

## Appropriate Patent Rules in Developing Countries - Some Deliberations Based on Thai Legislation

Jakkrit Kuanpoth<sup>†</sup>

Faculty of Law, University of Wollongong, NSW 2522, Australia

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TRIPS Agreement mandates adequate and effective protection for all inventions regardless of the field of technology. The fundamental questions are whether the extent of protection of pharmaceuticals will be beneficial for the socio-economic development of developing countries and how can the impact of the new system be monitored and controlled in the interests of the concerned countries and their populations. Under the Thai Patent Law, Section 46.50 provides for the grant of compulsory licenses, which in practical terms are difficult to implement so much so that no such licenses have been granted since 1979 when the Act came into force. Lack of know-how to work the patent in Thailand has also been a serious deterrent. Provision of a requirement for working of patented inventions is also part of the Thai Act. Section 36(2) of the Thai Patent Law authorizes parallel imports into Thailand if the products are marketed abroad by the patentee or his licensee. Section 9 (4) of the Act adopts the principle that methods of treatment are not patentable. Section 31 permits opposition to be filed after the application is published by the Patent Office. The implication of TRIPS and the Thai Patent Act on the pharmaceutical sector and on the patients in Thailand are discussed in this paper.

**Keywords:** TRIPS, Thai Patent Act, compulsory license, parallel imports, international exhaustion

The pressure pushed by the developed nations in the late 1980s led to signing on to the international agreement on intellectual property rights, TRIPS, which is now part of the World Trade Organization (WTO)'s multilateral agreements. The TRIPS Agreement demands for adequate and effective worldwide protection of all fields of technology, including pharmaceutical products, and for effective enforcement of patent rights throughout the world. Two crucial questions are worth examining: (1) is the extent of patent protection to pharmaceuticals of any advantage to the long-term improvement of standards of living and the provision of health care of the people in the developing countries; and (2) how could the profound impacts derived from patents be effectively controlled? While existing socio-economic research provides rich multi-disciplinary data on impacts of patents on pharmaceuticals,<sup>1</sup> this paper deals with the

second issue. It surveys established principles of the present patent rules with direct reference to pharmaceutical inventions. It discusses various legal problems relating to the use of non-voluntary licensing scheme and other measures aimed to minimize negative effects of pharmaceutical patents and to increase access to essential medicines.

### The Nature of Patents

It is interesting to note that the historical development of the patent system is a long one. The first patent Statute was enacted by the Venetian State in 1474.<sup>2</sup> It is, however, evident that an exclusive monopoly had been granted to traders or inventors as early as 500 BC.<sup>3</sup>

In England, the Crown issued monopoly right in the form of 'letters patent' for the first time in 1331 to foreigners who wished to practice their craft in the country. That was the grant of monopoly privileges by King Edward III to Johannes Kempe of Flanders for the introduction of the textile industry to England.<sup>4</sup> Letters patent conferred exclusive rights on such persons to sell a product or to use a process for a certain period of time. The introduction of the patent system was for the encouragement of transferring new technologies and establishment of new industries on a

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<sup>†</sup>Prof Jakkrit Kuanpoth is currently Senior Lecturer, Faculty of Law at the University of Wollongong, Australia. Earlier he taught at the School of Law, Sukhothai Thammathirat Open University, Thailand. He holds LLB (Hons) degree from Ramkhanhaeng University, LLM in International Economic Law from the University of Warwick and Ph.D. from the University of Warwick. He is a Barrister-at-Law at the Thai Bar. Email: jakkrit@uow.edu.au

national scale. The monopoly rights were provided on condition that the holder must work his imported invention in the country for a specific time and the patentee must teach the invention to others.<sup>5</sup>

Subsequently, the monopoly right was abused, as kings granted monopolies to favoured people who kept the prices of the commodities higher than they would normally have been. Because of the Crown's abuse of the royal prerogative and its use of patents as a source of patronage and revenue, but not to encourage invention, the Statute of Monopolies of 1623 was enacted in order to curb the royal ability to grant privileges and to abolish the unjustified monopoly power that was affecting free trade and competition in the country.

The Statute of Monopolies or the so-called 'Magna Carta of the rights of inventors'<sup>6</sup> is regarded as a landmark of the modern patent system. Section 6 of the Statute effectively stopped the monopoly power by prohibiting monopoly practices and declared all monopolies void. However, patent monopolies granted by the monarch were exceptionally excluded for fourteen years. The Statute recognized the right of the 'true and first inventor'<sup>7</sup> and established for the first time in history, the requirement imposed higher public interest for the grant of a patent, and limitation in time of the exclusive privileges.<sup>8</sup>

In the early stage of the English patent system, the patent holder had obligations to introduce trade and to teach details of his invention to indigenous tradesmen. Until the early eighteenth century, condition for disclosure changed from the work of the invention to disclosure in a documentary form. The inventor in exchange for a patent had to describe all details and manner of his invention in a specification.<sup>9</sup>

### **Compulsory Licensing and Local Working Requirement**

The concept of the modern patent system is based on reciprocity as used in the Statute of Monopolies. Patent is an instrument that compromises private and public interests. The State confers monopolistic proprietary privileges to an inventor, and in return the inventor provides adequate public disclosure of new knowledge and carries out local working of patented technology which will assist national economic development. A compulsory licence can be used by the State to achieve that economic goal. It authorizes the licensee to perform acts covered by the patent

exclusive rights (e.g. manufacturing, selling or importing the patented product). The compulsory licence can be granted on various grounds including non-working of patent.

### **International Rules**

Local working requirements, which have been a fixture of many countries' national patent law, are the primary means for effecting the goal of technology acquisition and promotion of economic development. The Paris Convention for the Protection of Industrial Property does not explicitly stipulate that patents must be effectively exploited in the granting State, but states in Article 5A(2) and (3) that each member has a right to adopt legislative measures (i.e. compulsory licensing and revocation or forfeiture) to prevent abuses of patent exclusive rights (e.g. failure to work).

The TRIPS Agreement seems to prohibit the imposition of local working as Article 27.1 requires equal treatment for both imported and locally-manufactured products.<sup>10</sup> However, it has been argued that TRIPS does not totally ban local working. The patent-granting country can still impose working obligations in accordance with Article 5A of the Paris Convention.<sup>11</sup> Since 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 authorization of the right holder) of the TRIPS Agreement, and possibly Article 5A of the Paris Convention which is incorporated into TRIPS through Article 2.1 of the TRIPS Agreement.<sup>12</sup> According to a general rule of treaty interpretation under Vienna Convention on the Law of Treaties, when general principles are in conflict with a specific provision, the specific rules shall take precedent.

This view is shared by prominent science and technology expert, Carlos Correa, who 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 him, 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).”<sup>11</sup>

If this interpretation is correct, the working of a patent through local production of goods can be legitimately required by WTO Members. It is interesting to note that patent laws of most developed countries still continue to regard the local working obligation as an essential element to balance the patent system.<sup>11</sup> Accession to WTO/TRIPS Agreement has not led those countries to repeal their local working provisions.

#### **Thai Law**

Compulsory licensing for local working is stipulated in Sections 46-50 of the current law of Thailand, the Patent Act B.E. 2522. Thai law regards non-working of a patent as an abuse. The law considers a patent not being worked in two particular circumstances: (1) when a patented product has not been produced or the patented process has not been applied for manufacture in Thailand, and (2) when the patentee refuses to sell the products protected by the patent, in the Thai market, in sufficient quantity, or when such products are sold at an excessive price. Importation is not considered 'working' of a patent. A patentee has an obligation not only to produce and sell the patented articles within the country, but also to work it at a level, or a substantial amount, sufficient to fulfil the Thai demand for the patented articles.

In one of the above situations, anybody can apply for a compulsory licence from the Department of Intellectual Property (DIP) to work the invention, but in return he has to pay a royalty to the patentee.<sup>13</sup> The person seeking a compulsory licence must submit an application to the Director-General of the DIP claiming that a request for authorization to use the 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.<sup>14</sup>

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 that such a product is sold but at an unreasonably high price, or does not meet the public demand without any legitimate reason.<sup>15</sup> This provision implies that the burden of proof of

non-working rests with the applicant rather than with the patentee. This constitutes a reversal of patent principle. As generally recognized, an obligation to work the invention is placed on the right holder. If there is no working, he should have a duty to present evidence to justify his inaction.<sup>16</sup> This reversal makes the Thai compulsory licensing system impractical, as the applicant has almost no chance of determining whether the patentee has a legitimate reason or not in not working the invention.

Section 46 of the Patent Act B.E. 2522 provides that an application for a compulsory licence can be made after the expiration of three years from the date the patent is issued, or four years from the filing date, whichever period expires last. This condition, which is drawn from Article 5A(4) of the Paris Convention, aims to provide sufficient time for the patentee to exploit his invention, but may not be sufficiently beneficial to protect the public interests. The period of time to obtain a compulsory licence by a third party is likely to be much longer than the time stipulated, as necessarily prior examination with respect to the requirements of patentability may take a long time,<sup>17</sup> especially in developing nations which lack staff and a systematic arrangement for patent examination. For example, the period of patent granting in Thailand is, on the average, three to four years. Since a compulsory licence cannot be issued during this period including another three year from the date of the grant of the patent, compulsory licensing procedure may be able to commence only after seven years from the time of filing the patent.<sup>18</sup>

Further, in cases where compulsory licensing application is under consideration of the courts rather than the administration, the procedure will definitely last longer.<sup>19</sup> Moreover, the patentee may resist or delay the grant of a compulsory licence by entering into a voluntary licence with one of its subsidiaries. The time lag, therefore, might act as an obstacle to an attempt by the patent granting country to use the compulsory licensing to safeguard public interests.

#### **Appraisal**

An examination at the DIP found no application for a compulsory licence being filed, and no single licence has been granted since the Patent Act entered into force in 1979. Apart from the complex granting procedure, there are three possible reasons why use of the system is so minimal in most developing countries. One is the lack of necessary know-how essential for the commercial working of patents.

Another reason may be the long period which a third party has to wait to apply for a compulsory licence. After the three or four-year period (unquestionably two or three more years from the filing date as discussed above), the technology relating to the patented invention, particularly those in rapidly evolving sectors, might have been considerably improved upon, and may become obsolete and irrelevant. Lastly, patent systems of most developing nations adopt the principle of compulsory licensing enshrined in the Paris Convention and the TRIPS Agreement. It is ironic that those nations are equally unwilling to occasional use of patent. The real difficulty may stem from political difficulties rather than economic or technical reasons.

### **Government Use Licence**

#### **Use of Patent for Public Interests**

The non-voluntary licensing for government use derived from 'Crown use' under English common law. By granting monopolistic patent rights, the Crown reserved the right to use patented inventions without the consent of or paying compensation to the patent holder.<sup>20</sup> The government use provision is considered necessary and in the larger public interest, and incidental to sovereign powers and functions of the State.

The Paris Convention does not specifically mention the government use. The non-voluntary government use is not subject to the requirements prescribed by Article 5A(4), which are applicable to abuses of patent rights such as failure to work or insufficient working. The powers of State to use the patented invention remain unaffected even after TRIPS enforcement. 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<sup>21</sup> 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.

Like the local working requirement, the government use provision 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 (Sections 55-59), 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 healthcare, environment and other matters of necessity.<sup>22</sup> A government use provision covers all uses of a patent by the State for either public non-commercial or commercial purposes. It may be made directly by the relevant government agency, or indirectly by any authorized body. The State exercising government use, however, must respect a number of conditions contained in TRIPS Article 31.

#### **Conditions for Non-Voluntary Government Use Licensing**

Under Thai law, Section 51 of the Patent Act B.E. 2522 provides for a government use licence. It lays down procedural and substantive rules to be fulfilled prior to exercising the government use licensing, including the following conditions:

#### *Grounds and Requirement for Consultation*

Thai patent law authorizes any ministry, bureau or department of the Government to issue a non-voluntary licence on various grounds of public demands. When the licence is sought on that basis, the State agency does not have to wait for a period of three or four years as in the case of compulsory licensing for local working. In line with TRIPS Article 31(b), Sections 47 and 47 bis 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. The State agency is required to notify the patentee in writing without delay after a licence is issued.

#### *Royalty Fees*

According to Article 31(h) of the TRIPS Agreement, the patent holder shall be adequately compensated, taking into account economic value of the authorization. The remuneration must be paid in all cases of non-voluntary licensing. When a compulsory licence is granted to remedy anti-competitive practices, the authority can determine the appropriate amount of remuneration by taking into account the necessity to correct such practices.<sup>23</sup> TRIPS, however, does not specify what amount of remuneration is adequate. The ambiguity of the term 'adequate remuneration' allows the granting country to compulsorily exploit the patent in exchange with the fee considered by the State to be reasonable.<sup>24</sup>

Section 51 of Thai Patent Law requires the licensing authority to offer the amount of remuneration and conditions for 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 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 Court of Intellectual Property and International Trade Court within sixty days.<sup>25</sup> It may be noted that the patentee can only appeal of the terms of the licence, but has no right to appeal the grounds for the decision to grant the licence. The appeal by the patent holder will not suspend the execution of the order.<sup>26</sup> This is significant to prevent the patentee delaying the issuance of the licence.

In the United States, the country experienced with the non-voluntary government use licence, the rate of adequate remuneration 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.”<sup>27</sup> Therefore the fees can be either a fixed sum per unit sold or a percentage of the net sales price of the product produced by the licensee (e.g. normally between 1 and 5 per cent). Other factors are also taken into consideration when a reasonable royalty is determined: expected volume of production, price under the non-voluntary licence, 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 anticompetitive practices, etc.

#### *Production for Export*

The significance of the compulsory licensing to improve access to essential medicines may be minimized when a country does not have capacity to manufacture required drugs.<sup>28</sup> 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 which is issued to combat anticompetitive practices may be exported to other countries. Secondly, 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 that less than half of the production authorized 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 compulsory licences to produce and export generic medicines to countries with insufficient or no manufacturing capacity in the pharmaceutical sector.<sup>29</sup> The 2005 Decision also waives the payment requirement in the eligible importing Member.<sup>30</sup>

Law of a large number of developing countries including Thai law still does not make operative to the decisions adopted by WTO. They may wish to adopt a provision permitting import of medicines they lack manufacturing capacity to produce. Countries with large generic producers like Thailand may consider incorporating into the national patent law provisions enabling the export of pharmaceuticals manufactured under the compulsory licensing.

#### **Revocation of Patents for Non-Working**

Since there is no specific TRIPS provision on forfeiture, any revocation of patents is compatible with the TRIPS Agreement. Article 5A(3) of the Paris Convention provides for the forfeiture of a patent, subject to three minimum requirements. First, when the owner of a patent supplies the local market through import, the granting State cannot exercise the forfeiture power.<sup>31</sup> Secondly, the State may prescribe the forfeiture only after a compulsory licence has already been granted and such a licence is inadequate to prevent the non-working of patent. Thirdly, the forfeiture shall not be applied before the expiration of two years from the grant of the first compulsory licence.

The Paris Convention provision is incorporated into Section 55 of the Thai Patent Act. The conditions under this provision seem to act as an obstacle for the use of this legal measure. The requirements make the forfeiture of patents a secondary remedy and essentially dependent on the grant of a compulsory licence. Since the use of compulsory licensing particularly in most developing countries is almost non-existent, the absence of the licence, which is a pre-requisite for the forfeiture, makes the forfeiture of patents unthinkable.

#### **Parallel Import of Patented Medicines**

Parallel import refers to the situation when products manufactured and sold abroad with the permission of the right holder are imported by third

parties into the country without authorization of the patent holder.<sup>32</sup> A number of factors (e.g. taxes, consumers' purchasing power, availability of brand name or generic products, etc.) cause price differentiation between countries, which create opportunities for cross border distributor to obtain a product in a low-price country and ship it to an unauthorized distributor in a high-price country.<sup>33</sup>

Many countries currently adopt the so-called 'international exhaustion' doctrine, which exclusive rights are exhausted after the first sale of the patented article regardless of the place of marketing, thus permitting parallel import.<sup>34</sup> Parallel import is the most effective and flexible method of enhancing competition and curtailing the serious restrictions of patents on prices. Unlike the compulsory licensing system, the importation right of the third party was automatic and was not subject to a length of time and complex granting procedures. The Doha Declaration clarifies Article 6 of the TRIPS Agreement that Members are free to establish their own regime for such exhaustion of right without challenge, subject to National Treatment and Most Favoured Nation Treatment under TRIPS Articles 3 and 4. Parallel import, however, can be hindered by other restrictions, such as, national health and safety regulation, process of drug registration, restrictive clauses imposed on the distributor in the country from which the drug is imported, etc.

Section 36(7) of the Thai Patent Act authorizes parallel import if the products are marketed abroad by the patentee or with his consent. However, the law is unclear if parallel imports could be made from sources unauthorized by the patentee (e.g. the producers who manufacture the drugs under a compulsory licence). In order to make essential products available in the local market, the law of developing countries should authorize parallel imports of patented products that are available in the foreign market at prices lower than the domestic prices due to compulsory licensing being granted in that country. It is equally important that all restrictions to parallel import be removed.

#### **Patentability of Further Uses of a Known Product**

The practice of the national patent office may affect the country's accessibility to medicine, particularly if patenting of trivial inventions is admissible. Generally, the invention is no longer

patentable when it belongs to the prior art and then lacks novelty. Some countries' patent laws make an exception in favour of the discovery of the new use of an existing product. Article 54(5) of the European Patent Convention (EPC), for example, recognizes patentability of a new medical use of a known substance (i.e. use of a substance in a surgical, therapeutic or diagnostic procedure) or a known mixture of substances, provided that such a use or mixture has not been known to the public.<sup>35</sup>

The above provision grants protection to an invention consisting of previously known substances for use in a new medical method:<sup>36</sup> for example a claim for product X (a known product) to be used as an active therapeutic substance (a new medical use).<sup>37</sup> This sort of claim, called a 'purpose-limited product claim' (not a use claim), is patentable and not considered the invention relating to medical treatment which is excluded from patent protection under Article 52(4) of the EPC. The essence of this provision is that a pharmaceutical invention is afforded dual protection. First, the inventor may assert either an 'absolute product claim' or a 'product claim for a particular use' for a new pharmaceutical product. If, instead, the substance or composition is known, then the inventor may defer to general patent law principles pertaining to 'use claims', provided that the use of such a product in medical way has never been known before.

To the extent that a single pharmaceutical substance can have multiple uses, the law, however, is unclear on the notion of the second and subsequent use of a known drug. Since the EPC prohibits the grant of patent when use of the product in 'any method' for the treatment of human and animal body is not new,<sup>38</sup> this implies that when the substance has been disclosed for use in medical treatment in any way, further uses of the substance are no longer patentable. The EPO Enlarged Board of Appeal considered this issue and ruled in G5/83, EISAI/Second Medical Indication<sup>39</sup> that the second and subsequent medical use was not patentable as it was equivalent to the method of treatment of human and animal body. The Enlarged Board went further by holding that a claim for a second or further use of 'a certain substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application', the so-called 'Swiss claim', was not included in this exclusion and it could fulfill

the novelty requirement. This decision was followed by the courts of the EPC members such as UK court in *John Wyeth and Brother Ltd's Application*.<sup>40</sup>

Section 9(4) of the Thai Patent Act adopts the principle that methods for medical treatment are not patentable. Like the Patent Office of many other developing countries, the DIP follows the practice of the EPO by treating first and second indications (i.e. a new medicinal use of the known substance) as a product claim, and thus not excluded from patent protection under Section 9(4) of the Patent Act. This is so despite the fact that Thai law has no parallel provision of Article 54(5) of the EPC that provides special treatment to medical inventions.

Regarding the criteria for patentability, it has to be taken into account that there are no internationally agreed criteria to define what constitutes a patentable invention. Thailand and other developing countries must preclude the necessity to copy or follow the procedures that are in place in other countries. They should make it clear that patents are available for new medical products or new chemical entities only. Allowing patentability for the first and subsequent uses or the new composition of a known drug would unnecessarily prolong the monopolistic market enjoyed by the patentee and deprive consumers of the right to essential medicines. Thailand and other developing countries should treat 'first and second indications' claims as a method of medical treatment and therefore non-patentable. It should conceivably deny a patent for pharmaceutical composition on grounds of lack of novelty (i.e. being 'anticipated by the effective ingredient that it contains').<sup>41</sup>

### **Opposition Proceedings**

It is extremely costly for a country to carry out accurate patent examination. The United States, for example, spends more than US\$ 1 billion per year to do exhaustive searches of the prior art and to carry out substantive examination of patent applications. Patent offices in developing countries do not have sufficient resources and qualified staff. Its staffs are generally under-trained and have less access to technological materials on prior art.<sup>42</sup> Thus, it is extremely important that patent law of those countries provides for patent challenge proceedings in order to detect an application's weaknesses and allow competitors to oppose the grant of a patent to such an application.

There are two types of opposition proceedings: pre-grant and post-grant. The former is the system that

opposition is considered by the national patent office during the examination process, and the latter refers to the proceedings brought by the opponent of a patent holder before the patent office or the courts. The post-grant procedure comes after the decision on the examination leading to official grant of the patent and the opposition is filed to challenge the decision. Challenging a patent before it is issued is an administrative process, and is generally faster and cheaper than post-grant court proceedings. While a successful opposition in a pre-grant procedure will prevent the entire issuance of the patent or limit the scope of the opposed patent claims, the post-grant patent challenge can result in one of these solutions: rejection of the opposition, nullifying the granted patent, and amending the patent.

The TRIPS Agreement is silent on the issue of procedures for patent opposition. The Japanese law, the EPC and law of the countries brought in line with the European Convention (e.g. that of the United Kingdom, the Netherlands, Germany, Sweden, Denmark, etc.) provide for a post-grant opposition procedure.<sup>43</sup> The current law of India is unique as it is the only patent law that provides for both pre- and post-grant opposition.<sup>44</sup> The patent systems of most developing countries seem to prefer a pre-grant opposition. Section 31 of the Thai Patent Act, for example, permits oppositions to be filed after the applications are published. Any person, without restriction as to their nationality or connections with the applicant, may initiate proceedings to oppose the grant of a patent within ninety days from the date of the publication. There are two reasons on which oppositions may be based: (1) lack of patentability; and (2) the applicant is not entitled to file a patent application. Other grounds likely to affect the validity of a patent (e.g. insufficient disclosure) cannot be raised as grounds for opposition under Thai law.

The United States and the European Union are now pressurizing developing countries to discard their pre-grant opposition proceedings.<sup>45</sup> Those countries are very skeptical about the negative effects of such pre-grant opposition, particularly, the very considerable delay in achieving the grant of a patent. Such procedures, they maintain, are unnecessary and done at the wrong time. Since the only document available after the date of publication would be the specification as filed, the person who lodges an opposition might not be certain as to what exactly he is opposing.<sup>46</sup>

The repeal of the present system for post-grant opposition may not benefit the developing countries wishing to increase access to medicines. It will be much more difficult for the competitor to oppose patents after grant as the patents are in force while the opposition litigation is pending. The pre-grant patent challenge is the best way to limit the number of granted invalid patents. It provides some form of low cost administrative procedure for the manufacturers of generic medicines, who are in a better position to check a drug's patentability than the patent office as they operate in the same field and are aware of the previous use of the medicine. However, since the pre-grant opposition proceedings can be used by third parties to delay the grant of a patent, it is necessary that the process is run in a transparent manner. It is equally important that the process for oppositions is independent, and fair and equitable to all parties.

### Conclusion

Given the detailed characteristics of patent systems relating to pharmaceuticals, it can be asserted that the implications of pharmaceutical patenting have strongly affected national socio-economic development of developing countries. The achievement of the developing countries in minimizing the impacts of pharmaceutical patents and maximizing the benefit of patent protection depends on the best combination of policies, efficient administrative system, and effective and appropriate legislations. The national patent system must be designed to serve the social, economic and technological needs of the granting country.

It is strongly recommended that the patent law of developing countries should be revised along this line: (1) extension of the objectives of the patent law to reflect objectives and principles of intellectual property protection as stipulated under TRIPS Articles 7 and 8; (2) clarification of rules of novelty and inventive step so as to prohibit claims to trivial inventions such as a new use of existing substances and a new indication or formulation; (3) strengthening and implementing provisions of compulsory licensing, government use, and parallel import; (4) incorporating national law provisions enabling import and export of pharmaceuticals produced under a compulsory licence in line with the Doha Declaration and the WTO Decisions; (5) adopting and implementing guidelines for non-voluntary licensing procedures and on remuneration; (6) adoption and

maintaining of the pre-grant opposition proceedings which are conducted by an administrative review.

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