Compulsory Licensing in a Nutshell

Tim Stirrup and Katherine Hebditch

Baldwins Intellectual Property, PO Box 5999, Wellesley St, Auckland (email: *tim.stirrup@baldwins.com* or *katherine.hebditch@baldwins.com*)

It would seem inconceivable that a government or competitor could ride roughshod over your hard-earned patent rights. Surely the right to exclusively exploit your invention is enshrined in law and international agreements? In exceptional circumstances this is exactly what can happen, and every major patent system in the world has provisions for the government or a court to intervene and grant a competitor the right to use the invention without the patentee's permission. These are known as compulsory licences and although the patent owner should still receive royalty payments, they are still a serious issue for patentees. While there may be a perception that the use of compulsory licensing is the domain of left wing governments sporting anti-capitalist, anti-imperialist ideologies this is not necessarily the case.

How are they granted?

World Trade Organisation (WTO) agreements dictate that compulsory licences may be granted where an invention is not being made available to the market in a country on reasonable terms, or not being made available at all. Alternatively, they may be granted in cases of national emergency or situations of extreme urgency.

Pharmaceuticals are most commonly associated with compulsory licensing provisions and have been the subject of a number of major cases in which negotiations over the price of patented pharmaceuticals have broken down and led to a compulsory licence being granted.

However, although many developing countries may have public health emergencies that could justify the grant of a compulsory licence, the reality is that they often lack the capability to manufacture high grade pharmaceuticals. In recognition of this fact, the WTO declared in 2003 that compulsory licences may be legitimately granted in developed countries to respond to public health emergencies in designated countries, with a particular emphasis on the least developed countries of the world.

Public health emergencies

While a compulsory licence has never been granted in New Zealand, the emergency/urgency provisions were put into practice in Canada in 2006. In this case, the Canadian government licensed the company Biolyse to produce and export a generic version of the drug Tamiflu (used to treat avian influenza or bird flu). The action was taken by the government on the premise that Roche (the patent owner) could not produce enough of the drug to meet potential demand in Canada or in the least developed countries in the event of a bird flu epidemic. However, these decisions are rarely taken solely on the basis of a lack of supply of a treatment for a potential public health crisis. Political and financial interests are often also very much to the fore.

In the face of a growing incidence of HIV/AIDS, Thailand granted a compulsory licence for the anti-retroviral (ARV) Efavirenz in 2006. It is estimated that this decision enabled the Thai government to save US$23 million per year over 5 years.[1]

Soon after, Brazil followed suit by issuing a compulsory licence for the import of a generic version of Efavirenz from India and in early 2010 Brazil started producing the drug locally. The Brazilian decision came after rejecting Merck's offer to lower the price from US$1.57 per dose to US$1.10 per dose. Instead Brazil demanded a cost of US$0.65 per dose, which was the offer made to Thailand. Indian generics were available at US$0.43 so the decision to grant a compulsory licence was made and resulted in an estimated US$30 million saving to the Brazilian government in 2007.[2]

The repercussions of grant

Although the issuing government may save millions on healthcare costs, the grant of a compulsory licence is often an action of last resort which must be weighed against the potential repercussions from trading partners and other countries. These repercussions can take the form of increased trade barriers and diplomatic pressure from governments and the pharmaceutical industry. Following the Thai decision to grant a compulsory licence the USA apparently retaliated by adding Thailand to its *Priority Watch List* and increasing import tariffs for a number of Thai exports to the USA.[3]

Retaliatory measures can seem hypocritical in the face of similar actions being taken by those same governments. For example soon after the Anthrax scare in 2001 the threat of a compulsory licence being granted in both Canada and the USA was enough to persuade Bayer to reduce the price of the antibiotic Ciprofloxacin from $1.77 per tablet to $0.95 and resulted in a saving to the US government of at least US$82 million.[4]

The USA has also granted what are, effectively, compulsory licences in numerous rulings. Since June 2006, the courts have issued decisions that have benefitted Microsoft[5] (on DRM technology patents), Toyota[6] (patent on automatic transmission system), and Direct TV[7] (set-top boxes) among others. In these cases, the courts have allowed continued infringement of the patent in return for court-ordered royalty payments to the patentee.

Compulsory licensing as a negotiating tool

Although the actual instances of compulsory licensing are few and far between, the real power of the compulsory licensing provisions lies in their use as a negotiating tool to drive down prices and promote competition. The use of this tool has been used to provide huge numbers of HIV/

AIDS sufferers with treatment that they might otherwise have been unable to afford.

The benefits to public health of using compulsory licensing as a negotiation tool must be weighed against the negative effects that would occur if compulsory licensing were to be abused and become commonplace. Such a culture of disrespect for intellectual property would be a severe impediment to the development of domestic research and development and result in severe trading sanctions from developed nations.

The grant of compulsory licences in any country is an area of patent law that provokes intense debate. On the one hand is the need for patent owners to be able to dictate the terms on which their inventions are used so they can recoup the costs of research and development. On the other hand is the need for governments to reduce costs and provide access to patented technologies that may be the difference between life and death. As the complexity and diversity of medicines continues to increase, as well as the prevalence of diseases such as HIV/AIDS, it appears that compulsory licensing will continue to be used to influence the terms of international trade for the foreseeable future.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact us: *tim.stirrup@baldwins.com* or *katherine.hebditch@baldwins.com*

References

1 Projected Cost savings of medicines in Thailand in 2007-2012. Ministry of Public Health and the National

2 Licença compulsória do efavirenz no Brasil em 2007: contextualização. Rodrigues, W.C.V., Soler, O. (2009) Pan Am J. Public Health **2009** *26*(6), 558.

3 Use of Compulsory Licenses; Selected National Experiences. Braun, J., IP Law and Policy Research Unit, University of Cape Town.

4 US takes a 'hypocritical' stance on Cipro. (Anthrax)(Ciprofloxacin) , Buttler, R. Chem. Ind. **2001**, November 5.

5 z4 Technologies, Inc. v. Microsoft Corp., 434 F. Supp.2d 437, 440 (E.D. Tex. 2006).

6 Paice LLC v. Toyota Motor Corp., 2006 WL 2385139, at * 5 (E.D. Tex. Aug. 16, 2006).

7 Finisar Corp. v. DirecTV Group, Inc., 2006 U.S. Dist. LEXIS 76380 (E.D. Tex. July 7, 2006).

Katherine Hebditch and Tim Stirrup of Baldwins Intellectual Property in Auckland specialise in chemistry and biotechnology patents. Katherine obtained her PhD in organic chemistry from the University of Manchester in the UK in 2004. She is currently working towards registration as a patent attorney. Tim obtained his PhD in molecular biology from the University of Southampton in the UK in 2007. He is also working towards registration as a patent attorney.