Chapter 15: Access to essential medicines, TRIPS
and the patent system

SUMMARY POINTS

· All countries should develop a national medicines policy that includes a national list of essential medicines that takes account of national needs. In some countries, the national constitution commits governments to providing equitable access to essential medicines and health care services.

· A national procurement strategy may assist governments to formalize a range of measures to purchase quality medicines at cheaper prices. Addressing corruption, eliminating tariffs on imported drugs, controlling mark-ups on drugs at wholesale and retail levels, requiring or creating incentives for the supply of generic versions of drugs by pharmacists and medical practitioners, and banning or limiting direct-to-consumer advertising of medicines, are some of the strategies that may reduce prices.

· Most essential medicines are not under patent, and generic versions can be produced or imported without infringing patent rights.

· Affordable access to essential medicines that are under patent depends partly on the terms of national patent laws, and on the actions of the patent holder. The Agreement on Trade-Related Aspects of International Property Rights (TRIPS) includes a number of flexibilities that can be used to reduce the prices of essential medicines and to better meet the goal of universal access. TRIPS does not prevent national governments from issuing compulsory licences in order to meet national health objectives, from choosing an exhaustion regime that best suits national circumstances (allowing parallel importing for example), or from defining patentability criteria in national patent legislation.1

· A patent holder may enter into a voluntary licence with third parties, such as generic producers, to produce, market and distribute a particular drug within a specified territory. Royalty-free, non-exclusive licences that include a large number of countries within the licensed territory, permit sale to both the public and private sector, and permit licensees to source active pharmaceutical ingredients from anywhere in the world are more likely to encourage robust competition and the economies of scale that are needed to substantially reduce prices. Other strategies that support access to essential medicines include tiered pricing, donation of drugs, non-filing of patents in least developed countries, and non-enforcement of patents.

Introduction

Ensuring universal access to free or affordable essential medicines is one of the “core obligations” for fulfilling the right to health.2 WHO has encouraged countries to amend their national legislation or constitutions to provide for this specific right3 (Box 15.1). For example, the Universally Accessible Cheaper and Quality Medicines Act of 2008, enacted by the Philippines, contains the following declaration of policy:
It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all. 4

The Act also states that any doubts about the interpretation of provisions of the Act shall be resolved by adopting a construction in favour of the protection of public health.5

**Box 15.1: Constitutional protections for access to medicines: examples from Panama and the Philippines**

<table>
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<tr>
<th>Political Constitution of the Republic of Panama6</th>
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<tr>
<td>Article 110. In matters of health, the State is primarily obligated to develop the following activities, integrating the functions of prevention, treatment, and rehabilitation:</td>
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<td>5. Establish, in accordance with the requirements of each region, centres which provide comprehensive health care services and supply medicines to the population. These health services and medicines shall be given free to those who lack economic means to purchase them.</td>
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<th>Constitution of the Republic of the Philippines7</th>
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<tr>
<td>Article 13.</td>
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<tr>
<td>Section 11. The State shall adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the underprivileged, sick, elderly, disabled, women, and children. The State shall endeavour to provide free medical care to paupers.</td>
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<tr>
<td>Section 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.</td>
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In some countries, the treaty obligations assumed by countries are enforceable through the domestic courts, providing members of the population with a legal pathway for seeking greater access to essential medicines at affordable prices.8 For example, Argentina’s Constitution refers to a number of human rights treaties which supersede domestic law (Box 15.2). In 2000, the Argentinian Supreme Court ruled that the right to life enshrined in the International Covenant on Economic, Social and Cultural Rights9 was enforceable under Argentinian law in that country’s domestic courts. The ruling provided, in part, that the government had a positive duty – going beyond what was specifically required by Argentinian legislation – to provide medicine to a disabled child.10
Box 15.2: Using international treaties to promote access to medicines: human rights treaties that supersede domestic law in the Constitution of Argentina

Section 75

22. The American Declaration of the Rights and Duties of Man; the Universal Declaration of Human Rights; the American Convention on Human Rights; the International Covenant on Economic, Social and Cultural Rights; the International Covenant on Civil and Political Rights and its empowering Protocol; the Convention on the Prevention and Punishment of Genocide; the International Convention on the Elimination of all Forms of Racial Discrimination; the Convention on the Elimination of all Forms of Discrimination against Woman; the Convention against Torture and other Cruel, Inhuman or Degrading Treatments or Punishments; the Convention on the Rights of the Child; in the full force of their provisions, they have constitutional hierarchy [above national law], ... [and] are to be understood as complementing the rights and guarantees recognized herein.

15.1 Establishing a national drugs policy

In order to ensure access to essential medicines, countries need to establish a national drugs policy. WHO has released comprehensive guidance on creating these policies, which should address access to, and the quality and rational use of, medicines. The WHO Model List of Essential Medicines can help to guide drug selection, although the development of a national list should take account of national priorities and disease challenges. A national drug policy, including a list of essential medicines and standard treatment guidelines, can increase the use of generics, improve prescribing practices and protect against drug resistance.

For example, during the 1990s, South Africa developed a national drug policy in collaboration with WHO. The Minister for Health appointed a Drug Policy Committee to develop a pricing plan for drugs used in both the public and private sectors, to develop a plan for the evaluation of drugs for effectiveness, and to develop an essential drugs list for use in the public sector. The committee also considered strategies for increasing the use of generic drugs, and for procurement and distribution, particularly in rural areas. The policy developed as a result of this process secures the right to universal access to essential medicines by committing the government to:

- ensure the availability and accessibility of essential medicines to all citizens;
- ensure the safety, efficacy and quality of drugs;
- ensure good prescribing and dispensing practices;
- promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information; and
- promote the concept of individual responsibility for health, preventive care and informed decision-making.
The South African government has since established the South African Drug Action Programme within the Department of Health to implement the new policy and to support provincial strategies.

15.2 Pricing and procurement

A national procurement policy is an important tool for assisting governments to purchase quality drugs at the lowest possible prices. An effective procurement strategy must accurately estimate the drug needs of the country and select the most appropriate purchasing strategy based on resources and time. There are four general methods for procuring pharmaceuticals: open tenders, restricted tenders, competitive negotiations and direct procurement.\textsuperscript{15} The procurement method chosen by a government should seek to achieve the following objectives: (1) to procure the most cost-effective drugs in the right quantities; (2) to select reliable suppliers of high-quality products; (3) to ensure timely delivery of essential medicines; and (4) to achieve the lowest possible total cost.\textsuperscript{16} Countries may choose to incorporate these objectives into national legislation or administrative guidelines, as Sri Lanka has done (Box 15.3).

Box 15.3: Sri Lanka’s National Procurement Strategy: guidelines for procurement of pharmaceuticals and medical devices\textsuperscript{17}

Section 1.1. All pharmaceuticals procured must fulfil quality, safety and efficacy criteria. All medical devices procured should satisfy quality, safety, performance, effectiveness and efficacy criteria.

Section 1.2. The strategic objectives of procurement of pharmaceuticals & medical devices should be:

- procure the most cost-effective pharmaceuticals and medical devices in the right quantities;
- ensure supplier reliability with respect to service and quality;
- arrange timely delivery to avoid shortages and stock outs; and
- achieve the lowest possible evaluated cost.

Section 6. Pharmaceuticals and medical devices may be procured by International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited/restricted International Competitive Bidding (LIB), in accordance with the applicable provisions stipulated in [procurement guidelines], subject to any modifications contained herein.

Section 7.2. To ensure that the [procuring entity] obtains competitive prices the [procuring entity] should have reference to historical prices and may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health. [The procuring entity] may also consult with neighbouring countries on prices offered to them and inquire into the possibility of pooled procurement schemes.

Pharmaceutical drugs are estimated to account for 25\% of global health spending. However, 10–25\% of public spending on procurement is thought to be lost to corruption.\textsuperscript{18} WHO has published
guidance to assist public authorities to avoid corruption. Important steps include registering medicines on the national list, licensing importers of pharmaceuticals and medical equipment, licensing pharmacists and dispensers of drugs, inspecting facilities, controlling the advertising and promotion of medicines, introducing oversight mechanisms for clinical trials, and developing a comprehensive plan for selecting and procuring essential medicines. In Kenya, neutral observers are invited to be present at committee meetings where large tenders are considered (Box 15.4). Other legal strategies include giving legislative protection to whistle-blowers, requiring members of the national drug registration committee to file a conflict of interest declaration, and prosecuting acts of corruption in a timely manner.

**Box 15.4: Applying good governance principles to procurement strategies in Kenya**

<table>
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<tr>
<th>Public Procurement and Disposal Regulations, 2006</th>
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<td><strong>12. Procedure for tender committee meetings.</strong></td>
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<tr>
<td>(8) To enhance transparency of the procurement process the procuring entity shall invite in addition to the representative of various departments, at least two observers to attend its meetings in cases where the value of the contract is estimated to be above fifty million shillings.</td>
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<td>(9) At least one of the observers invited under paragraph (8) shall come from a duly recognized private sector organization or discipline relevant to the procurement under consideration.</td>
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In addition to minimizing corruption, a national drugs policy can reduce the systemic costs that create barriers to access to essential medicines. This can occur by eliminating tariffs on the import of drugs that are not produced domestically and by controlling the mark-ups that can be applied to drugs that are resold in the private and public sectors. In South Africa, mark-ups on the prices of drugs at the wholesale and retail levels have been replaced with a fixed fee (Box 15.5). Programmes that create incentives for pharmacists and medical practitioners to dispense or prescribe generic versions of drugs, where available, can also reduce the price paid by patients and improve access. Argentina, the Plurinational State of Bolivia, Peru and Uruguay all require physicians to use generic names when writing prescriptions: this allows pharmacists to fill orders with cheaper alternatives to brand name drugs when they are available.

**Box 15.5: Monitoring pharmaceutical pricing: South Africa’s National Drug Policy**

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<th>Section 4.1. Rationalization of the pricing structure</th>
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<td>• A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmacoeconomists, and representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives.</td>
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<tr>
<td>• There will be total transparency in the pricing structure of pharmaceutical manufacturers,</td>
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wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals.

- A non-discriminatory pricing system will be introduced and, if necessary, enforced.
- The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee. ...
- A database will be developed to monitor the cost of drugs in the country in comparison with prices in developing and developed countries.
- Price increases will be regulated.
- Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well-being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.

In addition, laws that ban or limit the advertising of pharmaceuticals direct to consumers can reduce patient demand for unnecessarily expensive drugs. Direct-to-consumer advertising stimulates the prescribing of advertised medicines, and is rare outside the United States, where commercial free speech by pharmaceutical manufacturers is protected by the Constitution. Finally, where a branded medicine has previously received regulatory approval, governments may encourage the supply of generic or bioequivalent versions of the same drug by offering a faster, preferential process for regulatory approval, together with discounted registration fees.

15.3 Access to medicines, patents and TRIPS

The national drugs policy adopted by each country needs to be consistent with international law governing intellectual property rights. Medicines, as well as the processes required to produce them, are patentable under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS is one of the family of agreements that Members of the World Trade Organization (WTO) are required to implement. In order to implement TRIPS, all Members of the WTO are required to enforce national legislation that recognizes and enforces pharmaceutical patents. This section reviews some features of national patent laws that may influence access to medicines, and the prices at which medicines are available for purchase, within the context of countries’ TRIPS obligations.

(a) The purpose of patents

A patent is an exclusive right that enables the patent holder to exclude competing suppliers during the term of the patent. In return, the patent holder publicly discloses their invention: this facilitates free use of this information when the patent expires. Like any other property right, a patent may be sold, licensed or transferred. Patent laws are intended to encourage investors to make the huge investments that are required to discover, develop and deliver a new drug to market. In theory,
patent protection helps to ensure the continued development and availability of medicines in future, provided that markets can generate a return to the patent holder for their costs of research and development. When patent regimes work well, they promote technological innovation, by ensuring a return on investment for the patent holder, while also ensuring the transfer and dissemination of technology and the continued availability of generic medicines after the patent has expired. However, since patents eliminate competition, they can also lead to high prices for medicines during the term of the patent.

High prices, as well as the scale of need for particular drugs, may combine to defeat the goal of providing universal access to a national list of essential medicines, especially in low-income countries. Furthermore, the incentive to invest in research and development in order to bring new medicines to market may not be present when the market value of the innovation is small. In the case of “neglected diseases” that disproportionately affect poor populations and low-income countries, patents have failed to achieve their objective as instruments of innovation since both governments and patients lack the purchasing power to create a market that justifies the necessary investment in the first place. A variety of other policy instruments will be required to overcome market failure and to encourage research and development of neglected diseases.

(b) The TRIPS Agreement and intellectual property rights

The TRIPS Agreement came into force on 1 January 1995. WTO Members were given different dates by which to amend their domestic laws and practices in order to protect patent rights on pharmaceuticals, according to their status as developing countries and whether or not they had any previously existing laws recognizing patents in this area. Under Article 66.1, least developed countries were originally given until 2006 to recognize and enforce patents on pharmaceuticals, although this date has since been extended to 1 January 2033. On two occasions, the Council for TRIPS has granted a broader extension of time to least developed countries to implement the substantive provisions of TRIPS (other than the non-discrimination provisions), most recently to 1 July 2021.

Article 27 of the TRIPS Agreement states that patents shall be available for both products and processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. The period of patent protection is 20 years. In the case of products, Article 28 states that the rights of a patent holder include the right to prevent third parties from “making, using, offering for sale, selling, or importing” the product without the patent holder’s consent.

Since the majority of medicines that WHO considers to be essential medicines are not under patent, it follows that the obligation of WTO Members to implement patent laws covering pharmaceuticals should not constitute a barrier to access for most drugs included in a national list of essential medicines. The extent to which patent protection for a particular medicine affects price and availability will depend upon the terms of patent laws and the patent status of that drug in each country, together with the existence of any voluntary or compulsory licences that have been issued. In cases where the period of patent protection has expired, generic versions of the drug may be produced and imported without infringing any patent rights. During the period of patent protection,
national authorities, as well as private suppliers, will need to negotiate with the patent holder on commercial terms for the price at which the medicine can be imported into that country, or alternatively, negotiate for a licence to manufacture the medicine within the country – assuming that there are no other generic medicines that are equally effective.

Article 63 of the TRIPS Agreement requires WTO Members to notify the Council for TRIPS about the national laws, regulations, and judicial and administrative decisions that affect the scope of protection for patents and other intellectual property rights, and to respond to requests from other WTO Members about the scope of their laws. Disputes between WTO Members about a Member’s compliance with its obligations under TRIPS are considered by a panel of experts who are appointed to hear each complaint. The panel’s decision may be appealed to the WTO Appellate Body. The TRIPS Agreement provides for the imposition of trade sanctions by a Member on behalf of the patent holder in cases where another Member has failed to implement the report of the panel or Appellate Body and to act in accordance with that Member’s obligations under TRIPS.

Despite their obligation to implement laws granting and enforcing patents on pharmaceutical products, WTO Members retain considerable scope to adjust their patent laws in order to achieve public health objectives. For example, national laws may authorize the judiciary, the executive, or an administrative body to issue a compulsory licence to manufacture or import a patented drug without the permission of the patent holder in circumstances where licensing negotiations with the patent holder have failed or in cases of emergency or government use, in order to achieve the government’s policy of providing universal access to medicines, diagnostics, vaccines or medical devices. The Declaration on the TRIPS Agreement and Public Health, adopted by Trade Ministers at the Doha Ministerial Meeting in November 2001, states that “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”. Although the TRIPS Agreement does not refer specifically to compulsory licences, the wording of Article 31 recognizes that national patent laws may authorize public, non-commercial uses of patents by or on behalf of government, where the conditions set out in Article 31 are satisfied (Box 15.6).

**Box 15.6: Flexibilities recognized in Articles 8 and 31 of the Agreement on Trade-Related Aspects of International Property Rights (TRIPS)**

### Article 8

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

### Article 31

**Other Use without Authorization of the Right Holder**

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. …

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization...

In addition to licences issued on public interest grounds, the practice of WTO Members illustrates that national laws may authorize compulsory licences on a number of additional grounds. 48 For example, Zimbabwe’s Patent Act provides that during periods of emergency (which legislators have authority to define), national laws may authorize the use of a patent without the permission of the patent holder, due to the scale of the health threat caused by a natural disaster, epidemic or security threat, as well as the physical interruption of supplies at affordable prices (Box 15.7). Other grounds for the issuing of a compulsory licence may arise where anti-competitive practices and pricing policies of patent holders have inflated drug prices to the point where they are no longer affordable, or where the patent holder has failed to exploit a patent or to license it within the jurisdiction.49

Box 15.7: Public, non-commercial (government) use of patents: Patent Act of Zimbabwe 50

Section 34. Use of patented inventions for service of the State

(1) Notwithstanding anything in this Act, any department of the State or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section.

Section 35. Special provisions as to State use during emergency

(1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient—

... (b) for the maintenance of supplies and services essential to the life of the community; or

(c) for securing a sufficiency of supplies and services essential to the well-being of the community.

At the WTO Ministerial Conference in Doha, Qatar, in 2001, WTO Ministers affirmed that TRIPS should be implemented in a way that supports the right of WTO Members “to protect public health and…to promote access to medicines for all”. 51 The Declaration pointed to a number of provisions in
TRIPS that may assist Members to adjust their domestic laws to provide adequate protection to drug manufacturers and other patent holders within the territory of each Member, while acting to ensure that essential medicines remain affordable for all:

- As stated above, each Member retains the right, in accordance with their national laws, to grant compulsory licences (which authorize the use of the patent without the permission of the patent holder) and to determine the conditions to be satisfied before the compulsory licence is granted.

- In addition, each Member retains the right to determine what constitutes “a national emergency or other circumstances of extreme urgency” within the terms of Article 31. In either case, Article 31 authorizes the Member to waive the requirement to first seek a licence from the patent holder on reasonable commercial terms before issuing a compulsory licence to use the patent without the consent of the patent holder.

- Each Member also retains the right to define the circumstances in which, under their national laws, the patent holder’s rights in a drug are exhausted.

The operation of these and other TRIPS flexibilities is discussed below.

(c) Awareness of TRIPS flexibilities

It is important for national health authorities to be aware of the flexibilities in the TRIPS Agreement when considering strategies to improve access to essential medicines, and to carefully consider their benefits before entering bilateral or regional trade agreements that limit any of these flexibilities.52 By agreeing to enforce intellectual property rights that are more extensive than those recognized under the TRIPS Agreement, the cost of providing universal access to a national list of essential medicines may rise substantially. WHO, the WTO and the World Intellectual Property Organization, as well as the Commission on Intellectual Property Rights, Innovation and Public Health (established by the World Health Assembly in 2003), have published detailed guidance to assist national authorities to improve access to essential medicines.53 The United Nations Development Programme54 and the World Bank55 have also published reports to assist countries to use the flexibilities in TRIPS effectively, having due regard to their obligations to respect patents and other intellectual property rights.

Article 31 requirements

Article 31 of the TRIPS Agreement states that in circumstances where the national law of a WTO Member permits a compulsory licence to be issued, the Member must first seek permission to use the patent from the patent holder on reasonable commercial terms. However, prior attempts to obtain access to the patented drug on commercial terms are not required in the case of a national emergency (which each Member is free to define), in other circumstances of extreme urgency, or in cases of public, non-commercial use – such as when a government is seeking to ensure universal access to essential drugs, or is using the patent for other government purposes (Box 15.6, above).
The operation of Article 31 is illustrated by the case of Thailand, which issued government use licences for seven medicines for the treatment of HIV and cancer, over the period 2006–2008.56 Thailand’s National Health Security Act of 2002 established a universal health care scheme that included a right of access to medicines on Thailand’s National List of Essential Medicines.57 In October 2003, the government declared its intention to provide universal access to triple antiretroviral therapy for people with HIV. However, the cost of providing this treatment rose rapidly, reaching nearly US$ 51 million (2.1 billion baht) in 2003.

In 2007, the Minister of Public Health, Dr Mongkol Na Songkhla, appointed two committees to support the implementation of government use licences. The first, the Committee on Price Negotiation of Patented Essential Medicines, sought to engage pharmaceutical companies in negotiations for price reductions. However, with the exception of imatinib, a cancer drug produced by Novartis, the discounts offered did not meet the Health Minister’s benchmark that the discounted price should be within 5% of the price of generic versions of the medicine.58 In the case of lopinavir/ritonavir, a fixed-dose combination used to treat HIV infection, the cost per patient for middle-income countries, including Thailand, was US$ 2967 per year, although this was reduced in August 2006 to US$ 2200 per patient per year.59 The government issued a compulsory licence. By early 2008, the number of patients using lopinavir/ritonavir had tripled.60

Thailand’s Minister of Public Health expressed the motivation for issuing compulsory licences for essential drugs, under Thailand’s Patent Act, as follows:

> When a government such as ours declares a ‘compulsory licence’ to allow for public non-commercial use of patented products by the government for the greater public good, we are doing so to increase access to these essential, often life-saving, medications for the poor and marginalized members of our communities who were not consumers of these expensive, patented drugs. The more well-off members of our society continue to consult their own private physicians and continue to pay – out of their own pockets – the price of patented medications.61

In order to establish a clear legal basis for exercising the flexibilities that are permitted under the TRIPS Agreement, WTO Member States should enact legislation that sets out the circumstances in which the government reserves the right to issue a compulsory license. Apart from the exceptions mentioned in Article 31(b), such legislation should provide for a reasonable, yet time-limited period for negotiating with the patent holder before the designated national authority issues the licence (see Box 15.8). The legislation can reduce the administrative difficulty of issuing a compulsory licence by specifying which Minister or administrative body should perform this function, the approval process required, and by prohibiting patent holders from unreasonably stalling the process through litigation.62

**Box 15.8: Legislation authorizing the issuing of a compulsory licence: Industrial Property Law63 of Brazil**

| Article 68. The patent owner shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or if he uses it to abuse economic... |
Article 73. An application for a compulsory licence shall set forth the conditions offered to the patent owner.

(1) After an application for a licence has been submitted, the patent owner shall be invited to submit his comments within a period of 60 (sixty) days, at the end of which, in the absence of a submission from the patent owner, the proposal shall be deemed accepted under the conditions offered.

(6) In the arbitration of the remunerations, the circumstances of each case shall be taken into consideration and shall include the economic value of the granted licence.

(7) Once the case has been examined, the National Institute of Industrial Property shall decide on the grant and on the conditions of the compulsory licence within a period of 60 (sixty) days.

(8) Appeals from decisions to grant a compulsory licence shall not have a suspensive effect.

In circumstances where a Member issues a compulsory licence without the authorization of the patent holder, Article 31 of the TRIPS Agreement requires the patent to be used “predominantly” in order to meet the domestic needs of the WTO Member that has authorized the licence, and “adequate compensation” (which TRIPS does not define) shall be paid to the patent holder. However, in 2005, WTO Members approved an amendment to the TRIPS Agreement, which permits these requirements to be waived where certain conditions are met.

**WTO General Council Decision of 6 December 2005**

The amendment approved in 2005 sets out a special procedure for the benefit of WTO Members whose domestic manufacturing sector lacks the capacity to manufacture the quantities of medicine that are needed. The procedure works by allowing a Member that does have adequate manufacturing capacity to issue a compulsory licence for the manufacture and export of a generic version of the patented medicine to a Member that lacks domestic manufacturing capacity. Box 15.9 summarizes some of the key conditions that apply.

**Box 15.9: Key conditions that apply to compulsory licences issued under the WTO General Council Decision of 6 December 2005**

- The importing Member must notify the Council for TRIPS of the names and quantities of medicines that it needs, and indicate that a compulsory licence has or will be granted for those medicines that are under patent within its territory.
- The compulsory licence issued by the exporting Member shall contain conditions restricting the manufacture of the patented medicine to the amounts that are necessary to meet the needs of the importing Member. The medicines themselves must be clearly identified as being manufactured under the scheme so that they cannot be improperly diverted to third markets. All the medicines produced in this way must be exported to the importing Member.
• The exporting Member must post the amounts being exported and the distinguishing features of the shipment on a website, and notify the Council for TRIPS about the compulsory licence and the conditions that apply to it.

• Eligible importing Members are required to take reasonable steps to ensure that medicines imported under the scheme are not re-exported.

In order to use this procedure, the importing Member must either be a least developed country or must have notified the TRIPS Council of its intention to use the procedure. Countries exporting pharmaceutical products under the procedure to an eligible importing country must also notify the TRIPS Council when they do so. Unless they have opted out of doing so, all WTO Members are eligible to use the procedure, whether as countries that issue a compulsory licence and manufacture medicines for export to the importing country, or as an importing country that lacks domestic manufacturing capacity of its own and seeks to import essential medicines to meet its health needs. WTO Members with established pharmaceutical industries have an important role to play in making the procedure set out in the TRIPS amendment work effectively. Patent laws in exporting countries can help to achieve this by not imposing additional conditions on licensees and importing countries above those that are already imposed by the TRIPS amendment itself. For example, the TRIPS Agreement does not require either the importing or exporting Member to engage in commercial negotiations with the patent holder in circumstances where the importing Member is facing a national emergency or using the patent for a public, non-commercial purpose; for example, in order realize a government commitment to providing universal access to essential medicines. Given that the importing Member may only be capable of paying a modest price for medicines manufactured under the compulsory licence, exporting countries may also consider offering tax incentives to encourage pharmaceutical manufacturers within their territory to participate in the scheme.

**Exhaustion of patent rights**

National patent laws dealing with the exhaustion of patent rights may also influence the price and availability of essential medicines within that country. Exhaustion governs the “extent to which a [patent] holder can prevent the resale and importation of genuine goods”, once they have been placed on the market with its consent in either the same or another country. For example, national patent laws may be framed so that once a patent holder has exported a drug into a national market, or licensed its manufacture within that country and received compensation for doing so, the patent holder’s intellectual property rights in that drug are taken to be exhausted (so-called international exhaustion). Patents legislation that permits the resale or import of medicines that have been legitimately placed on the market by or with the consent of the patent holder in another country stimulates competition and helps to keep prices low. Medicines imported into a country in these circumstances may be unauthorized, but will not be infringing any patent rights, since the patent holder has authorized their first sale.

The practice of importing genuine products that have been placed on the market by the patent holder (or authorized licensee) in another country, without the permission of the patent holder, is known as “parallel importing”. By engaging in parallel importing, the importing country seeks to avoid the need to purchase the drugs at a higher price within their own domestic market, or to
negotiate with the patent holder for a licence on commercial terms. The importation of genuine pharmaceuticals from another country without the permission of the patent holder does not breach the TRIPS Agreement, since TRIPS leaves WTO Members free to establish their own laws for the exhaustion of intellectual property rights.\textsuperscript{73}

The principle of exhaustion can be implemented at the national, regional or global levels. For example, if the principle of international exhaustion applies within the domestic law of an importing country, the patent holder’s rights will be exhausted after the first sale anywhere in the world. An importing country will therefore be able to import medicines lawfully placed on the market anywhere in the world without infringing the patent holder’s rights.\textsuperscript{74} By contrast, if a principle of domestic exhaustion, or, alternatively, regional exhaustion, is applied, the patent holder would only lose the right to object to the resale of medicines within that country, or within the region, respectively.

The practice of parallel importing may constitute an infringement of the patent within countries that have adopted a principle of national exhaustion. By contrast, countries that implement a principle of regional or international exhaustion within their national patent laws may be able to resist the efforts of the patent holder to segregate markets and to insulate them from the cheaper prices that may be achieved through parallel importation from countries outside the region, or from any other country, respectively. Even in circumstances where national patent legislation adopts the principle of international exhaustion, there may be other obstacles to the practice of parallel importation. For example, if the export of medicines by an international distributor would breach a term of the distributor’s licence, the result may be that within the domestic law of the importing country, parallel importation is regarded as a violation of the rights of the patent holder.\textsuperscript{75}

As Box 15.10 illustrates, Kenya revised its intellectual property laws in 2001 to authorize the parallel importation of pharmaceuticals that were legitimately on the market in the exporting country. As confirmed by clause 37 of Kenya’s Industrial Property Regulations (2002), this would not authorize the import and sale of pirated or stolen medicines that could not lawfully be sold in the country of export.\textsuperscript{76} On the other hand, it confirms the principle of international exhaustion by permitting Kenya to import medicines from any country in which those medicines are lawfully available for sale.

**Box 15.10: Legislation authorizing parallel imports: an example from Kenya**

\begin{quote}
**Industrial Property Act**\textsuperscript{77}

Section 53. (1) The applicant or the owner of the invention shall have the following rights:

(a) to be granted the patent, where the relevant requirements under this Act are fulfilled;

(b) after the grant of the patent and within the limits defined in section 58 to preclude any person from exploiting the patented invention in the manner referred to in section 53; and

(c) to conclude licence contracts as provided for in Part X of this Act, and subject to the obligations referred to in subsection (2). ...

Section 58. (2) The rights under the patent shall not extend to acts in respect of articles which have
\end{quote}
been put on the market in Kenya or in any other country or imported into Kenya.

... 

(5) The rights under the patent shall be limited by the provisions on compulsory licences for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions.

(6) The rights of the patent shall not extend [to] variants or mutants of living forms or replicable living matter that is distinctively different from the original for which patents were obtained where such mutants or variants are deserving of separate patents.

**Industrial Property Regulations**

Section 37. The limitation on the rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.

**Restrictions on incremental patents**

The TRIPS Agreement requires WTO Members to grant patents for all products and processes “provided that they are new, involve an inventive step and are capable of industrial application”.79 Patent holders may seek patents for minor improvements or adjustments to a drug, such as another crystalline form, an alteration of the form of delivery, a dosage form, or for new uses of an existing drug (second medical indications). While some incremental innovations can bring important benefits to patients, some of these patents may simply serve to delay the entry of cheaper, generic versions into the marketplace. While incremental patenting (also called life-cycle management or “evergreening” – depending on the point of view) may increase the return on investment for the patent holder, it may also keep prices high. National governments seeking to ensure access to essential medicines at the lowest prices may consider amending their patent laws or the guidelines for patent examiners in order to restrict the award of patents to products that can truly be said to involve an inventive step and to be “novel”, resisting pressure to permit patents for small alterations, or new therapeutic uses of existing chemical compounds (**Box 15.11**).

**Box 15.11: Prohibiting patentability of minor adjustments to a pharmaceutical product in the Andean Community**

**Andean Community Decision: Common Intellectual Property Regime**

Article 21. Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

India’s Patents Act provides an example of national legislation intended to restrict the practice of incremental patents.81 India amended its national patent laws in 2005 to bring them into compliance with TRIPS. In *Novartis AG v Union of India*,82 the Supreme Court of India explained the statutory
requirements that must be satisfied. The Patents Act provides for patents to be granted for “inventions”. An invention must be:

- new;
- capable of industrial application; and
- must involve an inventive step that: (i) involves a technical advance over previous knowledge or has economic significance; and (ii) makes the invention not obvious to a person skilled in the art.  

However, under Indian law, not all innovations will fulfil the requirements for patentability. For example, the Act provides that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not an invention within the meaning of the Act. The Act also states that “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”.  

Novartis AG had applied for a patent for imatinib mesylate salt in beta crystalline form (brand name: Glivec), a drug used in treatment of leukaemia and a number of other forms of cancer. In the Novartis case, the Supreme Court of India explained that the bar for patentability is set higher for pharmaceuticals and chemical substances, since in addition to being an “invention”, the medicine must pass the hurdle set out in section 3(d), which excludes from patent different chemical forms of the same substance. The court accepted that “all the pharmacological effects of imatinib mesylate in beta crystalline form are equally possessed by imatinib in free base form”. Although Indian legislation does not exclude patent protection for incremental inventions of pharmacological substances that “lead to an enhancement of therapeutic efficacy”, there was no evidence before the court that the beta crystalline form of imatinib mesylate met this requirement.

**Regulatory review exception**

Article 30 of the TRIPS Agreement permits Members to pass legislation creating limited exceptions to patent rights, provided that they do not “unreasonably conflict with a normal exploitation of the patent”. This exception is generally recognized to permit national legislation authorizing researchers to conduct research on (and in some cases, research carried out using) the patented invention. For example, the Common Intellectual Property Regime of the Andean Community provides that the rights of the patent holder do not extend to “acts carried out exclusively for the purposes of teaching or scientific or academic research” (Box 15.12).

**Box 15.12: Exemptions from patent infringement liability: examples from the Andean Community and Kenya**

<table>
<thead>
<tr>
<th>Andean Community Decision: common intellectual property regime</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 53. A patent owner may not exercise the right referred to in the previous article with respect to the following acts:</td>
</tr>
</tbody>
</table>
(a) acts carried out in a private circle and for non-commercial purposes;
(b) acts carried out exclusively to experiment with the subject matter of the patented invention;
(c) acts carried out exclusively for the purposes of teaching or scientific or academic research;
...
(e) where the patent protects biological material that is capable of being reproduced, except for
plants, using that material as a basis for obtaining a viable new material, except where the patented
material must be used repeatedly to obtain the new material.

Kenya: Industrial Property Act
Section 58(1). The rights under the patent shall extend only to acts done for industrial or commercial
purposes and in particular not to acts done for scientific research.

Another common exception permits an applicant seeking marketing approval for a generic version of
a drug (and any other parties producing the active ingredient within the medicine) to use the patent
for the purposes of producing the drug and meeting regulatory requirements. For example, Canada’s
Patent Act stipulates that:

It is not an infringement of a patent for any person to make, construct, use or sell the patented
invention solely for uses reasonably related to the development and submission of information
required under any law of Canada, a province or a country other than Canada that regulates the
manufacture, construction, use or sale of any product.

In 2000, a WTO Panel confirmed that the regulatory review exception, as set out in Canada’s
legislation, is authorized by Article 30 of TRIPS. This interpretation facilitates the more rapid
introduction of cheaper, generic versions of a medicine into a national market after the brand name
patent has expired. However, while the patent provisions of TRIPS may not prevent an applicant
from seeking marketing approval for a generic version of a drug during the patent period, the
capacity to obtain early approval for generics may also be affected by legal requirements protecting
the exclusivity of test data, as explained below.

Protection of test data

Irrespective of whether a drug patent has expired, the capacity of generic drug manufacturers to
manufacture a particular drug may also be affected by national laws regulating the protection of test
data. The process of developing a pharmaceutical drug will involve the generation of a significant
amount of test data relating to the efficacy and pharmacological effects of the drug. These data will
be generated through clinical trials and other tests, and are a product of the efforts of the
originating company.

Not all countries will have the capacity to independently evaluate the safety, quality and efficacy of
pharmaceutical products submitted for marketing approval within a national market. Some
countries may simply rely on the fact that marketing approval has been granted by the United States
Food and Drug Administration, or by authorities in other countries. However, in cases where a
country requires the submission of test data as a condition to granting marketing approval, the TRIPS
Agreement requires WTO Members to protect such data against disclosure, except where steps have been taken to “ensure that the data are protected against unfair commercial use”. The requirement to protect test data only arises in circumstances where: data have not previously been published and have been generated through considerable effort, where the country reviewing a pharmaceutical product requires the submission of test data as a condition of giving marketing approval, and where the product itself utilizes “new chemical entities”.

The TRIPS Agreement does not define what constitutes “unfair commercial use”, nor is there authoritative WTO jurisprudence that settles this issue. Intellectual property laws in many developed countries recognize a fixed period of data exclusivity that disentitles regulatory authorities from relying on test data for periods of between five and 10 years from the date on which the originator product obtained marketing approval. Since the protection of test data is a distinct category of intellectual property, data exclusivity may be protected under national law regardless of whether a valid patent exists in respect of the same product in the same national market.

Where national laws grant data exclusivity protection to the holder of a pharmaceutical patent, regulatory authorities will not be entitled to rely on those data when considering subsequent applications for marketing approval for generic substitutes of the brand name drug. As a result, an applicant seeking marketing approval for a generic may be obliged to “duplicate tests (often involving suffering of animals) in order to reach results that are already known”. Data exclusivity may also interfere with the issuing of a compulsory licence, “as the entry of the generic product would be delayed for the duration of the exclusivity period or for the time it takes to undertake a new compilation of test data”.

Policy-makers in developing countries have considerable flexibility to define what constitutes “unfair commercial use”, and to ensure that any period of data exclusivity granted in legislation is appropriately balanced with the goal of ensuring a competitive market for the supply of essential medicines. For example, national laws may grant national authorities and courts the right to declare that the use by a generic manufacturer of a patent holder’s test data does not constitute “unfair commercial use” in circumstances where the government is issuing a compulsory licence to ensure wider access to essential medicines at affordable prices under a national drugs policy. To the extent that national courts and authorities give a wide interpretation to the exceptions recognized in data exclusivity provisions, they will facilitate faster access to essential medicines as soon as the patent expires, and support the efforts of national governments to realize this aspect of the right to health.

(d) Voluntary licence agreements for essential medicines

Pharmaceutical companies that hold patents or other intellectual property rights over essential medicines can decide when and how to exercise their exclusive rights and as a result may choose to enter into voluntary licences with third parties, such as generic producers, to produce, market and distribute a particular drug within a specified territory. Where the licence is non-exclusive and foresees moderate royalties or is royalty-free, the licence may encourage competition between generic producers to supply the market within the authorized territory, thereby reducing the market...
price. Voluntary licences have been widely used by companies producing HIV medicines, and could have a significant impact on the global epidemic of hepatitis C. To avoid legal disputes, it is important for the voluntary licence to clearly set out the actions that licensees are permitted to take, and the territories to which the licence extends.

Voluntary licences are part of a broader set of strategies that pharmaceutical companies can use, as part of their corporate social responsibility or humanitarian programmes, to increase access to essential medicines at affordable prices. Other strategies include tiered pricing, donation of drugs, non-filing of patents in least developed countries, and non-enforcement of patents. The originator company or rights owner may formalize their decision not to enforce patent rights by making a non-assert declaration, or by entering into a non-assertion covenant or immunity-from-suit agreement that sets out the conditions under which the rights owner will not enforce their patent rights.

The Medicines Patent Pool (MPP), established by the International Drug Purchase Facility (UNITAID) in 2006, negotiates licence agreements with patent owners and enters into sublicensing agreements with generic companies to produce licensed drugs and drug combinations for low- and middle-income countries. For example, in 2015, AbbVie entered into an agreement with MPP to grant non-exclusive, royalty-free sub-licenses for the manufacture and sale of lopinavir and/or ritonavir (LPV/r), two second-line HIV drugs, for prevention and treatment of HIV within (all) African countries. This licence agreement requires sub-licensees to demonstrate their capacity to manufacture these compounds in a manner consistent with WHO prequalification standards, to agree not to divert them outside African countries where this would infringe an existing AbbVie patent, and to cooperate in pharmacovigilence reporting responsibilities. In 2015 the MPP was expanded to include drugs for tuberculosis and hepatitis. The first licence issued for declatasvir, a hepatitis C drug, covers 112 countries.

There are a number of variables within licensing agreements that may help to increase competition and to reduce the market price for essential medicines. For example, royalty-free, non-exclusive licences – which include a large number of countries within the licensed territory, permit sale to both the public and private sector, and permit licensees to source active pharmaceutical ingredients from anywhere in the world – are more likely to encourage robust competition and the economies of scale that are needed to substantially reduce prices. Other variables that support access include the publication of licence agreements, permitting licensees to supply countries that issue compulsory licenses in accordance with TRIPS flexibilities, and not restricting the rights of licensees to challenge the licensor’s patent or to market the drug in countries where it is not under patent. Where the originator company permits the licensee to rely on its pharmaceutical data, this may speed up the process of obtaining marketing approval for the drug in countries where data exclusivity provisions apply. Originator companies may also contribute to local capacity in the manufacture and distribution of essential medicines by including technology transfer components within the licence. For example, the originator company may offer support to the licensee in meeting quality standards for manufacturing, packaging and storage, as well as registration requirements applicable within the authorized countries. Conversely, generic companies may also contribute expertise to the partnership with the originator company through their knowledge of registration processes and supply chain management within the authorized countries.
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77 The Industrial Property Act, 2001 (Republic of Kenya).

78 TRIPS Agreement, Article 27.

79 TRIPS Agreement, Article 27.


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