Compulsory Licences: Law and Practice in Thailand

Jakkrit Kuanpoth

Contents

Abstract When the WTO/TRIPS Agreement entered into force in 1995, around 100 countries had adopted compulsory licensing under national intellectual property law. The compulsory licensing measure can be effective in dealing with situations inhibiting access to medicines, for example when a patent holder fails to use the patent in the granting country or when he or she maintains artificially high prices for patented articles. Despite the significant international development, it remains to be seen how the flexibility margins provided by the TRIPS provisions can be used as safeguards to protect public health interests of the poor countries. Effective mechanisms are also required to support countries that are unable to make effective use of compulsory licensing due to the inefficiency of manufacturing capacity. This chapter examines the problem of using the legal mechanism of compulsory licensing by developing countries. It looks at Thailand's experiences with the use of compulsory licensing to increase access to medicines. Since the

J. Kuanpoth is Associate Professor and Head of Postgraduate Studies.

J. Kuanpoth
Faculty of Law, University of Wollongong, Wollongong, NSW, Australia
e-mail: jakkrit@uow.edu.au

R.M. Hilty and K.-C. Liu (eds.), *Compulsory Licensing*, MPI Studies on Intellectual Property and Competition Law 22, DOI 10.1007/978-3-642-54704-1_4,

majority of compulsory licences issued around the world are related to pharmaceutical patents, the chapter highlights the use of compulsory licensing in the context of a range of public health responses. It first discusses the use by Thailand of the compulsory government use licensing to increase access to medicines. It also examines international rules on compulsory licensing, including the provisions of the Paris Convention, the TRIPS Agreement, and the Doha Declaration on the TRIPS Agreement and Public Health. Finally, the chapter discusses various legal issues under the Thai Patent Act regarding the compulsory licensing provisions. It also highlights the possible impact, in a broad sense, of the use of legal mechanisms such as compulsory licensing, which aims to effectively maintain fair market competition and dilute the monopoly power of the patent holder.

1 Introduction

Essential medicines are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms and at a price that individuals and the community can afford. Essential medicines save lives and improve health only if they are available, affordable, and properly used. Nowadays, despite the potential health impact of essential medicines, and despite substantial spending on medicines borne by either the government or the patient, lack of access to essential medicines remains a serious public health problem in many developing countries. Over one-third of the population in developing countries in Asia and Africa still do not have regular access to needed medicines. It is even more tragic that most leading causes of death and disability in many developing countries can be prevented, treated, or alleviated with effective essential medicines.

Affordable prices are fundamental for improving access to medicines. Although the prices of essential medicines have significantly decreased in many cases, compared with local purchasing power in many developing countries, they remain too high. The high level of medicine prices stems from several factors, including lack of price competition, a non-transparent markup system, taxes and tariffs on medicines, the preference of health professionals and consumers for branded products instead of cheaper generics, and the lack of alternative sources for patented medicines.[1] Patent protection for pharmaceuticals is the main factor that leads to the restricted supply and overpricing of an essential product. Stricter patent protection has allowed firms to increase market share and charge high prices. The question of constraints as regards pharmaceutical patenting has been a subject of serious concern and has been intensely debated in the WTO meetings, which led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health at

[1] Kuanpoth (2006), pp. 31–36.

the WTO Ministerial Conference in Doha in November 2001.[2] The Declaration was an important step forward in improving access to medicines. It affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the WTO members' right to protect public health and that mechanisms, such as compulsory licensing, can be used to improve access to medicines for all.[3]

Compulsory licensing is a non-voluntary licence issued by the State authorising a third party to perform acts covered by the patents against the will of the patent holder. When the TRIPS Agreement entered into force in 1995, around 100 countries had adopted compulsory licensing under national intellectual property law.[4] This measure can be effective in dealing with situations inhibiting access to medicines, for example when a patent holder fails to use the patent in the granting country or when he or she maintains artificially high prices for patented articles. Despite the significant international development, it remains to be seen how the flexibility margins provided by the TRIPS provisions can be used as safeguards to protect public health interests of the poor countries.[5] Effective mechanisms are also required to support countries that are unable to make effective use of compulsory licensing due to the inefficiency of manufacturing capacity.

The aim of the chapter is to examine the problem of using the legal mechanism of compulsory licensing by developing countries. It will take a close look at Thailand's experiences with the use of compulsory licensing to increase access to medicines. Since the majority of compulsory licences issued around the world are related to pharmaceutical patents, this chapter will focus on the use of compulsory licensing in the context of a range of public health responses. The chapter is organised and divided into three major sections. First, it discusses the use by Thailand of the compulsory government use licensing to increase access to medicines. The second part examines international rules on compulsory licensing, including the provisions of the Paris Convention, the TRIPS Agreement, and the Doha Declaration on the TRIPS Agreement and Public Health. Third, the paper discusses various legal issues under the Thai Patent Act regarding the compulsory licensing provisions. It also highlights the possible impact, in a broad sense, of the use of legal mechanisms such as compulsory licensing, which aims to effectively maintain fair market competition and dilute the monopoly power of the patent holder.

[2] WTO Ministerial Conference (2001); See also Abbott (2005), pp. 317–358.

[3] Scherer and Watal (2002), pp. 913–939.

[4] Lybecker and Fowler (2009), pp. 222–239.

[5] Scherer and Watal (2002), p. 317.

2 Government Use Licensing in Thailand on Patented Heart Disease and HIV/AIDS Medicines

In November 2006 and January 2007, the Thai Ministry of Public Health issued government use licences against patents over three medicines: (1) efavirenz, Merck's anti-HIV drug (branded 'Stocrin'); (2) lopinavir/ritonavir (branded 'Kaletra'), an ARV distributed by Abbott Laboratories; and (3) clopidogrel, an anti-clotting drug sold by Sanofi-Aventis and BMS. Clopidogrel, which is sold under a brand name 'Plavix', is one of the world's biggest selling heart disease medicines, with annual sales of US$6 billion. It was estimated that around 200,000 Thai patients were suffering from heart conditions and blood clotting problems that could be treated with the drug. Although the past decade has seen a number of developing countries granting compulsory licences,[6] Thailand was the first developing country that issued a government use licence for a non-HIV medicine. The grant of a compulsory licence over a non-HIV drug reflected Thailand's view that the compulsory licensing can be used for patented medicines treating all sorts of ailments, not only HIV/AIDS.

As for drugs required for the treatment of HIV/AIDS, the Ministry of Public Health claimed that only around 20,000 infected people were able to access the HIV treatment.[7] The Thai Government pointed to high drug prices as the main factor for its inability to provide health care coverage. In the 2007 fiscal year, for example, public health accounts for 9.5 % of the total public expenditure, which is equivalent to 4,373 million baht (about US$112 million).[8] With this amount, the Government claimed that it could afford to provide medicines to one-fifth of the total 500,000 of the Thai people living with HIV/AIDS at the companies' price. The issuance of compulsory licences would allow the Ministry of Public Health to treat many more patients because it could switch to a generic version of the drugs that costs, on average, only one-seventh to one-tenth the prices of the patented and branded products, cutting the drug bill by two-thirds.[9]

HIV/AIDS is one of the leading causes of death in Thailand. Approximately, 300,000 have already died from HIV/AIDS-related illnesses since Thailand's first case of HIV/AIDS was reported in 1984.[10] The Thai Government started its

[6] The developing countries that have issued compulsory licences for patents on essential drugs include the following: Zimbabwe (April 2003: all ARV medicines), Malaysia (October 2003: didanosine, zidovudine, and FDC didanosine), Zambia (September 2004: FDC lamivudine+stavudine+nevirapine), Indonesia (October 2004 and March 2007: lamivudine and nevirapine, and efavirenz; September 2012: efavirenz, abacavir, didanosine, lopinavir, ritonavir, tenofovir, tenofovir/emtricitabine, and tenofovir/emtricitabine/efavirenz), Thailand (November 2006 and January 2007: efavirenz and lopinavir/ritonavir), Brazil (May 2007: efavirenz).

[7] Ministry of Public Health and National Health Security Office (2007), pp. 5–8.

[8] *Id*.

[9] Yamabhai et al. (2011), p. 28. See Baron (2008).

[10] WHO/UNAIDS/UNICEF (2007).

HIV/AIDS campaigns in the early 1990s with emphasis on prevention, which has subsequently proved to be remarkably successful in slowing down the rate of HIV infections.[11] In 1992, the Ministry of Public Health shifted its HIV/AIDS policy from prevention to the subsidisation of anti-retroviral (ARV) treatment and the introduction of locally produced, low-cost ARVs.[12] At the beginning of the campaigns, only mono-ARV therapy (i.e., AZT or zidovudine) was prescribed free of charge for a small number of selected HIV patients. However, drug resistance occurred as the virus evolved to escape the inhibitory effects of the drug, requiring a change of medication. The Ministry was forced to switch to the combination therapy of using two or three drugs, which is more potent in suppressing the virus but also more expensive than a single therapy, to treat HIV/AIDS.

In its early stage, the national health insurance scheme, which was introduced in 2002, did not cover ARV treatment, due to the high cost of drugs and limited public budgets, despite the fact that the Government was committed to providing universal access to all treatments, including ARVs. Many HIV/AIDS patients who received treatment under the national HIV/AIDS campaigns were forced to discontinue their treatment due to the limitations on the capacity of health systems. Since it was clear that the cost of ARVs far exceeds personal and national budgets, the Thai Government felt that it had no choice but to take different approaches to bring down the cost of ARVs, ranging from local manufacture or importing of generic medicines to coercive government use of patented drugs.

The Government instructed the Government Pharmaceutical Organisation (GPO), a state enterprise under the Ministry of Public Health, to carry out research and development in order to manufacture off-patent medicines. This led to the successful production of an ARV cocktail called GPO-vir (i.e., a fixed-dose combination of stavudine, lamivudine, and nevirapine), which costs US$31 per patient per month, compared to US$490 per patient per month for the imported brand-name drugs.[13] The issued government use licences authorised the Ministry of Public Health to import generic versions of the patented medicines from the countries where the prices are lower. In fact, a licence granted in November 2006 permitted the Ministry to import a batch of 66,000 bottles of generic efavirenz from India at half the price offered by Merck, increasing access to life-saving drugs for an additional 20,000 patients.

These strategies have increased Thailand's ability to provide basic health care services to its people. They have also made treatment with selected ARV medications available for all Thais under the national health care system since October 2005. There are several success factors contributing to the improvement of access to medicines in Thailand, including the country's relatively good health care and reliable supply systems, and the Public Health Ministry's policy that enhances

[11] Piot and Seck (2001), pp. 1106–1112.

[12] United Nations Development Programme (2004), pp. 13–18.

[13] The comparative prices quoted here refer to the prices offered by the GPO and the multinational companies during 2000–2002.

rational selection and use of drugs. The existence of a significant local capacity to manufacture generic drugs and capacity to research and manufacture affordable medicines is also critical to ensure accessibility, particularly over the longer term. The GPO is currently producing most of the first-line regimens of ARVs required for the local market. It also exports ARVs it produces to other developing countries at affordable prices. Finally, a combination of domestic capacities and the use of appropriate strategy such as the use of the non-voluntary licensing, among other factors, have increased the Thai Government's bargaining power in negotiations with brand-name companies over price discounts.

It is interesting to note that the use of the compulsory licensing by the Thai Government has attracted a variety of reactions.[14] The owners of the affected drugs expressed their concerns about the process of compulsory licensing. They maintained that the compulsory use of the patents by Thailand violated WTO/TRIPS rules. The arguments against the use of compulsory licensing by the Thai Government can be summarised as follows[15]:

- The Thai government did not engage in negotiations with the patent holder before issuing a compulsory licence.
- Thailand had not declared an emergency before announcing the licence.
- The Thai compulsory licensing does not meet the requirement of "public non-commercial use". The compulsory licences were issued to the GPO, a state enterprise under the Ministry of Public Health that operates on a for-profit basis.
- The royalty rate of 0.5 % of the total sale value to be paid to the patent holder is considered arbitrary and too low.
- The use of the compulsory licensing would reduce the patent owner's profits, thereby decreasing the incentive to continue research and development.

Thailand refers to the rules available in the WTO/TRIPS to justify its action on compulsory licensing. The Ministry of Public Health also contended that it was engaged in extensive discussion with the right holders for more than 2 years before it finally decided on government use licensing.[16] The use of the drugs by the State, according to the Ministry, would not affect the patented market, as the medicines distributed under the non-voluntary licensing scheme would be for those unable to pay, most of whom are already covered by the universal coverage. After the licences were granted, the two parties held several rounds of dialogue. The compulsory licensing had led the pharmaceutical companies to seek serious discussions with the Ministry, in which they finally agreed to lower their prices.

The move by the Thai Government brought an angry response from the Office of the United States Trade Representative (USTR).[17] In its 2007 and 2008 reviews, the

[14] United States Government Accountability Office (2007).

[15] PReMA (2007).

[16] Intellectual Property Watch (2007).

[17] Bangkok Post (2008).

USTR exerted extraordinary pressure on Thailand by placing Thailand on the Priority Watch List (PWL) under Special 301 of the Omnibus Trade and Competitiveness Act of 1988. It also threatened to revoke the trade privileges it grants to Thailand under the Generalised System of Preferences. The leverage, which was previously successfully applied by the United States on Thailand in 1992, causing Thailand to amend its patent law to protect pharmaceuticals,[18] is clearly pressure to discourage government use licensing. Furthermore, the fear of compulsory licensing has caused the United States to limit and prevent the compulsory licensing scheme under the bilateral Free Trade Agreement (FTA) it has negotiated with Thailand since 2003. The United States intends to use the bilateral platform to negotiate change in the patent law of Thailand on compulsory licences. In the FTA negotiations, it demanded Thailand to implement stricter laws concerning the licensing scheme, including, *inter alia*, narrowing the situations in which non-voluntary licences can be issued.[19]

So far, this chapter has provided a background on the case of non-voluntary licensing in Thailand. The next sections will present a theoretical and practical analysis of the international and national rules regarding the compulsory licensing mechanism.

3 International Law on Compulsory Licensing

A compulsory licence allows a government to authorise itself or a third party to perform acts covered by the patent exclusive rights (e.g., manufacturing, selling, or importing the patented product). The TRIPS Agreement does not mention the term 'compulsory (or non-voluntary) licence' throughout its text. It only authorises 'other use[s] of the subject matter of a patent without the authorisation of the right holder'. TRIPS Article 31 establishes the conditions under which WTO Members may grant a compulsory licence but does not limit the grounds upon which such licence can be granted. This provision, in conjunction with Article 2.1 of TRIPS and Article 5A(2) of the Paris Convention for the Protection of Industrial Property 1883, authorises the granting of compulsory licences in a wide variety of contexts, including non-working of patents, public non-commercial use, anti-competitive practices, etc.

[18] Sell (2002), pp. 500–501.

[19] Kuanpoth (2006), p. 17.

3.1 Compulsory Licensing to Enforce the Working Requirement

3.1.1 The Paris Convention

The function of the modern patent system is based on reciprocity between the granting state and the patent owner. Patent law of many countries requires the patent holder to work his/her invention within the country. Paris Union members may adopt measures to compel local working of patents subject to certain conditions. According to Article 5A of the Paris Convention, the member states cannot revoke patents they have granted by relying on the ground that the patentee has exploited his/her patent by means of importing the patented articles manufactured abroad into the country. This provision effectively recognises the monopoly power of the patentee to import a patented product. At the same time, it discourages local production of the patented products where a patent holder can import finished and lower cost products into the country.

Although the Paris Convention does not explicitly stipulate that patents must be effectively exploited in the granting state, the parties are entitled to enforce local working for national benefits.[20] As authorised by Article 5A, each member has a right to adopt legislative measures to prevent abuses of a patent holder's exclusive rights. The legal measures mentioned in the provision include compulsory licensing and forfeiture of patents. Paris Union members have a right to issue a compulsory licence to a third party for the prevention of patent abuses resulting from the exclusive right under a patent. An example of the abuses is provided in Article 5A(2), namely 'failure to work'. However, the term 'failure to work' in this provision is not clearly defined by the Convention. The lack of a definition may create uncertainty in the parties who are considering applying for a compulsory licence.

In addition to compulsory licensing, members of the Paris Union may impose forfeiture of the patents they have granted. But under Article 5A(3), the right to forfeit is subject to two conditions. First, a member state may prescribe forfeiture of the patent only in cases where a compulsory licence has already been granted and such a licence is inadequate to prevent the non-working or the insufficient working. Second, the forfeiture shall not be applied before the expiration of 2 years from the grant of the first compulsory licence. These requirements have made forfeiture of patents a secondary measure, subject to the condition that the use of compulsory licensing has proved to be ineffective.

It may be noted that some countries, particularly the United States, are dissatisfied with the existence of this provision. They take the view that allowing States to expropriate private proprietary rights is unfair and might lead to serious distortions of legitimate trade. At the Washington Conference in 1911 and the third and the

[20] Roffe (1974), pp. 15–26.

fourth sessions of the Diplomatic Conference on the Revision of the Paris Convention (held in 1982 and 1984, respectively), the United States and its allies proposed to prohibit the use of the compulsory licensing for local working. However, Paris Union members failed to reach an agreement on amending Article 5 of the Paris Convention.[21]

3.1.2 The TRIPS Agreement

While the Paris Convention recognises that local working may be required by the patent-granting state, the TRIPS Agreement does not address the issue of local working. Article 27.1 of the TRIPS Agreement requires equal treatments for both imported and locally manufactured products and so seems to prohibit the imposition of local working requirements.[22] However, there are several reasons to believe that TRIPS does not totally ban local working of patents. First, TRIPS does not limit the right of countries to establish compulsory licensing on grounds other than those explicitly mentioned in the Agreement. Second, the patent-granting country might impose working obligations in accordance with Article 5A of the Paris Convention, which is incorporated into TRIPS by virtue of Article 2.1 of the TRIPS Agreement.[23] Third, as Article 27.1 is a provision containing general rules of patentability, it is subject to specific rules under Article 28 (Rights conferred) and Article 31 (Other use without authorisation of the right holder) of the TRIPS Agreement.[24] According to a general rule of treaty interpretation under the Vienna Convention on the Law of Treaties, when general principles are in conflict with a specific provision, the specific rule shall take precedence. The particular or specific provision on compulsory licensing such as Article 31 will therefore take precedence over a conflicting general provision of Article 27.1.

Professor Carlos Correa contends that the Article 27.1 text must be read in conjunction with Article 28.1 and that the requirement of non-discriminatory treatment will apply to infringing products only, not the products coming from the patent owner. According to Correa, the provision "forbids discrimination between infringing imported and infringing locally made products, but it does not rule out the establishment of differential obligations with regard to non-infringing imported and locally-made products (i.e. products made or imported by the patent owner or with his/her consent)".[25] It is interesting to note that patent laws of most developed countries still continue to regard the local working obligation as an

[21] Bodenhausen (1991), pp. 30–34.

[22] Doane (1994), p. 465; Adelman and Baldia (1996), p. 507; Foster (1998), p. 283.

[23] Correa (2005), pp. 227–256.

[24] Champ and Attaran (2002), p. 365.

[25] See *supra* note 23, p. 243.

essential element to balance the patent system. Accession to the TRIPS Agreement has not led those countries to change their local working provisions.[26]

3.2 Government Use Licensing

The non-voluntary licensing for government use derived from 'Crown use' under English common law. By granting exclusive rights to the patent holder, the Crown reserved the right to use patented inventions without the consent of or paying compensation to the patent holder.[27] The government use provision is considered necessary and in the larger public interest and incidental to sovereign powers and functions of the State. Although the Paris Convention provisions are silent on the issue of government use,[28] this licence regime can be found in the law of many countries, including United States patent law (35 USC 181; 28 USC 1498), United Kingdom Patents Act 1977 (ss. 55–59), Australia Patents Act 1990 (ss. 163–169), etc. Countries, both developed and developing, implement such powers in the widest terms to cover all possibilities, particularly those involving national security, emergencies, defence, and public needs such as health care, environment, and other matters of necessity. For example, section 56 of the UK Patents Act 1977 provides for the use of patented inventions by the Crown in cases of supply for foreign defence purposes, production or supply of drugs and medicines, and production or use of atomic energy or research considered by the government agency to be necessary or expedient.

The government use provision is of special interest and a significant tool to achieve social and economic functions of the patent system. Articles 7, 8, and 31 of the TRIPS Agreement clearly intend to extend the social benefits of patents to other areas than the provisions of the Paris Convention. The Doha Declaration on the TRIPS Agreement and Public Health reaffirms that each country has the right to determine what constitutes a ground for government use, such as national emergency or other circumstances of extreme urgency. In fact, a government use provision covers all uses of a patent by the State for either public non-commercial or commercial purposes. It may also be issued in the public interest (e.g., the protection of the environment, public health, nutrition, and concerns of basic importance to the technological, social, and economic development of the country). TRIPS Article 31(f) stipulates that the use of a compulsory licence must be made predominantly for the supply of the domestic market, and the products produced under a compulsory licence may not be exported to another country. But the term "predominantly" is tantamount to "largely" or "mainly" (i.e., more than 50 %), and the export of drugs produced under the compulsory licence is

[26] *Id*. p. 240.
[27] *Feather v R* (1865), 6 B&S 257.
[28] Gontijo (2005), pp. 7–9.

not completely prohibited. This interpretation has been confirmed by the Doha Declaration on TRIPS and Public Health, in particular the decision of the TRIPS Council of 30 August 2003 on the export of drugs to WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector.

4 Compulsory Licensing Under Thai Law

The Thai patent law provides for the grant of a compulsory licence in four situations, including

(1) non-working or inadequate working of patents so as to meet the local demand for the patented products (section 46);
(2) use for working of dependent patents (sections 47 and 47bis);
(3) public non-commercial use of patented substances for meeting the public needs (section 51);
(4) use for public interest due to war or national emergency (section 52).

Under Thai law, the system of compulsory licensing is envisaged as a mechanism to encourage local working and improve free competition [i.e., situations (1) and (2), respectively] and to authorise the use of patented article for public interest [i.e., situations (3) and (4)]. While in the former situations a compulsory licence is granted to a private competitor, the compulsory licensing in the latter circumstances allows the State agency to authorise the use of patented substances for meeting public needs.

4.1 Thai Law on Local Working Requirement

Compulsory licensing for local working is stipulated in sections 46–50 of the current patent law of Thailand, the Patent Act B.E. 2522 (1979). According to section 46, non-working of the patent within the national economy is regarded as an abuse that would justify the grant of a compulsory licence. Although the term "working" is not clearly defined, the provision comprises both the manufacture of the product or the import of the patented product into Thailand. The patent may be worked either by the patentee or with his consent. Thai law considers non-working in two particular circumstances. First, section 46 explicitly states that the failure to work arises when a patented product has not been produced or the patented process has not been applied for manufacture in Thailand. Second, non-working also arises when the patentee charges a high price for a patented product and the latter is not available (i.e., affordable) in sufficient quantities to meet domestic demand.

In the above circumstances, any person seeking a compulsory licence must submit an application to the Director General of the Department of Intellectual Property (DIP) upon showing that a request for authorisation to use the patented

invention on reasonable terms and an appropriate amount of royalty had been made by him to the patentee but no agreement was concluded with the patentee within a reasonable period of time.[29] In addition, the applicant has to show that, within the specified time, the patented product has not been produced or the patented process has not been applied, in the country without any legitimate reason, or no product produced under the patent is sold in the domestic market or such a product is sold but at an unreasonably high price or does not meet the public demand without any legitimate reason.[30]

Proving abuse by non-working and the absence of reasons to justify such conduct is up to the applicant, which does not look justified in light of the fact that under the Paris Convention an obligation to work the invention in the granting country is placed on the patent holder. The patentee should thus have the duty to present evidence to justify his inaction,[31] the more so since justifying reasons for the inaction will be known foremost to the patentee. The current allocation of the burden of proof makes the Thai compulsory licensing system rather impractical. There has been no application for a licence, and no compulsory licence for exploitation of a patent on the grounds of non-working or insufficient working has been granted since the Patent Act B.E. 2522 entered into force in 1979.

4.2 Thai Law on Government Use Licensing

Sections 51 and 52 of the Patent Act B.E. 2522, in compliance with TRIPS Article 31, provide for non-voluntary government use licensing. Thai law also lays down procedural and substantive rules to be fulfilled prior to exercising government use licensing, including the following conditions.

4.2.1 Grounds for Government Use Licensing

Section 51 of the Patent Act provides for compulsory licensing for public non-commercial use, including for public consumption, defence, conservation of environment and natural resources, prevention of shortage of food or medicines, etc. Section 52 authorises the use of patented products in cases of a national emergency, e.g. health-related emergencies due to an insufficient availability of drugs on HIV/AIDS, anthrax, SARS, and bird flu. In these and other circumstances (e.g., war, epidemics, a natural catastrophe, etc.), the State agency may issue an

[29] Patent Act B.E. 2522, section 46, para. 3.

[30] Ministerial Regulations No. 6, B.E. 2524, clause 14(1). The Royal Gazette, Special Issue, 98 (196), 17 November 1981.

[31] Paris Convention, Article 5A(4) states: "... it should be refused if the patentee justifies his inaction by legitimate reason".

authorisation to use the patented substance at any time during that national emergency on terms and conditions as the State may deem fit.

4.2.2 Consultation with the Patent Holder

Although Thailand, as a WTO member, can use various public health safeguards in line with international rules to promote access to affordable generic medicines, it is important for the Thai Government to ensure that its act is in full compliance with all the requirements of the TRIPS Agreement, particularly the condition that the State undertakes a consultation with the patent holder prior to granting a compulsory licence. This condition can however be waived when a compulsory licence is granted: (1) to remedy anti-competitive practices, (2) in a national emergency or other circumstances of extreme urgency, or (3) for public non-commercial use.[32]

Sections 47 and 47bis of the Thai Patent Act do not require the prospective licensee to show that it has attempted but failed to obtain a voluntary licence from the patentee. However, the State agency is required to notify the patentee in writing without delay after a licence has been issued, but the law is silent on the details and content of this notification. Since the issuance of the government use licences on the patented medicines by Thailand was aimed for non-commercial purposes and for public interests (i.e., carrying out a service for public consumption), the Thai authorities may not be required to enter into prior consultation with the patent holder as permitted under Article 31(b).

4.2.3 Remuneration

As far as the rate of remuneration is concerned, TRIPS requires the government agency to pay adequate compensation to the patent holder, but it does not specify what amount of remuneration is adequate.[33] The ambiguity of the term 'adequate remuneration' allows the granting country to compulsorily exploit the patent in exchange for the fee considered by the State to be reasonable.[34] In the United States, a reasonable royalty refers to "the amount that a person desiring to manufacture [or use] a patented article . . . would be willing to pay as a royalty and yet be able to make [or use] the patented article, in the market at a reasonable profit".[35] Therefore, the fees can be either a fixed sum per unit sold or a percentage of the net sale price of the product produced by the licensee (e.g., normally between 1 and 5 %). Other factors may also be taken into consideration to determine a reasonable royalty: expected volume of production, price under the non-voluntary licence,

[32] TRIPS, Article 31(b).

[33] TRIPS, Article 31(h).

[34] Love (2005), p. 18.

[35] *Wright v United States*, 53 Fed. Cl. 466, 469 (Ct. Cl. 2002).

potential market price and profit margin, R&D and related legal costs, advertising and administrative expenses, possible substitutes, risks undertaken in first producing the invention, evidence of bad faith or anti-competitive practices, the country's economic and health situation such as evidence of how the public interest would be served by the invention, and so on.[36]

Section 51 of the Patent Act requires the licensing authority to offer the amount of remuneration and conditions for the granting of a compulsory licence to the Director General of the DIP. No guidelines are provided as to what is the reasonable remuneration. The law only requires both parties to enter into negotiations to evaluate the rate of the royalty. If the parties fail to reach an agreement within the period prescribed by the Director General, the Director General will make a decision as to the royalty and conditions. Parties may appeal the decision to the Board of Patents and, further, to the Intellectual Property and International Trade Court within 60 days.[37] The appeal provisions were adopted in order to comply with TRIPS Article 31(i) and (j), which requires that any decision relating to the authorisation of such use and the remuneration "shall be subject to judicial review or other independent review by a distinct higher authority in that Member". It may be noted that the patentee can only appeal the terms of the licence but has no right to appeal the grounds for the decision to grant the licence. In addition, the appeal by the patent holder will not suspend the execution of the order and will not delay the issuance of the licence.

4.2.4 Supply of Domestic Market and WTO Decisions 2003 and 2005

The significance of the compulsory licensing to improve access to essential medicines may be minimised when a country does not have capacity to manufacture the required drugs.[38] The problem is exacerbated by the fact that the products cannot be imported, as the newly invented drugs are likely to be under patent protection in the countries where they are manufactured. A couple of the TRIPS provisions permit production for export. First, under Article 31(k), the product produced under a compulsory licence that is issued to combat anti-competitive practices may be exported to other countries. Second, TRIPS Article 31(f) stipulates that the use of a compulsory licence must be made predominantly for the supply of the domestic market. This can be interpreted as meaning that less than half of the production authorised by a compulsory licence can be exported. Paragraph 6 of the Doha Declaration and the decisions of the WTO General Council of 2003 and 2005 reaffirm that WTO Members may issue a compulsory licence to produce and export generic medicines to countries with insufficient or no manufacturing capacity in the

[36] See *supra* note 34, p. 21.

[37] Patent Act B.E. 2522, sections 50 and 51.

[38] Harrelson (2001), p. 192.

pharmaceutical sector.[39] The 2005 Decision also waives the payment requirement in the eligible importing Member.[40]

The current law of Thailand does not implement the Decisions adopted by WTO. Thailand may wish to adopt a provision permitting import of medicines that it lacks manufacturing capacity to produce. Since there are large generic producers in Thailand, like the GPO, it may consider incorporating into the national patent law provisions enabling the export of pharmaceutical products manufactured under the compulsory licensing.

5 Conclusion

The non-voluntary or compulsory licensing system appears in the Paris Convention, the TRIPS Agreement, and many patent laws of both developed and developing countries. Patent rights are granted based on reciprocity between the inventor and society. The compulsory licensing is the very cornerstone of the patent system. While the law grants exclusive rights, the system ensures that such rights will not be abused by the patentee. When the patent holder fails to fulfil his legal obligation, it is justifiable for the State to intervene and allow another person to make essential products available to the public.

Although the compulsory licensing provisions under the patent law of Thailand looks promising, the failure or the success of the system depends upon a strong political will of the Government. The case of Thailand has proved that government action is essential to protect patients by offsetting the patentee's power to extract excessive prices. The non-voluntary licensing encourages private patent owners to negotiate with the government agency in order to provide medicines at a more reasonable price. It is also likely to lead to an increase in the production or import of the generic version of the drug. States, whether developed or developing, generally use legal measures to facilitate the domestic production of patented inventions and at the same time prevent a single company from dominating the market and creating barriers to entry for potential competitors. There is no reason why developing countries like Thailand should not continue to use these legal mechanisms to achieve the aim of guaranteeing public interests. It is therefore strongly recommended that the relevant authorities of developing countries should instigate employing this available mechanism against those patents that are failing to meet domestic demand.

[39] World Trade Organisation (2005).

[40] Abbott (2005), pp. 317–358.

References

Abbott FM (2005) The WTO medicines decision: world pharmaceutical trade and the protection of public health. Am J Int Law 99:317–358

Adelman MJ, Baldia S (1996) Prospects and limits of the patent provision in the TRIPS Agreement: the case of India. Vanderbilt J Transnatl Law 29:507–533

Bangkok Post (2008) Thai traders urge 'Extreme Caution' on CL. 14 February

Baron D (2008) Compulsory licensing, Thailand, and Abbott Laboratories. Stanford Graduate School of Business Case P-66

Bodenhausen GCH (1991) Guide to the application of the Paris Convention for the protection of industrial property as revised at Stockholm in 1967. WIPO Publication No. 611 (E), Geneva

Champ P, Attaran A (2002) Patent rights and local working under the WTO TRIPS Agreement: an analysis of the US–Brazil patent dispute. Yale J Int Law 27:365–393

Correa CM (2005) Can the TRIPS Agreement foster technology transfer to developing countries? In: Maskus KE, Reichman JH (eds) International public goods and transfer of technology under a globalized intellectual property regime. Cambridge University Press, Cambridge, pp 227–256

Doane M (1994) TRIPS and intellectual property protection in an age of advancing technology. Am Univ J Int Law Policy 9:465–479

Foster G (1998) Opposing forces in a revolution in international patent protection: the US and India in the Uruguay round and its aftermath. UCLA J Int Law Foreign Aff 3:283–298

Gontijo C (2005) Changing the patent system from the Paris Convention to the TRIPS Agreement: the position of Brazil. The Heinrich Böll Foundation, Global Issue Paper No. 26, Berlin. http://fdcl-berlin.de/fileadmin/fdcl/Publikationen/GIP_Gontijo-Patente.pdf. Accessed 2 Aug 2012

Harrelson JA (2001) Note: TRIPS, pharmaceutical patents, and the HIV/AIDS crisis: finding the proper balance between intellectual property rights and compassion. Widener Law Symp J 7:175–201

Intellectual Property Watch (2007) Thailand presents report on compulsory licensing experience. http://www.ip-watch.org/2007/03/12/thailand-presents-report-on-compulsory-licensing-experience/?res=1024&print=0. Accessed 1 Nov 2012

Kuanpoth J (2006) Harmonisation of TRIPS-plus IPR policies and potential impacts on technological capability: a case study of the pharmaceutical industry in Thailand. ICTSD-UNCTAD project on IPRs and sustainable development, Geneva. http://www.iprsonline.org/unctadictsd/regional_research.htm. Accessed 15 July 2012

Love J (2005) Remuneration guidelines for non-voluntary use of a patent on medical technologies. World Health Organisation, WHO/TCM/2005.1, Geneva

Lybecker KM, Fowler E (2009) Compulsory licensing in Canada and Thailand: comparing regimes to ensure legitimate use of the WTO rules. J Law Med Ethics 37:222–239

Ministry of Public Health and National Health Security Office (2007) Facts and evidences on the 10 burning issues related to the government use of patents on three patented essential drugs in Thailand. Document to support strengthening of social wisdom on the issue of drug patent, Bangkok. www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf. Accessed 14 Nov 2012

Piot P, Seck AMC (2001) International response to the HIV/AIDS epidemic: planning for success. Bull World Health Organ 79:1106–1112

PReMA (2007) Statement from the President of the Pharmaceutical Research and Manufacturers' Association of Thailand (PReMA). Press Release, Bangkok

Roffe P (1974) Abuses of patent monopoly. World Dev 2:15–26

Scherer FM, Watal J (2002) Post-TRIPS options for access to patented medicines in developing nations. J Int Econ Law 5(4):913–939

Sell SK (2002) TRIPS and the access to medicines campaign. Wis Int Law J 20:481–522

United Nations Development Programme (2004) Thailand's response to HIV/AIDS: progress and challenges. UNDP, Bangkok

United States Government Accountability Office (2007) Intellectual property: U.S. trade policy guidance on WTO declaration on access to medicines may need clarification. GAO-07-1198. http://www.gao.gov/assets/270/267763.html. Accessed 14 Nov 2012

WHO/UNAIDS/UNICEF (2007) Towards universal access: scaling up priority HIV/AIDS interventions in the health sector. http://www.who.int/hiv/mediacentre/universal_access_progress_report_en.pdf. Accessed 28 July 2012

WTO Ministerial Conference (2001) 4th session, Doha, 9–14 November 2001. WT/MIN(01)/Dec/2, 20 November 2001

World Trade Organisation (2005) Implementation of paragraph 11 of the General Council decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Council for trade-related aspects of intellectual property rights, IP/C/41. www.wto.org/english/news_e/pres05_e/pr426_e.htm. Accessed 12 July 2012

Yamabhai I et al (2011) Government use licenses in Thailand: an assessment of the health and economic impacts. Global Health 7:28. http://www.globalizationandhealth.com/content/7/1/28. Accessed 25 Mar 2013