

Patents and Access to Medicines in Thailand – The ddI case and beyond*

*Jakkrit Kuanpoth***

I. Introduction

In 2003, it was estimated that, globally, 30 million people have died since the beginning of the HIV/AIDS epidemic, while 40 million people were living with HIV/AIDS. Among them, 6 million people in developing countries are in need of treatment with anti-retroviral medicines. Yet only 300,000 of them have access to such medicines.

Thailand is currently one of the countries that are facing an AIDS crisis. It is estimated that around one million adults and children are living with HIV/AIDS. While the number of new anti-retroviral drugs entering the market continues to grow, only about five percent of the affected population in Thailand has access to them. The main reason for the inaccessibility of anti-retroviral drugs in Thailand is the high cost of treatment. Treatment with anti-retroviral drugs is currently not covered by the national health insurance. Thus, HIV/AIDS treatment in Thailand depends upon the consumers' ability to pay, and only one percent of HIV/AIDS patients can afford to purchase anti-retrovirals for themselves. As the number of those infected and affected by HIV/AIDS continues to increase, individuals, families and the society face an increasing economic and social pressure to provide appropriate health care, psychosocial support and medical treatment that would prolong the lives of those infected.

For these reasons, the initiative of an NGO and two Aids patients to, first, have the Thai government grant a compulsory licence over one of the AIDS medicaments, the ddI drug, and, second, request (partial) revocation of the corresponding patent has evoked interest far beyond Thailand. Due to the peculiarities of Thai patent law, the request for a compulsory licence looked more promising, but ultimately failed, while the request for invalidation, assisted by a public campaign, was successful. The case has revealed serious defects of the Thai patent system that highlight the difficulties for developing countries to properly use and apply the patent system as a motor of domestic innovation.

II. Facts of the ddI Cases

Didanosine (ddI) is one of the anti-retroviral drugs that the World Health Organisation (WHO) recommends for HIV/AIDS treatment. The drug when used with zidovudine and lamivudine, has proved an effective reverse transcriptase inhibitor against the disease, especially for patients intolerant to zidovudine, or in whom zidovudine has failed.¹

The ddI drug was developed in the U.S. by two scientists working for the National Institute of Health (NIH), a U.S. public research institution. In 1989, two patents (U.S. 4861759 and U.S. 5616566) over ddI were issued by the USPTO to the Department of Health and Human Services. The patents were subsequently licensed to Bristol-Myers Squibb (BMS), a company incorporated in Delaware, in order to produce and market the product world-wide under the trade

* The article was published in *Intellectual Property Quarterly*, No.2, 2006, pp.149-159.

** LL.B. (Hons.), Barrister-at-Law (Thai Bar), LL.M. (Warwick), Ph.D (Aberdeen); Senior Lecturer, Faculty of Law, University of Wollongong, Australia.

¹ In order to be effective over time and to reduce the likelihood of resistance, the WHO recommends that anti-retroviral treatments be taken in certain combinations. The standard treatment recommended by the WHO is a "triple cocktail" therapy that includes at least one protease inhibitor and two other drugs.

mark “Videx”. The licensing agreement, under which BMS agrees to pay royalties of 5 percent of sales, contains a fair pricing clause and requires commercialisation of ddI for the public benefit.²

Having secured marketing rights over ddI, BMS improved the drug based on NIH’s formulation as a single tablet containing ddI and an appropriate amount of antacid. In 1991, the company filed a patent application for the improved formulation of ddI, yet the application was rejected by the USPTO on grounds of obviousness. BMS re-submitted a second application with the USPTO in 1997, initially with the same result.. The rejection was based on the fact that the method of combining ddI with the appropriate amount of antacid was well known to the person ordinarily skilled in the art. The company responded by arguing that non-obviousness was based on the new buffer system that helped to reduce the antacid component. The claims were finally accepted by the examiner after BMS had agreed to limit the composition to specific ingredients and proportions.

BMS filed a corresponding patent application with the Department of Intellectual Property (DIP) of Thailand on 7 July 1992 for ‘improved oral dosing formulations of dideoxy purine nucleosides’. It was claimed in the application that invention related to pharmaceutical components providing improved oral dosing formulations of ddI. The claims were directed to the method of adding a buffer (antacid) that provided the following advantages for the treatment of HIV/AIDS:

- (i) improve pharmaceutical formulations for nucleosides which are not stable in acid in order to reduce the amount of ddI and facilitate oral dosage,
- (ii) reduce acid in the stomach, thereby minimising the side effect of diarrhoea and/or the imbalance of pH and electrolytes, and
- (iii) improve the taste.

The claims in the application filed in Thailand were identical to those contained in the second US application. BMS could not file a patent over the original version of ddI due to lack of novelty. And as the Thai Patent Act was amended only in 1992 to allow for the patenting of pharmaceutical substances, neither could the NIH. Thus, BMS could only claim an improved dosage formulation of ddI, not ddI as such.

Although Thai patent law requires applications to be substantively examined, the DIP due to limited resources and facilities hardly conducts a patent search and examination, but simply grants patents pursuant to the examination results of foreign offices, particularly those of developed countries that are considered more capable of thoroughly examining applications.

The patent application that was filed in Thailand claimed a drug dosage between 5-100 mg of ddI per dose. In 1997, after the application was published, BMS requested the DIP to amend its application and remove the limitation on the dosage range mentioned in the claims. Under Sec. 20 Patent Act B.E. 2522, an amendment to a patent application can be made only when it does not incorporate additional subject matter into the essential elements of the invention. The Ministerial Regulation No.21 B.E. 2542, Clause 16, which implements Sec. 20, requires that an application for the amendment must be made before the publication of the application unless so authorised by the DIP’s Director-General.³ The DIP approved the request for amendment, and in January 1998, a patent covering all dosage forms of ddI was granted to the company. The

² At least in this case, the high price of the pharmaceutical was not the result of high research costs. In fact, many essential drugs, like ddI, were developed within publicly funded research. Often, private companies have entered into licencing agreements with public research institutes in order to get the medicines to market.

³ Sec. 20 Patent Act B.E. 2522 as amended in 1999.; Ministerial Regulation No. 21 B.E.2542, Clause 16.

amendment made the patent application in Thailand equivalent to the first US application for the ddI formulation that had been rejected by the USPTO.

III. The Request for a Compulsory Licence

Soon after the patent was granted, in 1999, a campaign against the ddI patent was launched by the AIDS Access Foundation and the Network of People Living with HIV. BMS was accused of charging exorbitant prices for ddI,⁴ and DIP of issuing a patent over the ddI formulation. The Thai government was urged to issue a compulsory license under Sections 51 and 52 of the Patent Act B.E. 2522 and to allow the Government Pharmaceutical Organisation (GPO) to manufacture the drug. However, the government refused to invoke the compulsory licensing scheme, fearing negative trade repercussions from Thailand's trading partners. Instead, it asked the GPO to produce ddI in powder form, which was not covered by BMS' patent. That was fine as far as it went, yet the powdered form of ddI had several disadvantages, e.g. more side effects and more difficulty to consume.

Just as everywhere, political factors play an important part in the use of compulsory licensing in Thailand. One factor to reckon with seems to be the lack of political will by the Thai government to actually invoke the scheme of compulsory licensing in the public interest. The legal issues regarding compulsory licensing in Thailand are the following.

1. Grounds for Compulsory Licensing

The Thai patent law provides for the grant of a compulsory license in four situations, including:⁵

- (i) non-working or inadequate working of patents so as to meet the local demand for the patented products, Sec. 46 Patent Act;
- (ii) use for working of dependent patents, Secs. 47 and 47^{bis};⁶
- (iii) public non-commercial use of patented substances for meeting the public needs, Sec. 51;
- (iv) uses for public interest due to war or national emergency, Sec. 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 (i) and (ii), respectively), and to authorise the use of patented article for public interest (*i.e.* situations (iii) and (iv)). While in the former situations, a compulsory license 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. Although the mechanism is important and can be used to enhance access to medicines, there is still a practical difficulty in applying this provision due to the incongruity of the Thai legal system.

⁴ In 1999, ddI could be obtained in Thailand for 50 baht for a 100-mg tablet, while the standard regime of ddI for an average Thai adult with HIV/AIDS is two 100-mg tablets twice a day. This means a patient would have to spend 200 baht per day. While a 100-mg AZT could be obtained at 12.35 baht from a hospital, ddI was set at a much higher price. Unlike AZT, ddI back then was available only from BMS, and was so expensive that it was not included in the list of essential drugs.

⁵ The extent of the discussion regarding various grounds for compulsory licensing is reflected in C. CORREA, "Integrating Public Health Concerns into Patent Legislation in Developing Countries" (South Centre, Geneva 2000).

⁶ When the exploitation of an invention under a patent cannot be made without infringing a patent held by another person, the holder of the patent desiring to exploit his own right may apply for a compulsory license to use the invention contained in the other patent on condition that he is prepared to cross-license his own patent on reasonable terms.

2. Compulsory Licensing for Failure to Work the Invention

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 and 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 is defined as charging such a high price for a patented product that the latter is not available (i.e. affordable) in sufficient quantities to meet domestic demand, Sec. 46 Patent Act. It follows from this provision that a patentee has an obligation not only to work the invention, but also to work it in a manner sufficient to fulfil domestic demand. In conformity with Art. 5 Paris Convention, the failure to work must not be less than three years.⁷

In the above circumstances, any person seeking a compulsory license must submit an application to the Director-General of the DIP upon showing that no agreement with the patentee could be reached within a reasonable period of time.⁸ Proving abuse by non-working and the absence of reasons to justify such conduct is up to the applicant⁹, 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.¹⁰ The patentee should thus have the duty to present evidence to justify his inaction, 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.¹¹

3. Compulsory Licensing in the Public Interest

a) Compulsory Licensing for Public Non-Commercial Use

A compulsory license 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), Sec. 51 Patent Act B.E. 2522. Authorisation for the production under a compulsory licence in the above circumstances can be granted to government undertakings or other private enterprises.

TRIPS requires a consultation with the patent holder prior to granting a compulsory license save in the in the following three situations:¹²

- (i) to remedy anti-competitive practices,
- (ii) in a national emergency or other circumstances of extreme urgency, or

⁷ It might be appropriate to note that already Art. 5 Paris Convention was a hotly disputed provision that replaced the far stricter rules on forfeiture many countries had adopted. For a history of the provision, *see* A. KOURY MENESCAL, *Those Behind the TRIPS Agreement: The Role of the ICC and the AIPPI on International Intellectual Property Decisions*, [2005] I.P.Q. 155.

⁸ The earliest time for applying for a compulsory license is three years from the grant of the patent or four year from the filing date, whichever period expires later.

⁹ Patent Act B.E. 2522, Sec. 46(3); Ministerial Regulations No. 6 (B.E. 2524), clause 14(1).

¹⁰ According to Article 5A(4) Paris Convention, a compulsory licence “... should be refused if the patentee justifies his inaction by legitimate reason”.

¹¹ As mentioned above, due to the fact that BMS did not develop ddI itself and was bound by a fair-pricing clause in the agreement with the NIH, charging exorbitant prices should at least have made a *prima facie* case for an abuse without good reason.

¹² TRIPS Agreement, Article 31(b).

(iii) for public non-commercial use.¹³

The TRIPS provision regarding the issuance of a compulsory license for ‘public non-commercial use’ is particularly favourable to developing countries as it may include the situation when the government authorises a state-owned enterprise to produce generics for public distribution for free. Although the current law of Thailand envisages compulsory licensing in the case of public non-commercial use, it does not waive the obligation for consultation with the patent holder, Sec. 51(2) Patent Act. Such waiver should be available so as to facilitate the granting of a compulsory license.

b) Compulsory Licensing in Cases of Emergency

Sec. 52 Patent Act also 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 authorisation to use the patented substance at any time during that national emergency on terms and conditions as the State may deem fit. No use has been made of this provision despite the emergency situation related to the AIDS epidemic.

c) Review of Compulsory Licensing

Thai patent law has gone further than the country’s current international obligations under TRIPS by permitting a judicial review of a compulsory licence. Such review by a court would allow the patentee to delay the grant of a compulsory license. In fact, the assessment of a strong compulsory licensing mechanism lies not so much in its actual use, but in the threat thereof.¹⁴ Overly cumbersome review procedures with a deferential effect will not do much to safeguard the country’s public health. It is advisable that this provision should be replaced by an administrative review in order to avoid time-consuming court procedures and any possible delaying tactics adopted by the patent holders.

d) Export of Products Produced Under a Compulsory Licence

TRIPS Article 31(f) stipulates that the use of a compulsory license must be made predominantly for the supply of the domestic market, and the products produced under a compulsory license 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 license is 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.¹⁵ Currently, Thai patent law does not allow for the compulsory licensing for export purposes. Since the Thai pharmaceutical sector is well-known for its ability to produce cheap medicines, and many countries have seen Thailand as the source of generic versions of branded drugs, Thailand may wish to revise her law so as to allow the export of generic drugs to those countries that have granted a compulsory licence, but lack production facilities.

4. Appraisal of the Compulsory Licensing Scheme in Thailand

¹³ CORREA, *op. cit.*, at 102-103.

¹⁴ J. RICH, “Roche Asks for Meeting with Brazil Health Minister”, NY Times, Aug. 24, 2001.

¹⁵ WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Paragraph 6. For a detailed analysis of the Doha Declaration, see: C. TUOSTO, The TRIPs Council Decision of August 30, 2003 on the Import of Pharmaceuticals under Compulsory Licences, [2004] E.I.P.R. 542;

The procedure for granting a compulsory licence in Thailand seem rather complex and cumbersome. As of 2004, no application for a compulsory licence has been filed and no compulsory licence has been granted since the Patent Act B.E. 2522 entered into force. Both in the legal and economic context, the ddI patent would have made a compelling case for the grant of such licence, or at least for the DPI threatening to do so should the patentee not lower the prices of its products.¹⁶

IV. The Cases for having the ddI Patent Invalidated

After attempts to secure a compulsory licence failed, the AIDS Access Foundation, an NGO, and two Thai HIV patients went to court in order to have the patent amended or invalidated.

1. Lawsuit for an Amendment of the Claims

In May 2001, the above plaintiffs filed a lawsuit before the Thai Intellectual Property and International Trade Court (CIPITC)¹⁷ against BMS and DIP. The plaintiffs alleged that the patent was wrongly granted for the ddI formulation as such and sought invalidation or an amendment of the claims.

The plaintiffs asserted that the decision to allow an amendment of the application broadened the scope of BMS' patent beyond what was initially claimed. It was also alleged that for the above reasons, the DIP was not entitled to allow the amendment.

On 2 October 2002, the CIPITC confirmed the plaintiffs' position and held the amendments unlawful. The court ordered the DIP to revoke the invalid claims and restore the original limits to the formulation. The judgment thereby permitted third parties to produce generic versions of ddI tablets containing more than 100 mg of ddI per dose without infringing BMS' patent rights.

Both BMS and DIP appealed to the Supreme Court. In addition, the DIP requested the Supreme Court to defer the enforcement of the first instance ruling. The latter request was attacked by many domestic interest groups and academics on the grounds that it protected the interests of a company rather than public interest. If approved, the request would have allowed BMS to exclude third parties from producing ddI tablets in any dosage.

2. Lawsuit for Revocation of the Patent

On 9 October 2002, days after the first ruling, a second lawsuit was filed by the Foundation for Consumer Protection of Thailand and three HIV patients against BMS and the DIP. This time, the plaintiffs sought an outright revocation of the patent. The plaintiffs asserted that the grant of a patent over the ddI formulation was unlawful due to a lack of novelty. They also argued that

¹⁶ When governments issue a compulsory license, the result is often a sharp decrease in prices, similar to the introduction of other competitive forces like generic drugs. The cases of the U.S., Canada and Brazil provide good examples of the successful application of this safeguard. *See* C. CHIEN, "Cheap Drugs at What Price to Innovations: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", 18 Berkeley Technology Law Journal 853 (2003); N.A. BASS, "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century", 34 George Washington International Law Review 191 (2002); U.K. Commission on Intellectual Property Rights (CIPR), Final Report, Integrating Intellectual Property Rights and Development Policy 42 (2002).

¹⁷ For details on the working of this court, see V. ARIYANUNTAKA, TRIPS and the specialised Intellectual Property Court in Thailand, 30 IIC 360 [1999].

the idea of adding buffer (antacid) to create an improved pharmaceutical formulation in order to reduce acid in stomach and facilitate the oral dosage was obvious to a person skilled in the art. Both novelty (Sec. 5 Thai Patent Act) and non-obviousness (Sec. 54) are requirements of patentability.

Prior to the oral hearing, BMS sought a settlement with the plaintiffs. After several rounds of negotiations, an amicable agreement was reached and signed by BMS, the Foundation for Consumers and the three HIV patients. The company agreed to surrender all its exclusive marketing rights under the ddI patent in Thailand and to withdraw its appeal in the first lawsuit, while the plaintiffs agreed to withdraw the second lawsuit.

3. Legal Issues involved

a) Standing to Sue

Patents can be challenged by, either, initiating (i) invalidation proceedings, or (ii) a counterclaim in an infringement suit. The Patent Act does not provide for opposition proceedings before the DIP.

Under Sec. 54 Thai Patent Act, a patent may be challenged by (i) any interested party, and (ii) the public prosecutor. In practice, the prosecutor will file a petition to the court only when there is a request from the DIP. This means that anyone who wants to challenge the validity of the patent has to bring the case to court at his own expense. And unlike the law of some countries (for example, the UK or Japan) that provides for the revocation of patent by any person,¹⁸ Thai law requires an "interested person" typically interpreted as someone who cannot use a product or process due to the existence of the patent in question.¹⁹ This certainly includes manufacturers or competitors, while here, the plaintiffs were not affected in their commercial activities by the existence of the patent. Still, there was no doubt that the absence of generic versions of the ddI formulation was a serious handicap to AIDS patients.

The court found that since a patent confers exclusive rights on the holder, particular care should be taken for patent rights over pharmaceuticals which are basic necessities for people. Patents enable pharmaceutical manufacturers to charge prices above marginal costs and the exercise of patent rights by the owner may lead to higher prices and restricted supply of essential products. The court noted that the WTO Doha Ministerial Declaration on TRIPS and Public Health adopted on 14 November 2001 expresses concern of Members over "the gravity of the public health problems afflicting many developing and least-developed countries", and specifically recognises concerns about the effects of patents on pharmaceutical prices.

The court reaffirmed the conditions under which Thai patent law should apply to protect the right of the public regarding access to medicines, and ruled that "interested persons" should not be confined to manufacturers or competitors that are excluded from using the patented invention. In the case of pharmaceuticals, those who are in need of the patented medicines must also be regarded as interested persons allowed to request the revocation of a patent on the grounds set out below.

b) Grounds for invalidation

The validity of a patent may be challenged at any time after grant by raising a nullity action before the CIPITC based on the following grounds:

¹⁸ See UK Patent Act 1977, Section 72; Japanese Patent Act Sec. 123(2).

¹⁹ Supreme Court Decision No. 7377/2538.

- (i) the invention under the patent was not patentable (Secs. 5 and 9), or
- (ii) the patent was granted to a person not entitled to apply for a patent, Secs. 10, 11, 14.

Limiting the grounds of invalidity to these two circumstances is clearly a defect in the Thai patent law. In particular, the law does not mention:

- insufficient disclosure (different from, e.g., Arts. 100 b), 83 EPC);
- subsequent amendments broadening the scope of the original filing (different from, e.g., Arts. 100c), 123 (2) EPC);
- fraud or misrepresentation in obtaining the patent²⁰.

In the first dDI lawsuit, the plaintiffs nonetheless challenged the validity of the patent on the grounds that a subsequent amendment had broadened the original claim. The court was willing to hear this ground that was argued in two steps.

First, whether or not such amendment should have been allowed by the DPI. As a general rule, amendments should be allowable when made within time limit and without extending the ambit of the right. As mentioned above, amendments after publication required approval by the Director-General of DIP under Clause 16 of the Ministerial Regulation, and such approval was obtained.

Second, while the Director-General can authorise amendments after publication, he has no authority to approve amendments extending the scope of the invention. It was disputed whether BMS's request for removing the dosage range of 5-100 mg amounted to an extension of scope. BMS asserted that the deletion of subject-matter did not add anything to the essential features of the invention. The court disagreed, since the amendment would allow BMS to prohibit anyone from producing dDI tablets of any dosage range, rather than only between 5-100 mg.

c) Remedies

The plaintiffs in the first case did not petition for the revocation of the dDI patent, but for reverting the application to its unamended form. While the court acknowledged that the Patent Act B.E. 2522 contained no special provisions for correcting the claims, it ruled that there was no reason to bar the court from ordering such correction, the more so since the alternative, the revocation of the patent, was less favourable to the patentee. The ruling has established a new precedent that when the court finds a patent invalid, the court may allow the claims to be amended instead of revoking the patent.

d) Evaluation

This ruling was a landmark judgment in that it took cognisance of the Doha Declaration and showed that the Declaration, while perhaps not legally binding carries weight in the interpretation of the law.²¹ The judgment was also significant in that it has manifestly increased the awareness that access to treatment is a human rights issue. The suit against BMS and the court verdict were not least the result of a public display of strength and solidarity. The ruling also sets a precedent in Thailand about the legal rights of civil society to challenge the validity of patents. It could equally provide the basis for challenging patents on essential drugs in other

²⁰ Which has been developed in the US based on common law since the case *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944) and may particularly translate into a duty to prosecute patent applications before the patent office in good faith, candour and honesty: *Molins plc v. Textron Inc*, 48 F.3rd 1172, 1178.

²¹ The Doha Declaration is a Ministerial Declaration within the WTO that generates no legally binding force for governments or courts in the Member States. See A.O. SYKES, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha Resolution", 2002 Chicago Journal of International Law 1.

countries and strengthen the ability of civil society to gain access to treatment for those infected with HIV/AIDS.

V. Appraisal of the ddI Cases - Patents and Innovation in Developing Countries

The effectiveness of the patent system primarily depends on the quality of the technical examination. While the number of patent applications in developing countries is increasing, it is worrying that the limited resources of developing countries' do not permit an efficient patent examination and thus a promotion of inventive activities among local inventors. The patent office's laxity in issuing patents often results in invalid patents being granted. In developed countries, it is not uncommon to find a number of invalid patents being issued each year.²² In view of the weaker patent examination system, it is thus logical to assume that the number of invalid patents granted in the developing countries like Thailand is even higher..²³

No doubt, the costs resulted from the improper granting of patents are high²⁴, especially when life-saving drugs are concerned. It is perhaps fair to say that the lack of governmental competence is the biggest obstacle for Thailand to maximise the benefits of her intellectual property system and to minimise the costs to consumers and local manufacturers. Thailand may wish to increase the capability of the patent office, including subsidising the patent application and examination, and increasing the salaries of examiners. Proceedings for the invalidation or amendment of patents before the patent office should be introduced. A straightforward administrative procedure is necessary because it would allow the patentee's competitors to challenge the validity of the patent at relatively low cost prior to an infringement action. The system would also reduce the excessive burden on the courts and contribute to speedy proceedings of patent invalidation. In addition thereto, a developing country like Thailand may incorporate a disgorgement remedy into its national patent law which would require the patent holder to return excess profits earned from an invalid patent.

VI. Conclusion

The development of new anti-retroviral drugs has made HIV/AIDS a manageable disease. But those life-saving medicines are beyond the reach of most patients in Thailand due to their high cost. The problem of inaccessibility can be exacerbated by the patent office's inability to accurately examine patent applications, thereby granting patents that should not have been granted at all, or should have been granted in a more restricted form only. The social costs of improvidently granted patents are substantial, the more so in the case of life-saving medicines like ddI. It is necessary that less complex invalidation proceedings are introduced in order to overcome the inadequacies of patent examination practice. Attempts should also be made to simplify the procedure for obtaining a compulsory license in order to make essential drugs available for all, as is prevised by the Doha Declaration.

²² R.M. SHERWOOD ET AL., "Promotion of Inventiveness in Developing Countries through a More Advanced Patent Administration", 39 IDEA 473 (1999).

²³ See for example L. TANASUGARN, "When Patent Rights may not be Enforceable: The Case of the Kwao Krua Patent" 105 (The Intellectual Property and International Trade Law Forum: Special Issue 1999, Bangkok 1999).

²⁴ As is argued by J. FARRELL/R. MERGES, Incentives to challenge and defend patents: Why litigation won't reliably fix patent office errors and why administrative patent review might help, 19 Berkeley Technology Law Journal 943 [2004]. The authors argue that "Since litigation cannot fix all errors, we urge better USPTO funding and higher standards of initial review, better incentives (not limited to formal duties) for applicants to find and disclose prior art information, and the creation of a cheap and workable administrative ex-post review" (943). Also A. JAFFE & J. LERNER, Innovation and its Discontents, Princeton 2005, argue that the grant of invalid patents is one of the biggest obstacles to innovation.