How public health affects patent rights

**Peter Ollier** previews Question 202, being discussed today, which looks at the controversial area of how public health issues affect patent rights.

**Compulsory licensing**

But paragraph 31 of TRIPs has caused even more debate. This relates to compulsory licensing, which is perhaps the most extreme and controversial of the limitations that public health issues can place on exclusive patent rights. Article 31 states that a compulsory licence may be issued if “prior to such use, the proposed user has made efforts to obtain authorisation 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 a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use”.

This issue is not confined to developing countries: in 2006 the Italian Competition Authority granted a compulsory licence for GlaxoSmithKline’s patents relating to sumatriptan succinate to a local chemical company after GSK had refused to grant a voluntary licence. The most high-profile debate on compulsory licensing in the last two years has taken place in Thailand. In late 2006 the Thai military government angered originator pharmaceutical companies when it issued a compulsory licence for Merck’s antiretroviral drug efavirenz. The product is marketed by Bristol-Myers Squibb in the US and some European countries under the brand name Sustiva and in other countries – including Thailand – by Merck under the name Stocrin.

In January 2007 the government issued two more compulsory licences for Kaletra, another AIDS drug produced by Abbott, and for Plavix, a blood-thinning medicine developed by Sanofi-Aventis and Bristol-Meyers Squibb to treat heart disease. Plavix was the world’s second biggest-selling drug in 2005, with world-wide sales of $5.9 billion. Then in January this year, a few days before he left office, the health minister Mongkol Na Songkhla asked a committee to begin the process of issuing compulsory licences for Femara (letrozole), made by Novartis; and Tarceva (erlotinib) and Taxotere (docetaxel), which are produced by Genentech and Sanofi-Aventis respectively. Novartis’s anti-cancer drug Glivec had also been threatened with a compulsory licence, but the Swiss drug maker reportedly offered it for free to cancer patients under Thailand’s universal health insurance programme. Thailand’s group report for this question, written by Chavalit Uttasart and Kallayarat Chinsrivongkul of Chavalit & Associates, states that under the Thai Patent Act, the government may grant a compulsory licence for “the prevention of severe shortages of food, medicine or other consumption items; or for other public interest”. And the government has used this section to issue the seven compulsory licences.
All reporting countries have provisions in their laws on compulsory licences but, as the summary report notes, very few have actually granted them. In addition to Italy, Brazil has granted two compulsory licences to its Ministry of Health on public interest grounds for Merck’s efavirenz. In the Philippines between 1985 and 1992, eight compulsory licences were sought, of which five were granted.

Thanks to the WTO decision of August 2003 at Doha, it is now possible to grant a compulsory licence to export a drug to a less-developed country that cannot produce the medicine itself. The majority of reporting countries have ratified this amendment, but few compulsory licences have been issued using this new flexibility. The only successful example so far has been Canada’s compulsory licence to export the triple combination AIDS therapy drug TriAvir to Rwanda.

Although this is the only example of a successful compulsory licence for export at present, two applications in India are being contested. In September last year Hyderabad-based generic company Natco Pharma applied to the Delhi Patent Office for compulsory licences to export two drugs to Nepal and Ukraine using a Doha-style compulsory licence. The drugs were Sutent, which is made by Pfizer, and Roche’s Tarceva.

Apart from the controversial area of compulsory licences, a number of other exceptions exist. These include exceptions for research or experimental use. The vast majority of groups that submitted responses do allow some form of exception, but countries differ on whether the experimental use can have a commercial aim. Belgium, Denmark, Germany, Sweden, Switzerland and the UK noted in their reports that a commercial aim was not ruled out. Other countries allow experimental use for a purely scientific purpose, while in the US the experimental use is allowed solely for “gratifying a philosophical taste, or curiosity, or for mere amusement”.

In addition to the exception for experimental use, some countries also allow a Bolar-type exception that allows experimental use by generic drug makers so that they can obtain market authorisation while the patent is still in force and be ready to launch the drug once the patent duration runs out. The European Union has a Community-wide exception. In some countries, such as France and Germany, the exception is not limited to obtaining marketing approval for a generic, but also includes approval on innovative drugs.

China’s National People’s Congress is considering amendments to the country’s patent law that would introduce a Bolar exception, while in June this year the Philippines passed a Cheaper Medicines Act that introduced a Bolar exception. Judging from the reports submitted on this question, there is broad agreement on the need for both experimental use and Bolar exceptions.

**Parallel problems**

The Cheaper Medicines Act in the Philippines is a good example of how a government can limit patent rights to increase access to medicines. In addition to introducing a Bolar exception the Act also introduces international patent exhaustion for medicines and allows the government or any third party to import these drugs. International exhaustion for medicines is one of the areas in Question 204 where there is little agreement. Within the European Economic Area, regional exhaustion applies. The summary report states that in most other countries, there is national exhaustion.

At present, the countries explicitly allowing parallel imports are: Argentina, Colombia, Egypt and Peru. But China may soon be joining them. Article 74 makes it very clear that international exhaustion applied in China:

Where the patentee has obtained a patent in China or the patentee permitted person produces patented product in other countries or regions or after the sale of a patented product was directly obtained by using the patented product, any other person shall not use, offers to sell or sells that product.

In South Africa national exhaustion applies, but the parallel importation of medicines has specifically been allowed after an amendment to the South African Medicines and Related Substances Act, which empowers the minister to allow the supply of more affordable medicines to protect public health.

The trend towards allowing international exhaustion in the Philippines and China might worry some patent holders. But Elliot Papageorgiou, a partner at Rouse & Co International in Shanghai, indicates that for developing countries such as China, that are net importers of patented products and technologies, it makes sense to allow parallel imports. “Giving protection against parallel imports in the short and medium term is going to be viewed by these developing countries as counter-productive, as it will raise the cost of technology inputs and thus the cost of domestic production,” he says.

In addition to these well-known limitations to patent rights, some countries also allow an exception for individual prescriptions, while Brazil, uniquely, has a double examination system for pharmaceutical patents – one by the Brazilian Patent Office and one by the regulatory authority, ANVISA, to take public health policy grounds into account. Brazil’s report states: “In some cases, broadly definable arguments, such as public interest or national health interests, are used as a basis for denial.”

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