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Compulsory licensing issues and trends in Asia



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Government-use compulsory licensing has almost always stirred up controversies and debates with regard to its appropriateness, actual benefits and detriments. Patent owners and advocates of IP protection remain firm on the position that while a country has the right to override patents by issuing compulsory licenses (CLs) in certain limited circumstances, this should be viewed as a last resort, not a preferred method of tackling public health issues. On the other hand, patient rights groups, NGOs and pro-CL governments argue that implementing CLs is in line with international obligations under the WTO framework, which affords member states the right to challenge patents in order to promote access to medicines and resolve public health problems. Although most of the earlier CLs issued in Asia mainly focused on solving health crises relating to HIV/AIDS or other epidemics, Thailand and India began to implement CLs as a means to increase access to drugs whose market prices are regarded as being too costly, including cancer drugs and cardiovascular drugs. This new trend is a slippery slope, and could easily turn into abuse of the patent system beyond what was intended under the WTO framework.

Protection of intellectual property, including patents, was specifically recognized by the WTO in the TRIPS Agreement [1]. As an exception to patent rights, Article 31 of the TRIPS Agreement recognized that a member state may grant CLs where necessary, but it also set out a number of conditions and limitations for such government-use CLs. In particular, to provide an opportunity for fair negotiations, Article 31 subparagraph (b) mandated that before a CL is granted, the proposed user must have made efforts to obtain authorization from the patent owner on reasonable commercial terms, and such efforts must have been unsuccessful after a reasonable period of time. An exception is in the case of ‘a national emergency or other circumstances of extreme urgency’, for which a government need not consult with the patent owner in advance of granting the CL; however, the government should notify the patent owner as soon as reasonably practicable thereafter. Article 31 subparagraph (c) also limited the scope and duration of the CLs to the purposes for which they were authorized, and subparagraph (f) further restricted the CLs to the supply of the domestic market. In short, the TRIPS Agreement provides members with compulsory licensing flexibility, but with strong safeguards against an abuse of such power.

Subsequently, with the rise of public health problems and issues regarding access to medicines, especially global concerns over the HIV/AIDS epidemic, at

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Keywords: access to medicines • Asia • compulsory license • Doha declaration • government-use compulsory license

the Ministerial Conference of the WTO in Doha, the “Declaration on the TRIPS Agreement and Public Health” [2] was adopted on 14 November, 2001 to clarify the TRIPS Agreement’s compulsory licensing flexibility in respect of public health. The so-called ‘Doha Declaration’ served to reaffirm the rights of WTO members to implement CLs in accordance with the TRIPS Agreement provisions. The Doha Declaration in particular stated that each WTO member would have the right to determine what constitutes a national emergency or other circumstance of extreme urgency. Public health crises, including those relating to HIV/AIDS, were expressly recognized as crises that could represent a ‘national emergency or other circumstance of extreme urgency’. In addition, Paragraph 6 of the Doha Declaration tackled situations where some countries did not possess the drug-manufacturing capacity to supply their domestic markets, to the extent that issuance of a CL in that country would be meaningless [2]. In light of this, on 30 August 2003, the General Council of the WTO issued a (temporary) waiver, whereby ‘exporting members’ may produce for export medicines for use in ‘importing members’, in the case that such importing members do not have sufficient pharmaceutical production capacity to benefit from a CL [3]. The Council subsequently announced its intention to adopt the 2003 waiver as a permanent amendment of the TRIPS Agreement. However, as of August 2013, the permanent amendment has not yet been accepted. The period for acceptance by members has already been extended threefold, and the third extension will expire again on 31 December, 2013 [4].

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Since the adoption of the Doha Declaration, Asia has seen a continual rise of government-use CLs being considered and implemented by several nations. Led by Malaysia, Indonesia and Thailand, a handful of countries in Asia have chosen to invoke the CL mechanisms to solve their public health issues.

Malaysia was the first Asian country that issued a CL for pharmaceutical products. On 29 September 2004, the Malaysian government issued a 2-year government-use CL to import from India three HIV/AIDS medicines, which are didanosine/ddI (patented by BMS), zidovudine (patented by GSK) and a combination of lamivudine and zidovudine (patented by GSK). Under

the CL, the selected Indian generic manufacturer was allowed to export and sell these medicines under fixed ceiling prices to the Malaysian government for exclusive supply to government hospitals for 2 years.

Indonesia also issued its first government-use pharmaceutical CL by way of a Presidential Decree in 2004, in order to address the urgent needs of the community in the effort to control the HIV/AIDS epidemic. The first two HIV/AIDS drugs that were subject to CLs are nevirapine and lamivudine (also used for treatment of hepatitis B). Again, in 2007 the Indonesian government issued the second CL on nevirapine, lamivudine and another HIV/AIDS drug, efavirenz (patented by Merck).

Taiwan also issued a CL for an avian influenza medicine (Tamiflu®) in 2005, which expired at the end of 2007. Unlike the previous CLs implemented in Malaysia and Indonesia, Taiwan’s CL action was accompanied by a number of conditions which effectively limited the use of the CL to when there is a pandemic and existing supplies of medicine would be exhausted.

In the following years, the CL trend in Asia not only continued, but grew to a much larger magnitude when Thailand, by the Ministry of Public Health, acting under a postcoup military-appointed administration, began to issue its first batch of CLs on three patented drugs from December 2006 to January 2007. Although Thailand began its CL actions by targeting two HIV/AIDS drugs, efavirenz (Merck) and a combination of lopinavir and ritonavir (Abbott’s Kaletra), the Public Health Ministry quickly turned to utilize CLs for medicines for noncommunicable diseases (NCDs), including a cardiovascular medicine, clopidogrel (Sanofi-Aventis’ Plavix) and a range of cancer medicines, which were later targeted in its second batch of CLs in 2008. The legitimacy of the CLs issued in Thailand was debated extensively, both in Thailand and overseas, especially with regard to whether the correct legal procedures had been complied with by the Ministry of Public Health. Notwithstanding the controversy, there was a further announcement of CLs on three additional NCD drugs in early 2008. The second batch of CLs included a breast cancer drug, letrozole (Novartis), a breast and lung cancer drug, docetaxel (Sanofi-Aventis) and a lung cancer drug, erlotinib (Roche). Novartis’ leukemia drug, imatinib, was also targeted, but in the end, a CL was not issued for this drug.

After the CL episodes in Thailand during 2006–2008 (which remained a controversial issue for several years thereafter), no other Asian country further announced a CL on pharmaceutical products until 2012, when the CL actions returned once again in an even larger magnitude. First, India invoked its first CL against Bayer’s

Nexavar® (sorafenib), which is used for the treatment of kidney and liver cancer. (Bayer's appeal against the CL is ongoing). Following a new trend started by Thailand, the CL mechanism is no longer used just to solve crises in relation to the HIV/AIDS epidemic or other severe communicable diseases. Instead, CLs are also imposed on NCD drugs that are considered too expensive. The Indian government also continues to consider additional CLs for other costly cancer drugs, including breast cancer drugs Herceptin® (Genentech) and Ixempra® (BMS), and the leukemia drug Sprycel® (BMS).

Yet, the latest and largest CL announcement in Asia to date was issued in Indonesia. The September 2012 Presidential Decree called for what would be Indonesia's third CL mandate and the broadest government-use CL ever issued in Asia, if implemented in full. The Decree covered seven HIV/AIDS and hepatitis medicines, including efavirenz (Merck), abacavir (GSK), didanosine (BMS), a lopinavir/ritonavir combination (Abbott's Kaletra), tenofovir (Gilead Sciences), a tenofovir/emtricitabine combination (Gilead Sciences' Truvada) and a combination of tenofovir, emtricitabine and efavirenz (Gilead Sciences/Merck' Atripla). However, as of August 2013, the Indonesian government has not yet authorized any companies to produce generic versions of the drugs involved.

The developments described above strongly suggest that the trends within Asia appear to be tilting in favor of utilization of CLs to promote access to 'costly' medicines, where the notions of 'national emergency or other circumstances of extreme urgency' have become a lesser determining factor for invoking CLs. Perhaps Asia's rapid economic growth has also emboldened its governments, making them less fearful of the potential drug availability risks or adverse political effects that CLs may lead to. Furthermore, almost every country in Asia, from least to highly developed nations, maintains the ability to issue government-use CLs. This fact seems to suggest that, at a minimum, most governments perceive CLs as a potentially necessary tool for keeping vital drugs available and affordable in their countries.

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Websites

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