizing current law to improve access to ARVs and makes recommendations for the implementation of Vietnamese patent law.

**Keywords** Vietnam; patents; ARV; access to medicines

Antiretroviral (ARV) drugs, where they are accessible, have been shown to prolong the lives and increase the health and well-being of people living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). Increasing access to life-saving HIV/AIDS treatment is now the single most pressing challenge in the fight against the disease. Yet, of the estimated six million people worldwide in need, only a fraction of this number are able to access them. The Vietnam Ministry of Health (MOH) reports that over 80,000 HIV/AIDS cases have been detected to date, but estimates that the real number is likely to be closer to 200,000 (MOH, 2003). The majority of reported HIV cases are among injecting drug users (50–60% of the total reported cases), with HIV prevalence among injecting drug users at 30%. Recent epidemiological data suggest that HIV is becoming a more generalized epidemic in the most hard-hit areas of the country including Quang Ninh, Ho Chi Minh City and Hanoi. The prevalence among pregnant women is nearing or has surpassed 1% in these areas. Nationwide, HIV prevalence among military candidates reached almost 1% in 2001. HIV cases have been reported in all 64 provinces of Vietnam (World Health Organization [WHO], 2004).

As the number of those infected and affected by HIV/AIDS continues to increase, individuals, families and society face increasing economic and social

pressures to provide appropriate healthcare, psychosocial support and medical treatment that has the potential to prolong the lives of those infected. Yet, the most effective therapy for people with HIV/AIDS—ARV therapy—is largely unavailable in Vietnam. In 2003, the government provided ARV drugs for approximately 50 individuals at a cost of nearly \$5,000 per person per year (MOH, 2003). It provides ARV treatment primarily to those who have been infected through occupational exposure. The current cost of ARV therapy is prohibitively expensive for nearly all other affected Vietnamese.

Recent research indicates that healthcare providers in Vietnam often prescribe only one or two ARV drugs at a time, instead of the international medical standard of triple-drug therapy. International health authorities, including the WHO, do not recommend the use of mono- or dual therapies. Mono- and dual therapies are not as effective in reducing morbidity and mortality and their use leads to HIV drug resistance within a much shorter time frame than triple combinations.

The cost of the extremely limited access to affordable ARV therapy for individuals and families, and to the healthcare system, is enormous. Recent research in Vietnam indicates that healthcare expenditure for families with one HIV-positive member is ten times higher than those for families without a member living with HIV/AIDS (United Nations Development Programme, 2003). Data from developing countries such as Brazil and the Ukraine demonstrate that there are significant social and economic benefits to providing universal free access to ARV therapy for people living with HIV/AIDS. People with access to ARV drugs live longer, have far fewer health problems and are able to contribute as productive members of society for much longer than those without access to ARVs. Brazil, for example, reported a \$1.1 billion cost savings, 40–75% reduced mortality, 60–80% reduced morbidity and an 85% reduction in hospitalizations from providing universal free access to ARVs between 1996 and 2001 (Teixeira, 2002). The Vietnam National AIDS Strategy aims to provide ARV drugs to 70% of the people living with HIV/AIDS. To reach even this limited target, the government must find ways to reduce the price of ARV therapy and make it easily and cheaply available to people who need it.

In general terms, whether a country is able to provide affordable ARVs to people in need is determined by the pricing structure of the drugs, which is in turn based on the patent environment that regulates them. Trade agreements, including the bilateral trade agreement with the United States, the new Vietnamese patent law that resulted from recent entry to the World Trade Organization (WTO), and other laws and regulations on importation and production of pharmaceuticals will affect Vietnam's ability to ensure equitable access to ARVs. Increasing access in many developing countries, including Vietnam, requires a thorough understanding of this environment and of the legal options that will allow the production and/or importation of affordable treatments (Rozek and Tully, 1999). This article provides an analysis of current patent law in Vietnam with regard to the

production and importation of pharmaceuticals. It then reviews the current situation of supply of ARVs with regard to pharmaceutical patents and Vietnam's obligations and practices against international agreements. The article concludes by suggesting options for utilizing current law to improve access to ARVs and makes recommendations for the implementation of Vietnamese patent law.

### **Availability, Affordability and Use of Antiretrovirals**

#### ***Local Production***

In 2004, nine different ARVs were registered in Vietnam (Kuanpoth and Duong, 2004). Most of them were the innovator's branded products, and were imported. However, they are not always available and their high prices render them unaffordable for most people with HIV/AIDS. In addition, four manufacturers have a licence from the MOH for the local production of ARV drugs. However, only one company (STADA Vietnam JV Ltd) is actually producing it; currently, the company has two ARV products on the market (lamivudine and a combination tablet of lamivudine + zidovudine). STADA procures raw materials from a company in India and supplies the assembled product in Vietnam (Kuanpoth, 2006). It is also exporting the finished product of lamivudine to some countries in Africa (Kuanpoth and Duong, 2004). The company plans to launch a locally produced generic version of indinavir shortly. Unfortunately, the WHO does not list indinavir as an optimal treatment option in either a first- or second-line regimen.

The restricted market and manufacture of ARVs in Vietnam, in combination with the fact that most ARV drugs are under patents, implies that not a single, appropriate first-line triple regimen (as recommended by the WHO) is available from local producers. Because recent WHO guidelines have highlighted that all five first-line ARVs should be available in order to be able to provide proper first-line ARV treatment to all those who require it, the local production and supply of first-line ARVs ought to be expanded to include efavirenz, nevirapine and stavudine.

It may be noted that local manufacturers in Vietnam have not been prequalified by the WHO. It would be advisable for local manufacturers to prepare and apply for WHO prequalification because many donors, including the Global Fund for AIDS, TB and Malaria, impose this as a condition for providing funds for the procurement of ARVs. In fact, prequalification not only opens up the possibility of supplying ARVs to Vietnam using donor funds, but may also expand export possibilities, because donor agencies may consider procuring ARVs for neighbouring countries from prequalified Vietnamese manufacturers.

#### ***Prices of Antiretrovirals***

Available data indicate that the price of ARVs in Vietnam is generally much higher than current international best prices (WHO, 2003). The prices of two locally

produced ARVs (lamivudine 150 mg and lamivudine + zidovudine 150 + 300 mg) are considerably lower than imported ARVs, but still significantly above the best price available on the international market (see Appendix A).

While the prices of locally produced ARVs are considerably lower than those of the imported ARVs currently on the Vietnamese market, they are five to seven times higher than the current best offer on the international market. This is caused, at least in part, by the fact that the market for ARVs is very small. Only a small percentage of those who need these products can afford to buy them, while public funds for procurement of ARV drugs in Vietnam are still very limited.

Thus, the government of Vietnam may wish to consider both importation and ways of reducing the cost of locally produced ARVs in order to improve their affordability and accessibility. The parallel import of ARVs could, in principle, be used as a means to increase competition and put pressure on local producers to reduce their price. Prices can be reduced further by waiving taxes, duties and fees on both finished products and raw materials; such waivers should probably also include packaging materials and non-active ingredients.

#### ***Rational Prescription and Use***

Prices obviously have implications for the availability of and access to medicines. But the relatively high prices of ARVs also have implications for rational use. Anecdotal evidence suggests that people living with HIV/AIDS take incomplete ARV regimens or on an irregular basis. While there are multiple reasons for this, the high prices of ARVs, combined with the very low economic status of people with HIV, figure prominently among them. This is aggravated by the fact that not all ARVs required for triple therapy are registered, which is probably one of the causes of the frequent prescription of inappropriate and/or outdated dual therapy. Another compounding factor is the irregular supply and availability of ARVs in both the public and private sector.<sup>1</sup> The result is that a relatively high percentage of those who have any access to ARVs are using them in a haphazard way. Thus, there is a considerable risk that resistance will occur quickly, which may necessitate an early switch to considerably more expensive second-line therapy by a relatively large percentage of patients. This is undesirable for medical reasons (treatment options will quickly run out) as well as financial reasons (the cost of second-line treatment is three to 11 times higher than that of first-line treatment).

The problems associated with the prescription and use of mono- or dual therapy could be addressed by focusing on increasing access to triple fixed dose combinations (FDCs). However, interrupted use (whether due to supply problems or for financial reasons) may continue all the same. There is a clear and urgent need for the implementation of a comprehensive supply system that will ensure the continued availability of ARV drugs. This system may or may not include the private

sector. Preferably, ARVs should be distributed free to patients, or at a nominal fee. Furthermore, proper training of prescribers, and the development of information materials explaining the importance of adherence to triple therapy, is urgent.

### **Patent Status of Certain ARV Medicines in Vietnam**

A search of patent documentation at the National Office of Intellectual Property (NOIP) found that most ARV drugs recommended for HIV treatment are under patent protection, or subject to patent applications, in Vietnam (see Appendix B). The entities that own those patents, or have filed the applications, are foreign originator companies. These companies therefore can use patent rights to prevent anyone from commercially using the drugs.

The drugs are protected in Vietnam as a product or process patents or both. In the case of a patent over the drug or a patent over the process for manufacturing the drug, the patent holder can restrict the use of the patented drug or the drug that has been obtained directly from the patented process. For example, a patent is granted for a drug comprising lamivudine as an active ingredient. This product patent gives the holder the right to make, dispose of, offer to dispose of, use, import or store the drug whether for disposal or otherwise. The manufacturing, importing or selling of any drug that contains lamivudine as the only active ingredient would be regarded as an infringement of the patent and subject the infringer to legal action.

Vietnam has followed the practice of the European Patent Office (EPO) and other developed countries by protecting new use and a new composition (i.e. a formulated product containing a known active ingredient and appropriate additives) of the known drug, even though the drug itself is known and comprises part of the state of the art (Kuanpoth and Duong, 2004). Because of this practice, patents have been granted to a new use, a new indication or a new composition of some known ARV drugs. For example, didanosine is an old and known drug and cannot be patented as an active ingredient, but several patents have been issued to protect didanosine in different forms, including combinations of previously known didanosine, products comprising didanosine in a combined preparation, compositions comprising didanosine as an antiretroviral agent and a pharmaceutical kit comprising didanosine as an antiretroviral agent. Obviously, this patent-granting practice has allowed pharmaceutical companies to claim exclusive rights over formulations that do not generate a truly new and inventive product.

Because the production and importation of several generic ARV drugs, needed in order to provide treatment in line with international and WHO standards at affordable prices, is not feasible without infringing patents, Vietnam may have to apply available legal options (particularly compulsory licensing) to ensure the availability of these medicines. Availability may promote competition and increase the affordability of ARV medicines.

## **Vietnam and its Obligations under International Intellectual Property Agreements**

### *The Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health*

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a comprehensive agreement containing new multilateral rules and regulations with relatively high standards of intellectual property (IP) protection. The TRIPS Agreement has previously linked trade measures to the enforcement of intellectual property (IP) rights. Member countries have to conform their national laws to the WTO standards. The TRIPS Agreement requires all WTO members to provide a 20-year patent protection for “any inventions, whether products or processes, in all fields of technology”, including pharmaceuticals.

However, the TRIPS Agreement, as reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health (WTO Ministerial Conference, 2001), leaves room for developing countries to protect public health interests and improve access to medicines. Members may apply any possible legal measures to combat abusive practices, provided that certain conditions stipulated in the TRIPS Agreement are fulfilled (Correa, 2000a; Rein, 2001). Feasible options under the TRIPS Agreement include:

- the adoption of the principle of the international exhaustion of rights so as to facilitate parallel imports of cheaper drugs (article 6);
- flexible interpretation to each provision of the TRIPS Agreement in light of its objectives and principles (articles 7 and 8);
- exclusion of certain biotechnological inventions, as well as medical methods for the treatment of human and animals (article 27);
- provision for limited exceptions to patent rights such as research exemption, Bolar provisions, prior users' rights, etc. (article 30); and
- the use of compulsory licences for making patented drugs available (article 31).

### *Vietnamese IP Law*

Before 2006, Vietnam protected IP rights under the Civil Code, which entered into force on 1 July 1996. The implementation of the Civil Code relating to the protection of IP rights was elaborated under various decrees and circulars. There were two regulations for the protection of patents and trade secrets relating to pharmaceuticals, including:

- decree 63/CP, 24 October 1996, for the Implementation of the Provisions of the Civil Code on Industrial Property which was amended and supplemented by Decree 06/2001, 1 February 2001; and
- decree 54/2000/ND-CP, 3 October 2000, for the Protection of Industrial Property Rights upon Business Secrets, Geographical Indications, Trade Names



and Protection of Rights against Unfair Competition Relating to Industrial Property.

In an attempt to gain WTO membership, Vietnam revised its IP legislation by enacting Intellectual Property Law 50/2005 (IP Law), which came into force on 1 July 2006. The law, which consists of 6 parts, 18 chapters, 222 articles, provides protection for all subject matters of IP rights as demanded by the TRIPS Agreement (Vale, 2006). The new IP law revised the patent system in many areas, including the introduction of the requirements for utility solutions, the adoption of priority rights in line with the Paris Convention for the Protection of Industrial Property (Paris Convention), improvement of the enforcement provisions including introducing border control mechanisms, etc.

One of the aims of Vietnamese law on patents is to provide a temporary monopoly for inventors in order to foster the development of a required technological base, and to assist in the acquisition of foreign technologies. The law also intends to create fair competition among businesses.

#### *Vietnam and International IP Agreements*

Vietnam up until now has been a party to five international IP agreements, including (1) the Agreement Establishing the World Trade Organization and the TRIPS Agreement; (2) the Paris Convention; (3) the Convention Establishing the World Intellectual Property Organization; (4) the Patent Cooperation Treaty; and (5) the Madrid Agreement on the International Registration of Marks.

#### *Vietnam and WTO/TRIPS Agreement*

In 1995, Vietnam began the process of filing its application to the WTO and has undergone several rounds of negotiation with the WTO Working Party on Vietnam's Accession to WTO. It finally gained WTO membership and became the WTO's 150th member on 11 January 2007. The entry of Vietnam into the WTO is of great significance because its ratification implies important changes in the IP laws in compliance with the TRIPS Agreement provisions (World Bank, 2006).

#### *Bilateral Trade Agreement Between Vietnam and the United States*

On 13 July 2000, Vietnam and the United States signed the "Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations" (BTA). The agreement entered into force on 10 December 2001 and is the most comprehensive bilateral agreement that Vietnam has ever signed with another country. The BTA can be considered to be the first phase in the introduction of international IP norms to Vietnam as it contains several provisions similar to those enshrined in the TRIPS Agreement.

An important section of the BTA, articles 1–18 of chapter II, requires both countries to provide a level of protection for IP rights<sup>2</sup> consistent with the prevailing TRIPS Agreement standards. Vietnam has agreed to implement fully the obligations

of chapter II of the BTA within the following time periods, calculated from 10 December 2001:

- 12 months for trademark and patent obligations;
- 18 months for trade secrets and most copyright and neighbouring rights obligations;
- 30 months for obligations with regard to encrypted programme-carrying satellite signals; and
- 24 months for IP enforcement obligations.

### **Pharmaceutical Patenting under Vietnamese Law**

The IP Law of Vietnam stipulates three conditions that a patentable invention has to satisfy: (1) novelty; (2) inventive step; and (3) industrial applicability. The novelty provision is similar to the novelty standard used in many other countries, which requires that a patentable invention should not be known, used or described in a publication anywhere in the world (IP Law 50/2005, article 60(1)). In addition, the invention must be able to be described as an “inventive step”, which means it is the result of creative activity and is not obvious to a person ordinarily skilled in the art. To be considered as an inventive step, an invention must possess a certain degree of improvement on existing knowledge. Industrial applicability refers to the fact that the invention must be able to be usefully developed and applied in an industrial or commercial context.

There are two distinct kinds of inventions that are protected as patents under Vietnamese law: inventions and utility solutions (called utility models in other countries) (IP Law 50/2005, article 58(2)). The IP Law provides patent protection for inventions for 20 years from the date of filing of the application, on the condition that the patent holder pays annual maintenance fees to the NOIP, which administers patent granting in Vietnam.

#### ***Product and Process Patents***

As in other countries, patent protection in Vietnam can be obtained either as a product or a process patent. A new pharmaceutical substance itself can be patented, provided that it is not obvious to a person skilled in the art. A patent can also be issued to protect new and non-obvious pharmaceutical processes.

The subject matters excluded from patentability listed in the IP Law include, among others, animals and plants, biological processes (except for bio-engineering processes) for cultivating animals and plants (IP Law 50/2005, article 59(5)) and inventions contrary to the interests of society, public order or humanitarian practices (Dzung, 2007). Although the law does not make provisions relating to the patentability of genes and gene sequences, the practical approach of this rule is that these two subjects are patentable if they meet the requirements of novelty, inventive step and industrial applicability (Kuanpoth and Duong, 2004).

Vietnamese law expressly prohibits the granting of patents for methods for the treatment of the human or animal body (Dzung, 2007, p. 141). The intention of the law is to protect medical practitioners from the restrictions of monopoly privileges,

while at the same time allowing for healthy competition. In other words, medical methods are not under patent and this gives physicians the freedom to treat their patients with any appropriate method that they see fit. However, when the required drugs are not available in the market due to the restrictions of an exclusive monopoly, it is doubtful that a physician can reasonably carry out the most appropriate and beneficial medical treatment.

### *Special Cases of Pharmaceutical Patents*

There are two issues relating to the patentability of a known pharmaceutical. When a pharmaceutical substance has already been known to the public, the claims to the product as such are ruled out. Alternative solutions for the pharmaceutical company are: (1) to claim new pharmaceutical compositions; or (2) to claim a new use of the product that already has a pharmaceutical use.

First, it is common for a research-based pharmaceutical company to claim that a broad pharmaceutical composition, containing a known active ingredient and appropriate additives, and formulated by them, is a new composition. To the research-based company, such a claim is advantageous as the claim is not limited to any specific pharmaceutical indication. The commercial use of the claimed compound, in any way, would constitute a patent infringement. Whether the claims directed to a pharmaceutical composition should be permitted is the question. Some developed countries and regions (e.g. the United States, the European Union and Japan) have permitted patenting of these inventions. In accordance with this line of practice, composition claims are accepted in Vietnam (Dzung, 2007).

Second, an invention used in one area may have applications in other areas. For example, an agrochemical substance may be used as a pharmaceutical product, or a well-known drug can have a new therapeutic application. The pharmaceutical companies may claim the use of a known compound as a new pharmaceutical. It is questionable whether the claim to a new use of the known drug should be permissible, because this type of claim is equivalent to a claim to a method of treatment. As already mentioned, Vietnamese law excludes methods of treatment from patentability.

According to the practice of the NOIP, the claim to a new use or the first medical indication of a known compound (e.g. the use of compound X as an antiretroviral agent) is patentable. The claim to a second use or the second medical indication, or the so-called Swiss claim (e.g. the use of compound X for the preparation of an agent for the treatment of disease Y), is also accepted by the NOIP. The NOIP follows the guidelines of the EPO by treating first and second medicinal indications (i.e. new medicinal uses) as a product claim, and thus not prohibited from patentability under article 59 of the IP Law (Kuanpoth and Duong, 2004).

Article 7 of the BTA, in compliance with the TRIPS Agreement, article 27, both of which deal with “patentable subject-matters”, requires Vietnam to protect pharmaceuticals, both the product and the process. However, the BTA and the

TRIPS Agreement do not define “product” and “process” (Correa, 2000b, pp. 20–6). This leaves Vietnam considerable freedom to determine what should be protected under product and process patents.

It is advisable that the national law of Vietnam limits the scope of patentability to new pharmaceutical substances and new processes for manufacturing pharmaceuticals only. Patent protection would therefore only be available for a new medical product or new chemical entity that would satisfy the stipulated criteria for patentability. Given that a single medical product can have multiple uses and formulations, providing patents for the subsequent uses or the new composition of a known drug would unnecessarily prolong the monopolistic market enjoyed by the patent holder and deprive consumers of the right to essential medicines (Correa, 2000b, pp. 23–4). This suggestion should be followed immediately as it does not require any amendment to the existing legislation but only a change in NOIP practice.

Vietnam should treat claims to use an aspect of a medicine as a method of medical treatment and therefore as a non-patentable subject matter. It should also treat a pharmaceutical composition as being “anticipated by the effective ingredient that it contains” and therefore not patentable on the grounds of lack of novelty (Correa, 2000b, p. 55).

### **Compulsory Licensing**

Vietnamese law has adopted several available options in framing the national patent legislation. One of these options is the system of compulsory licensing. Compulsory licensing means a non-voluntary licence issued by the state to a third party without the consent of the patent holder, on the condition that the licensee pays reasonable remuneration to the patent holder in return. A compulsory licence authorizes the licensee to perform acts covered by the patent rights (e.g. manufacturing, selling or importing the patented product) without the consent of the patent holder.

Under Vietnamese law, a compulsory or non-voluntary licence is a licence granted by the Ministry of Science and Technology (MOST) without the consent of the patent owner. The licensee can legally exploit the rights under patents, which would otherwise be regarded as an infringement of the patent. A compulsory licence may be granted in one of the following circumstances (Correa, 2000b, pp. 93–100).

#### ***Public Non-Commercial Use***

According to the IP Law, article 145(1)(a), a compulsory licence can be issued in situations where public interest is involved, including: (1) the needs of national defence and security; (2) prevention and treatment of diseases; and (3) other urgent needs of society.

This provision is important and can be applied in order to improve access to medicines. When issuing a compulsory licence on the basis of meeting public needs, Vietnamese law does not require consultation with the patent holder. The waiver of

consultation, in compliance with the TRIPS Agreement, article 31(b), aims to avoid the delay of the issuance of the licence.

#### ***Non-Working or Inadequate Working of Patents***

According to articles 136(1) and 145(1)(b) of the IP Law, when the patent holder does not use the invention to satisfy a demand for the patented product in the domestic market, this becomes grounds for the MOST to issue a compulsory licence. In other words, a compulsory licence can be issued in the event that the patent holder does not use the patented invention domestically or does not use it to fulfil a domestic demand for the patented product to satisfy the needs of national defence, security, disease prevention, treatment and nutrition for people or to meet other social urgent needs (e.g. selling the medicinal product at an excessive price). Although the term “use of patents” is now clearly defined under the new law by referring to the manufacture of the product or the import of the patented product into Vietnam,<sup>3</sup> the working of the invention may be done by the proprietor or by a voluntary licensee (Kuanpoth and Duong, 2004).

#### ***Refusal to Issue a Voluntary Licence***

Under article 145(1)(c) of the IP Law, a compulsory licence may be granted when the patent holder has refused to grant a voluntary licence to others. However, it has to be proved that the proposed user has made efforts to obtain authorization from the patent holder to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful. This provision aims to facilitate the establishment or development of commercial or industrial activities.

#### ***Use to Remedy Anti-Competitive Practices***

The monopolistic position conferred by patents may allow the patent holder to resort to anti-competitive practices such as fixing or maintaining unreasonable purchase or selling prices, or engaging in price fixing or other collusive agreements with another enterprise, etc. Article 145(1)(d) of the IP Law authorizes the state to issue a compulsory licence to remedy the situation. Although the TRIPS Agreement provides that in issuing a compulsory licence in this circumstance the state authority does not have to follow the conditions under articles 31(b) and 31(f) of the TRIPS Agreement (i.e. there is no need for prior negotiation with the patent holder, and the condition that supply should be “predominantly for the domestic market” is also waived), the Vietnamese law does not waive these conditions. This may unnecessarily delay the grant of compulsory licences.

The Vietnamese IP law incorporates most of the possibilities for compulsory licensing in order to encourage a competitive environment and guarantee the availability of essential medicines. However, the existing law of Vietnam does not contain a specific provision for compulsory licensing in cases of national emergency and circumstances of extreme urgency. The government of Vietnam may wish to consider adding such a clause, because, under the TRIPS Agreement, it would be allowed to waive prior negotiations with the patent holder. This would mean that

the relevant government agency would be permitted to use the patented invention by itself or issue authorization of rights on relevant patented products to any enterprise without consultation with the patent holder. As the Doha Declaration makes it clear that each country has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, the public health crisis should be regarded as a national emergency and that the provision is used to facilitate access to ARV drugs on that basis.

### **Imports of Medicines**

The large variation in drug prices in the world market has led to the evolution of a marketing practice called “parallel importing”. Parallel import refers to the situation where products manufactured and sold abroad with the permission of the patent holder are imported by third parties into a country without the authorization of the patent holder. Because of the price differentials of pharmaceuticals across markets, a distributor will obtain a product in a low-price country and ship it to an unauthorized distributor in a high-price country, who will then compete directly with the patent holder or the authorized distributor in that country.

There are three situations in which drugs manufactured and sold abroad are legally imported into the country, including (Correa, 2000b, pp. 100–2):

- import of generic drugs in situations where there is no existing patent;
- parallel import of drugs put on the market with authorization of the patent holder; and
- parallel import of drugs sold under compulsory licensing.

### ***Import of Generic Medicines***

Generic medicines are drugs that are not protected by a patent or whose legal protection has expired. They can be marketed under a brand name or a generic (non-proprietary) name. Non-research-based companies generally market generic drugs. These firms do not normally engage in research and development (R&D), but only sell low-priced generics. Competition in the generic drug market can create downward price pressure and is considered to be the most essential factor in improving access to medicines.

Generic versions of medicines can be produced locally or may come from other markets where generic drugs exist. Local pharmaceutical distributors tend to use legal rights, under patent and trademark law, to create territorial restrictions that block the import of generics. Vietnam, indeed all developing countries, should encourage local generic production and the import of foreign-made medicines from countries where prices are much lower due to the absence of patent protection (Maskus, 2000). The possibility for the entry of foreign generic drugs will confront the licensed distributors with competitive pressure to set lower prices (Abbott, 1998; Beal, 1998).

Under the current law of Vietnam, anyone can import drugs that are not patented in the country, subject to various import regulations. The importer, however, has to obtain an import licence from the MOH, required so that the MOH can ensure that the import of the generics will not have negative effects on patients, especially when the imported drugs are substandard. However, health and safety regulations must be carefully implemented to ensure that they do not become a barrier to cross-border trade in pharmaceuticals. Vietnam and other countries should attempt to bring the varied national drug regulations into line, in order to remove barriers to the import of medicines. However, when the medicine to be imported is under patent protection in Vietnam, an import is possible only when a compulsory licence is issued to authorize import of the patented drug (IP Law 50/2005, articles 124(1)(d), 133, 136, and 145).

### ***Parallel Import***

When the patented medicine has been sold in a foreign market by the company that owns a patent in Vietnam or with the consent of that company, the subsequent import or resale of the medicine will not infringe the company's patent right (Bala and Sagoo, 2000). The exclusive rights to the product have been exhausted by the act of selling it. This is known as "the principle of exhaustion of right".<sup>4</sup> Countries implement this principle differently. Some apply the principle when drugs are sold within the national border only (called national exhaustion), but other countries and regions, notably the European Union, impose no restrictions on import when drugs are put on sale in countries that are members of the community (called regional exhaustion). There are many countries that currently incorporate the principle of international exhaustion of right into their national legislation. Under the principle, the patent rights are exhausted after the first marketing of the patented article by the right holder or with the holder's consent, regardless of the place of marketing (Heath, 1997).

The BTA Vietnam signed with the United States, in line with article 6 of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, does not specify the principle of exhaustion that Vietnam must adopt. Vietnam is free to establish its own regime for such exhaustion of right without challenge, subject to the principles of National Treatment and Most-Favoured-Nation Treatment. Under article 125(2)(b) of the IP Law, Vietnam law stipulates that it is permitted to import and use the patented article that has been put on sale either in Vietnam or in a foreign market by the patent holder or with his/her consent. This provision allows for the importation of medicines that have been marketed with low prices by the patent holder or anyone associated with the patent holder (e.g. a voluntary licensee, a distributor or a subsidiary).

The provision on the international exhaustion has been maintained in the national legislation, even after Vietnam became a WTO member. It is equally important that relevant regulations concerning the importation of medicines should

be revised, with one of its aims being to facilitate the parallel imports of drugs to meet the country's need for essential medicines.

It should be noted that on 28 May 2004, the MOH adopted the "Regulation on Parallel Import of Medicines for Treatment of Humans". The Regulation provides for the issuance of a licence for parallel import of medicines into Vietnam. It contains provisions that ensure the quality of the imported drug. The most significant provision is article 9, which specifies that the Head of the Vietnamese Bureau of Medicine Control is authorized to issue the licence for parallel import and that the decision relating to the application for a licence must be made within 15 days. This may provide a fast-track mechanism for parallel import of medicines and should be investigated by those seeking to improve access to ARVs in Vietnam.

### *Import of Drugs Sold under Compulsory Licensing*

The possibility for a developing country to search for alternative sources of supply for medicines has become increasingly difficult since 2005 when India, the world's major supplier of generic medicines, was obliged to implement pharmaceutical product patents. India was then no longer able to supply other countries with generic versions of medicines, especially newly developed medicines, such as those for the treatment of resistant HIV or other diseases (Dhar, 2006). Full-scale pharmaceutical patenting may eventually wipe out all alternative sources of drug supply and multinational companies could then become the sole source of drugs for poor countries.

However, countries that have sufficient manufacturing capacity might still be able to use compulsory licensing to produce and export drugs to the countries that need them. While the TRIPS Agreement requires that a compulsory licence be granted "predominantly" for the supply of the domestic market, this does leave some room for export (TRIPS Agreement, article 31(f)). Moreover, in cases where a compulsory licence has been granted to remedy anti-competitive practices, there is no export restriction (TRIPS Agreement, article 31(b)). Finally, the Doha Declaration and WTO Decisions of 30 August 2003 (WTO General Council Decision, 2003) and of December 2005 (WTO General Council Decision, 2005) permit the export of medicines to a country with insufficient or no manufacturing capacities in the pharmaceutical sector.

Because the current law of Vietnam adopts all measures related to compulsory licensing and parallel imports, Vietnam must implement these provisions extensively. Implementing these mechanisms and strengthening collaborations could significantly improve access to medicines. The collaborative efforts should be sought not only with other countries (e.g. Canada, India, China, Thailand, etc.) but also among relevant government agencies. At the international level, inter-country collaboration should have the common aim of increasing access to medicines and making those essential products affordable for all. Vietnam and other ASEAN members should pool productive resources and create a regional supply of drugs. Vietnam must be prepared to use compulsory licensing to facilitate



the production and export of medicines that it has the capacity to produce. At the same time, it may also need a compulsory licence for the import of drugs for which it lacks manufacturing capacity.

A united stand is also required among government agencies of Vietnam, particularly between the health authorities and those in the MOST and the NOIP. National and international cooperation should be focused not only on looking at ways of lessening obstacles for the use of compulsory licensing and parallel import of medicines but also on the exchange of information regarding patents and pharmaceuticals.

### **Defences to Patent Infringement**

Vietnamese law, in line with the TRIPS Agreement and the BTA, provides for defences to a patent infringement action. Apart from defences under the compulsory licensing and the parallel importing provisions mentioned earlier, the IP Law does not regard the following acts as infringing patent rights:

- personal use for non-commercial purposes (IP Law 50/2005, article 125(2)(a));
- experimental use (IP Law 50/2005, article 125(2)(a));
- use of patented objects on a foreign vessel that temporarily or accidentally enters Vietnam (IP Law 50/2005, article 125(2)(c)); and
- prior users' right (IP Law 50/2005, articles 125(2)(d) and 134).

The TRIPS Agreement and the BTA provide general terms for the exceptions to patent rights, only requiring that “such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties” (TRIPS Agreement, article 30).<sup>5</sup> Vietnam is therefore entitled to adopt a wide range of defences to patent infringement. Unfortunately, many exceptions to patent infringement that are part of the law of many countries are absent from the patent legislation of Vietnam, including Bolar provision<sup>6</sup> and individual prescriptions.<sup>7</sup>

### **Drug Regulations and Problems of Data Exclusivity**

While patents and patent law are of utmost importance in the pharmaceutical sector—and play an important role in determining whether a medicine can legally be imported, sold or used—medicines also require marketing authorization (i.e. have to be registered) before they can legally be manufactured, imported, sold and/or used. Vietnamese law requires pharmaceuticals to be registered with the competent authority, the MOH. It generally takes between 6 and 9 months for a drug to be registered. In special situations (e.g. when there is an urgent need for drugs for the prevention of epidemics), the MOH may permit the distribution of a drug that is not registered in Vietnam (Kuanpoth and Duong, 2004).

### ***Drug Registration***

Only a limited number of ARVs are currently registered in Vietnam (see Appendix C). This is an important additional factor limiting access to ARVs and it poses challenges in providing appropriate treatment. The study in 2004 found that not even one single WHO-recommended triple regimen can be formed out of the ARVs registered in Vietnam (Kuanpoth and Duong, 2004). The lack of sufficient registration may stem from the fact that the Vietnamese MOH does not register the drug unless the applicant can prove that the manufacturing, importing and selling of the said medicine will not infringe the IP rights of other companies. This obligation is imposed on the person who seeks to register the drug in order to prevent counterfeit drugs from entering the market. While the counterfeiting problem can be addressed through the formulation and implementation of comprehensive strategies involving strengthening, adoption and enforcement of legislation, regulations and inspections, it is doubtful that the linking of registration with patent status can have any significant effect on this problem. By contrast, the obligation unnecessarily restrains the entry of generic medicines.

The person who seeks registration of generic medicines should not have any responsibility to inform the drug regulatory authority regarding the IP infringement because it concerns the private right of the patent holder. The law of most countries, as well as the TRIPS Agreement, makes it very clear that IP rights are private rights. The owner of the rights must protect their own interests, not the state. The practice of linking patent status to registration obviously provides legal protection for IP rights that are much stronger than any other rights of the private party, and therefore should be revised.

### ***Registration of Imported Drugs***

Organizations (e.g. companies, private enterprises, foreign-owned capital enterprises, etc.) may be licensed by the drug regulatory authority to import drugs to Vietnam that have been registered with the MOH. The Vietnamese regulation requires a licensed importer to satisfy the following requirements:

- meeting the criteria for good manufacturing practice (GMP) and the criteria for preservation and transportation of drugs promulgated by the MOH;
- having financial resources and business experience (i.e. having been in business for more than 3 years);
- possessing management skills and quality assurance (e.g. a system to examine and assure quality of drugs, including at least a university-degree pharmacist for supervising such a system);
- having no record of violating pharmaceutical rules within the last 3 years; and
- having adequate staff specializing in import/export matters.

The above-mentioned requirements apply to both profit and non-profit organizations. Manufacturers that import raw materials for local assembly need to obtain a licence from the drug regulatory authority. Foreign enterprises that have

no establishment in Vietnam may supply medicines to Vietnam under import/export contracts with local enterprises that have obtained a licence to trade in pharmaceuticals. In addition, donor agencies or non-governmental organizations wishing to import medicines would have to do so via an established and licensed import agency.

In cases where the import of drugs is carried out by charitable organizations, the import has to comply with the requirements and conditions stipulated under Circular no.13/1998 on Guiding the Reception, Management and Usage of Foreign Medicinal Aid to Vietnam. Circular no.13/1998 has laid down criteria for the import of drugs for donation in the country. Significantly, it requires that the imported drugs must be of good quality and must come from reliable sources. Furthermore, authorization by the Department of Pharmaceutical Management of the MOH is required before the import of the drug can be made.

#### ***Registration of Imported Drugs for Personal Use***

Vietnam has adopted regulations for importing drugs to the country for personal use. Imported drugs for non-commercial purposes refer to drugs that are bought from a foreign country and then brought into Vietnam. The drugs must be brought into the country for personal use and must not be sold in the market. Under the regulation, the importation of such drugs for non-commercial purposes shall not exceed US\$30 per one import and the value of each individual drug shall not exceed US\$10. Further, a person cannot import the same drug to Vietnam for non-commercial purposes more than three times a year.

In other countries, people who have started ARV therapy and face problems due to interrupted supply, or because they need drugs that are not yet registered, can consider purchasing quantities of such drugs abroad, and importing them for their personal use, provided of course that they can afford it. While obviously not being a structural or ideal solution, it is a solution that can increase individual patients' options. This strategy has been used especially during the "start-up" phase of providing treatment, when supply may be erratic.

Vietnamese law, however, seriously limits such importation. In the case of expensive medicines, like ARVs, the import regulations obviously severely restrict the amount that can be imported. Even with the cheapest first-line regimen available on the international market (e.g. stavudine, lamivudine and nevirapine), an individual could at most import a 1-month supply for personal use. For the cheapest second-line regimen, this would translate into just a 1-week supply. In addition, the same person may only receive/import medicines in this way no more than three times per year.

There is no public health rationale for limiting the value of such imports so dramatically. Presumably, this measure was meant to discourage commercial sale; however, the same objective could be achieved by simply prohibiting the commercial sale of medicines imported for personal use. If the goal of improved access to ARVs is to be achieved, appropriate legislative structures relating to the import of

drugs must be established. The existing regulations clearly act as a barrier to the import of generic medicines to Vietnam and should be considered for revision.

### *Problems of Data Exclusivity*

The problem of data exclusivity concerns the regulatory authority and third-party use of clinical tests, and other data, submitted during the regulatory approval processes. As mentioned earlier, the organization that seeks registration of medicines must submit data relating to the drug's quality, safety and efficacy (the so-called test data) to the drug regulatory authority. Because the origination of these data involves considerable effort, international agreements demand protection for such data.

Article 39.3 of the TRIPS Agreement obliges the member states to protect undisclosed test and other data relating to new chemical entities against "unfair commercial use" and "disclosure" of the data when the state requires submission of such data as a condition of approving the marketing of pharmaceutical products (Correa, 2002).

The BTA requires Vietnam to provide protection for test data higher than the TRIPS Agreement standard. In addition to the protection against unfair commercial use and disclosure, article 9.6 of the BTA obliges Vietnam to prohibit third parties (e.g. company A, which is a generic producer seeking to introduce generic versions) from relying on the test data previously submitted by the first company (e.g. company B, which is an originator company) in support of an application for product approval, for at least 5 years. This is tantamount to granting exclusivity protection over test data to the originator company.

Furthermore, while the TRIPS Agreement requires protection only for new chemical entities, the BTA does not contain such a limitation. This means exclusivity protection must be provided for all kinds of data submitted for marketing approval, including data with respect to compositions, dosage forms and new uses of a known drug.

Because of the data exclusivity provision under the BTA, the regulatory authorities of Vietnam cannot rely on the data submitted by the originator company to register generic versions of the same drugs for 5 years after registration of the originator product. Moreover, registration for a second or subsequent indication triggers a new 5-year exclusivity period. Small generic manufacturers have to enter into a long and costly testing process before the marketing approval of a generic drug can be obtained, and this will effectively delay the generic registration for 5 years. It may also restrain the effectiveness of the compulsory licensing system, potentially preventing the Drug Administration from registering the generic drug produced under the compulsory licence. Thus, the person to whom a compulsory licence is granted cannot use the licensed invention efficiently and independently without the cooperation of the patent holder. There is no doubt that this obligation unnecessarily confers monopolistic protection to pharmaceutical companies and could damage public health efforts in Vietnam.

## **Conclusion and Recommendations**

Vietnam is currently providing patent protection for pharmaceutical products to a level that is as high as the standards under the TRIPS Agreement. Patent law also necessarily fits into the Vietnamese policy objective of protecting public interests, and it does this by excluding market monopolization from some important sectors such as medical treatments and biological inventions. Social interests and personal benefits are well balanced by the provisions of compulsory licensing and parallel importing.

It was found out that most of the ARV drugs recommended for HIV/AIDS treatment are under patent protection or subject to patent applications. Because production and import of generic versions of these patented ARVs is prohibited, ensuring that all the necessary first and second triple regimens will be available in Vietnam at affordable prices will be a complicated process. The characteristics of patent and drug regulatory systems, and the practices related to their implementation, exert a powerful influence on the public health response to the epidemic and have important implications for access to HIV/AIDS medicines.

More specifically, the fact that there are a significant number of patents and patent applications for HIV/AIDS drugs is limiting the possibilities for making use of lower-priced generic versions of several important ARV drugs. It appears inevitable that the Vietnamese government will have to make use of the legal mechanisms that are available under the existing legislation in order to make these treatments widely available. To improve access to affordable ARV drugs for people living with HIV in Vietnam, the following options and recommendations should be considered:

- Encourage any interested person to import to Vietnam the same drugs sold at a lower price in a foreign country by the patent holder or with the holder's consent. However, the possibility for parallel import may be constrained by the restrictive clauses imposed on the distributor in the country from which Vietnam wants to import the drug. This problem could be dealt with by the application of competition law and inter-country collaboration, which may, however, be time consuming.
- Undertake price negotiation with the companies that hold patents on ARVs in Vietnam. Negotiation with the patent holder is probably the quickest and safest method of improving access to ARVs (quick because the drugs sold by the patent holder have been registered, and safe because there is no risk of patent infringement). But it appears to be an impractical solution as negotiations will not always result in affordable prices because of the unequal bargaining power of the negotiating parties.<sup>8</sup>
- Issue a compulsory licence for either importation or local production of ARVs. This will, however, require strong political will and determination from the Vietnamese government, because there is bound to be pressure to abandon this strategy. However, other countries, both developed and developing, have successfully used this legal measure to facilitate the availability of patented

products. There is no reason why Vietnam should not use this mechanism to achieve the aim of guaranteeing public interests. However, while it is advisable to apply compulsory licensing, the fact that the compulsory licence alone is inadequate in addressing the problem of accessibility must be considered. In order to further facilitate access to medicines, Vietnam could provide for a registration-waiver or fast-track registration of the product produced under compulsory licence (short term). Failing that, the product would have to go through the full registration process (medium/long term).

- Facilitate import and use of ARVs for non-commercial uses. As all the ARVs are patented or under patent application in Vietnam, it is strongly recommended that small- and large-scale imports of ARVs for personal use or non-profit distribution are potentially exempted from a patent infringement action under the current legislation. The Vietnamese government should initiate a cooperative scheme for ARV donation with foreign and intergovernmental organizations with the aim of providing ARVs free of charge to people living with HIV/AIDS.

## Appendix A

**Table A1: Cost per Patient per Year (US\$)**

	Lamivudine 150 mg	Lamivudine + zidovudine 150/300 mg
Current price of imported ARVs (originator company)	\$1,860–2,240	\$2,336
Best offer by originator company (Vietnam not eligible)*	\$69	\$237
Locally produced	\$487	\$949
International best price (WHO prequalified)	\$65 (Hetero, India)	\$197 (Cipla, India)

*Note:*

\*Most originator companies only offer their best prices to Sub-Saharan Africa or least-developed countries. Hence, Vietnam is not eligible (a notable exception is Boehringer Ingelheim, which offers its best price to all “low-income countries”, as defined by the World Bank; Vietnam does fall into this category). Second-best prices offered by some companies (Merck and Roche) are considerably higher than their best prices. Other companies (Glaxo Smith Kline and Bristol-Myers Squibb) do not provide any price indication.

*Source:* Kuanpoth and Duong (2004).

## Appendix B

**Table B1: Patent Status of Antiretrovirals**

Antiretroviral drug (X)	Patented/pending patent applications	
	Pharmaceutical composition having only X as an active ingredient	Pharmaceutical composition having X and another compound
<b>First-line ARVs</b>		
Zidovudine	Yes	Yes
Lamivudine	Yes	Yes
Nevirapine	Yes	Yes
Efavirenz	Yes	Yes
Stavudine	No	Yes
<b>First-line FDCs:</b>		
Stavudine + lamivudine	No	Yes
Zidovudine + lamivudine	Yes	Yes
Zidovudine + lamivudine + nevirapine	No	Yes
Stavudine + lamivudine + nevirapine	No	Yes
Zidovudine + lamivudine + efavirenz	Yes	Yes
Stavudine + lamivudine + efavirenz	Yes	Yes
<b>Second-line ARVs:</b>		
Tenofovir	No	Yes
Didanosine	No	Yes
Abacavir	No	Yes
Ritonavir	No	Yes
Lopinavir	No	Yes
Saquinavir	No	Yes
Lopinavir + ritonavir	No	Yes
<b>Other ARVS</b>		
Nelfinavir	Yes	Yes
Amprenavir	No	Yes
Indinavir	No	Yes
Zidovudine + lamivudine + abacavir	No	Yes

Source: Kuanpoth and Duong (2004).

## Appendix C

Table C1: Antiretrovirals Registered in Vietnam (July 2003)

	Registered	
	Originator brand	Generic
First-line ARVs:		
Zidovudine		
Lamivudine	Yes	Yes*
Stavudine	Yes	
Nevirapine		
Efavirenz		
Stavudine + lamivudine		
Zidovudine + lamivudine	Yes	Yes*
Zidovudine + lamivudine + nevirapine		
Stavudine + lamivudine + nevirapine		
Second-line ARVs:		
Abacavir		
Tenofovir		
Didanosine	Yes	
Lopinavir/ritonavir	Yes	
Ritonavir	Yes	
Saquinavir	Yes	
Other ARVs:		
Indinavir	Yes	
Nelfinavir		

Note:

\*Locally produced ARVs.

Source: Kuanpoth and Duong (2004).

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### Notes

- 1 Currently, the Vietnamese government allocates the annual sum of US\$ 200,000 for ARVs. Because of the current Vietnamese guidelines and the limited financial capability, only one drug (azidothymidine) is prescribed free of charge for governmental officials (e.g. health workers, police, etc.) who were accidentally exposed to HIV.
- 2 Under article 2(3) of chapter II of the BTA, "intellectual property rights" refer to copyrights and related rights, trademarks, patents, layout designs (topographies) of integrated circuits, encrypted programme-carrying satellite signals, confidential information (trade secrets), industrial designs and rights in plant varieties.



- 3 Article 27.1 of the TRIPS Agreement stipulates that the patent holders can satisfy the obligation of working the patents through imports.
- 4 “Exhaustion of rights” is a legal principle that can be described as a situation where the IP rights are exhausted as to a particular article upon the first authorized sale of that article by the holder of IP rights or with the holder’s consent such as the sale by the holder’s licensee. The purchaser of that article can use and resell the article without patent liability.
- 5 Similar terms are found under article 7(4) of the BTA.
- 6 The “Bolar provision” was first adopted under the US Hatch–Waxman Act or the Drug Price Competition and Patent Term Restoration Act of 1984, and subsequently introduced into the patent law of many other countries. This provision provides a defence to a patent infringement action when an act of testing of a patented medicine is committed for the purpose of obtaining market approval of a generic product. The generic medicine would, however, be marketed only after the patent has expired or a compulsory licence is granted for exploitation of the patent.
- 7 The law of many countries provides an exception to exclusive rights for an act relating to preparation for individual cases in a pharmacy, or by a medical doctor, of the patented medicines described in a doctor’s or dentist’s prescription. This exception does not cover general private consumption but aims to exclude health professionals from the effects of patent rights. It extends not only to anyone involved in the preparation or use of the medicine but also to the doctor or dentist who writes out the prescription.
- 8 Although Vietnam may apply compulsory licensing on patented ARVs before entering into price negotiations with patent holders, as in the case of Brazil, it seems that these negotiations will be difficult and time consuming. Vietnam appears to lack the expertise needed to negotiate prices in this situation. In addition, no one person or organization in Vietnam has a clear and firm mandate to undertake such negotiations. Ideally, the negotiator/procurement staff should have access to market intelligence and should have experience; this may make it difficult to identify an appropriate person or organization. If need be, negotiators/procurement staff could be trained with the help of similar institutions in other countries.

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