

## Compulsory Licensing of Patented Drugs under National Emergency

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Patent protection to pharmaceutical products by the TRIPS Agreement had made serious concerns in the developing countries regarding accessibility, availability and affordability of life saving drugs. TRIPS Agreement, at the same provided flexibilities to the member countries to even off the adverse effects of pharmaceutical patent system especially in cases involving public health. National emergency, being such flexibility allows member countries to invoke compulsory license for accessing life-saving drugs in cases of national emergency without any pre-conditions. By the Doha Declaration the freedom is also vested upon the individual countries to define the term 'national emergency'. This triggers apprehension among the patentees about the abuse of such wide discretion by these countries. But these concerns are found negative by the analysis of case studies of compulsory license issued on national emergency. Countries are very cautious while invoking this provision.

**Keywords:** Compulsory license, patent, national emergency, TRIPS Agreement, Doha Declaration, HIV/AIDS

Pharmaceutical patent protection was one among the important changes that the TRIPS Agreement brought to the national patent systems. This had a major blow on access to affordable medicines in developing countries. This had also diminished the role played by the generic pharmaceutical companies in aiding access to affordable medicines in WTO member countries. Access to affordable medicines is an extreme need of the developing countries. This is exemplified by the fact that 400 million people lack health care, including access to medicines, vaccines, and diagnostics and medical devices, of whom 300 million live in middle-income countries.<sup>1</sup> Citizens of developing countries suffer the majority of global infections, and millions die of treatable diseases.<sup>2</sup> At the same time TRIPS also contains various flexibilities that the member countries could adopt to even off the adverse effects of pharmaceutical patent system. Compulsory license is one of the safeguards that international IP law provides to address the undesired effects of pharmaceutical patents on access to important medicines.<sup>3</sup>

The Compulsory license system under the TRIPS provides various conditions for the grant of it.<sup>4</sup> It includes prior negotiation with the patentee to get a voluntary license on reasonable commercial terms. But this condition cannot be followed in all the circumstances. One such situation is a public health

crisis. TRIPS specify special provisions in such circumstances so as to overcome the crisis. It thus, stipulates under its Article 31(b):

*“This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;”*

Thus, the TRIPS Agreement provides for the waiver of the condition in cases of national emergency. But none of the document gives a definition to the term 'national emergency' leaving it to the individual countries to decide.

### **National Emergency: Meaning and Definition**

The term “national emergency” is not defined in the TRIPS Agreement. An emergency is a serious, unexpected, and often dangerous situation requiring immediate action.<sup>5</sup> To the World Health Organisation (WHO), “emergency is a term describing a state. It is a managerial term, demanding decision and follow-up in terms of extra-ordinary measures (Oxford Pocket Dictionary, 1992). A “state of emergency” demands

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to “be declared” or imposed by somebody in authority, who, at a certain moment, will also lift it. Thus, it is usually defined in time and space, it requires threshold values to be recognized, and it implies rules of engagement and an exit strategy. Conceptually, it relates best to Response.”<sup>6</sup>

National emergency is a term that is used to describe a crisis that involves the security and safety of the country.<sup>7</sup> It can also be defined as a situation beyond the ordinary which threatens the health or safety of citizens and which cannot be properly addressed by the use of other law.<sup>8</sup> The Black’s Law Dictionary defines national emergency as “a state of national crisis; a situation demanding immediate and extraordinary national or federal action.”<sup>9</sup> A national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory.<sup>10</sup>

Though, the proper definition of national emergency as far as patent law is concerned is not given anywhere, even in the TRIPS negotiation history, an indication as to what can be a situation of national emergency is provided in the Doha Declaration on the TRIPS Agreement and Public Health and it reads:

*“5.c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”*<sup>11</sup>

The Doha Declaration thus explains what situations can be considered as national emergency calling for the issuance of a compulsory license. It also identifies certain diseases that can lead to the situation. But this is not an exhaustive list. Thus, the Doha Declaration acts as a guide and it confers the right to define the term national emergency upon each member countries. The Declaration is also silent on other factors that should be taken into consideration while declaring an emergency.

According to N. Lalitha, “most of the countries provide for the use of patented inventions without the consent of the patent holder in emergency situations such as war, famine, natural catastrophe, etc.”<sup>12</sup> Although all the countries legislation contain the clause on compulsory licensing but dimension of issuing this license varies and depends upon the different factors like health status, disease burden and

development status and innovation capacity. India is a developing country with a population of more than 1 billion and having low economic status while high disease burden.<sup>13</sup> Like in the case of India, all other countries have their unique conditions which will decide the circumstances of national emergency. Therefore, the declaration of emergency and the resultant compulsory license vary differently for different countries. This may leads to a situation where there is an abuse or misuse of this provision, as feared by the patentee thereby undermining the rights of the patentee by giving ample freedom to the nations to decide what constitute a national emergency so as to issue a compulsory license. Case study of instances of compulsory license in the eve of national emergency can offer some clarification in this regard.

### **Instances of Compulsory License under National Emergency**

Countries around the world are using the compulsory license provision as provided in the TRIPS. Government use of a patent is the widely used type of compulsory license. Situations of national emergency can easily result, where a government finds itself faced with an unanticipated crisis, while its capacity to respond to the crisis in the interest of public protection is limited. This normally occurs in situations where a serious pandemic suddenly erupts or a situation threatening peace and stability arises.<sup>14</sup> A thorough analysis of cases on compulsory license on national emergency is vital in finding out the conditions under which and the circumstances upon which member countries are issuing compulsory license.

#### **Zimbabwe**

On 24 May 2002, the Minister of Justice, Legal and Parliamentary Affairs declared a period of emergency in Zimbabwe for a period of 6 months in order to tackle the rapid spread of HIV/AIDS among the population of Zimbabwe.<sup>15</sup> This enabled the State or a person authorised by the Minister to make, use or import any generic antiretroviral drug (ARV). In 2003, this period was extended by 5 years, till 31 December 2008. In Zimbabwe, where over 2,000 people die of the disease every single week, AIDS is threatening the very future of the country. Life expectancy has dropped to less than 41 years, compared to 70 years before the epidemic.<sup>16</sup>

### **Mozambique**

The Government of Mozambique on 5 April 2004 declared a national emergency and granted a compulsory licence (No. 01/MIC/04) for the local manufacture of a triple combination of lamivudine, stavudine and nevirapine; antiretroviral drugs which have proved to be the most effective and economical treatments.<sup>17,18</sup> It also specified that the grant will be expired as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end.

The decree also contained the reasons for such an emergency which necessitated the issuance of compulsory license:

- a. the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under-development and misery and,
- b. High rates of morbidity and mortality have put Mozambique among the ten countries in Africa worst hit by this disease. Current estimates are that at the end of 2002 over 1.5 million Mozambicans were infected by HIV, of whom more than 100,000 are suffering from full-blown AIDS. The AIDS death toll is so far well over 200,000 and about 360,000 children have been orphaned by the pandemic,
- c. In spite of multiplication and diversification of vigorous prevention campaigns the spread of the virus is still on a climbing trend as shown by the high number of infections,
- d. Anti-retroviral drugs are already available, which prolong lives of those infected with HIV/AIDS, and that until now, at this day, the international patent owners have failed to make such drugs accessible at affordable prices to most of the Mozambican people.<sup>19</sup>

Thus, the reasons leading to a national emergency is quite clear and justifiable in the Decree itself. The Government had made all its prior-efforts to cut down the spreading of the disease such as campaigns which all went in vein. It also pointed out that in spite of such a situation, the patentees failed to make the life-saving drugs accessible at affordable prices to these patients making an emergency to issue a compulsory license.

### **Swaziland**

On 20 April 2004, an emergency with regard to HIV/AIDS was declared by the Ministry of Health and Social Welfare. This leads to issuance of a compulsory license to import HIV/AIDS drugs to

Swaziland until such time as it is no longer considered essential to address the public health crisis. At an estimated 25.9% [24.9%–27.0%] in 2009, Swaziland has the highest adult HIV prevalence in the world.<sup>20</sup> According to the World Health Organisation country profile for HIV/AIDS Treatment Scale-up, 2005, Swaziland is one of the most severely HIV-affected countries. The first AIDS case in Swaziland was reported in 1987; today more than one in three adults is infected and Swaziland faces a generalized HIV/AIDS epidemic. The HIV prevalence rate among pregnant women is currently estimated to be 43%. According to Swaziland's ninth HIV seroprevalence survey conducted in 2004 among women attending antenatal care clinics, the HIV prevalence rate among 15- to 19-year-olds declined from 32% in 2002 to 29% in 2004, indicating that the number of new infections in this age group may be declining. However, the prevalence rate was increasing in other age groups, the hardest hit being those 25–29 years old, with a prevalence rate of 56%. Most deaths have occurred among young people. Rural and urban areas do not differ significantly. About 75–80% of the people with tuberculosis are coinfecting with HIV. The epidemic has been fuelled by poverty, unemployment, a large migrant population, conservative religious and traditional beliefs against condom use and frequent multiple sexual partners and has severely affected society and the economy.<sup>21</sup>

### **Zambia**

Zambia also issued a compulsory license under a national emergency situation for the same triple combination of lamivudine, stavudine and nevirapine; antiretroviral drugs on 21 September 2004 as that of Mozambique, for a period of 5 years, till 31 July 2009.<sup>22,23</sup> The reasons were also given in the order as in the case of Mozambique. It stated that the current estimates are that at the end of 2003 over 917,718 Zambians were infected by HIV, of whom unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far well in excess of 835,904 and about 750,504 children have been orphaned by the pandemic.

### **Indonesia**

Indonesia issued compulsory license three times. It issued a compulsory license on October 5, 2004 pursuant to the urgent need to control HIV/AIDS epidemic in Indonesia through a Presidential Decree regarding exploitation of patent by the government on

ARV (No 83, 2004), through provision of patented ARVs, nevirapine and lamivudine for 7 and 8 years respectively. In 2007 Indonesia amended its decree to add one more ARV drug under compulsory license, efavirenz. Again in September 2012, the government announced that they were going to issue compulsory license on seven HIV/AIDS and hepatitis B medicines, efavirenz, abacavir, tenofovir, lopinavir/ritonavir, didanosine, and fixed-dose combinations tenofovir/emtricitabine and tenofovir/emtricitabine/efavirenz citing urgent need to improve patient access.

#### **Eritrea**

On 8 June 2005, Minister of Health, State of Eritrea has declared an emergency period for HIV/AIDS, and issued compulsory license to import HIV/AIDS drugs to Eritrea.<sup>24</sup> It also made it clear that these drugs will be used for non-commercial purpose only.

#### **Ghana**

On 26 October 2005, the Minister of Health, Republic of Ghana declared an emergency situation with regard to HIV/AIDS and thereby issued compulsory license for all drugs for importation into Ghana of generic HIV/AIDS drugs.<sup>25</sup> It was also mentioned that this will not be for any commercial purpose and will be used solely by the Government.

The study above reveals that the countries that used the compulsory license in national emergency are all low income African countries.<sup>26</sup> All of them have used it to fight against the HIV/AIDS epidemic that corroded most of the African countries. The misuse of the provision was not visible in any of the cases. In fact they have all used it for emergency situation emerged out of HIV/AIDS which was clearly within the definition provided by the Doha Declaration.

#### **Conclusion**

National emergency is a situation under which the pre-requisite conditions for granting compulsory license can be waived. The other situation i.e., public non-commercial use can also be taken. In such cases the patentee shall be informed of such a grant promptly. But this can also be waived in national emergency situations. The patentee needs to be informed only after the issuance of compulsory license.

The definition which was offered by the Doha Declaration is only explanatory in nature. That will neither restrict nor prohibit the member countries from the using the flexibility of defining the term

national emergency taking into account the health crisis faced by such member country. The Doha Declaration which has given ample freedom to the member countries to define the term is in no way affect the rights of the patentee. The countries declaring emergency and thereby issuing compulsory license are so prudent that they have respect for the TRIPS obligations and the rights of the patentee. They have used these provisions only in very extreme situations and only when they have failed to suppress the emergency situation by all other means.

The case studies disclose the fact that the countries using the compulsory license provision to address the public health issues. HIV/AIDS epidemic was, in fact, the only ground used by these countries to invoke compulsory license. This is evident from the case studies above. Misuse by the countries of the flexibilities as feared by the patentee is baseless. In fact the study shows that member countries are not utilizing the TRIPS flexibilities to its fullest extent. During the period 2002-2012, one can find only 7 instances of compulsory license on the ground of national emergency/extreme urgency. This is self-explanatory of the fact that abuse of compulsory license due to giving the right to define the national emergency on the member countries is in no way evident. Rather its usage is very limited and only under a truly emergency situation, that also only after when all other efforts by the nation to control the emergency situation became inadequate.

Thus, it can be concluded that the use by the countries of the TRIPS flexibility in the form of national emergency for the issuance of compulsory license is in neither against the TRIPS Agreement nor against the legitimate expectations of the patentee. The rights of the inventor as protected by the patent law will not be affected by such usage. In fact the usage of such provision by the countries is only to address the extreme health crisis which will be ceased when such crisis come to an end. Therefore there is no conflict with two interests, the public interest to protect health and the private interest to protect the invention which is the basis of the intellectual property rights.

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- (a) authorization of such use shall be considered on its individual merits;
  - (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
  - (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
  - (d) such use shall be non-exclusive;
  - (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
  - (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
  - (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
  - (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
  - (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
  - (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
  - (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:
- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
  - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
  - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.”
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