In summary

– TRIPS has established internationally agreed rules governing the protection and enforcement of IP rights relating to compulsory licensing (Article 31)

– Over time the use of compulsory licensing has expanded and recent developments in jurisdictions worldwide have caused patent owners to query this expansion

– The fear is that compulsory licensing is no longer viewed as an exceptional policy tool, but is being misused to obtain free/low-cost access to innovations and/or to assist domestic industries

– Compulsory licences issued for products in Thailand and Taiwan have upset patent holders and concerns have been raised about Draft Amendments to the Patent Law in China and amendments to patent law recently adopted by Switzerland

– Countries appear increasingly to be moving beyond TRIPS' limitations, engaging in activity that is of questionable compliance with Article 31 – a trend that bears close scrutiny

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Is the exception becoming the rule?

More governments are using IP without consent

Following the expansion of compulsory licensing rules, its recent use by various governments shows a worrying trend, say Lisa Peets and Mark Young of Covington & Burling

Compulsory licensing – when a government authorises a third party to use a patented technology or other intellectual property (IP) without the right holder's consent – has long been among the most highly controversial aspects of IP regimes. The grant of a compulsory licence requires governments to balance the need to protect IP rights and promote innovation against other social objectives that may justify limited exceptions to IP law. This balancing act has played out most recently and publicly on issues relating to access to medicines. Compulsory licensing has a far greater reach and impact than the pharmaceutical sector alone, however.

While countries historically have been largely successful at negotiating the delicate balance surrounding compulsory licensing, recent developments suggest a worrying trend towards a broader use that threatens to undermine the rights of patent owners. Right holders and governments should monitor these developments closely.

International rules

In the international arena, the Paris Convention for the Protection of Industrial Property of 1883 established the first rules relevant to compulsory licensing of patents. Specifically, the Convention recognises the right of each member *'to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work"*.

The subsequent World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) incorporated and expanded on the Paris Convention

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provisions. Broadly speaking, TRIPS establishes internationally agreed rules governing the protection and enforcement of IP rights (IPRs). Within this context, TRIPS permits compulsory licensing of patents, but only where a variety of conditions aimed at protecting the right holder's interest are met. Article 31 sets out the conditions that must be respected before a WTO Member grants a compulsory licence as follows:

- **Authorisation on individual merits.** Although TRIPS does not specify the circumstances in which a Member may grant a compulsory licence, it does make clear that licences must be granted on a case-by-case basis.
- **Negotiation required.** Unless the compulsory licence is granted to remedy an anticompetitive practice, or in the case of 'national emergency', 'extreme urgency' or 'public non-commercial use', the proposed user must make an effort (for a reasonable period of time) to obtain authorisation from the patent owner on reasonable commercial terms and conditions before a compulsory licence can be issued.
- **Proportionality.** The scope of a compulsory licence must be limited to the purpose for which it was granted. A compulsory licence should be terminated once the circumstances that led to it being granted cease to exist and are unlikely to recur.

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- **Limitations.** All compulsory licences must be non-exclusive and non-assignable.
- **Domestic market.** Unless the compulsory licence is granted to remedy an anticompetitive practice, it must be predominantly for the supply of the domestic market of the WTO Member state granting the licence. While some exports are allowed, the main use of the compulsory licence must not be in relation to exports (subject to the WTO Council Decision of 2003 – see below).
- **Adequate remuneration.** Taking *'the economic value of the authorisation'* into account (i.e. what a licensee would normally be expected to pay for a licence), the patent owner must be paid adequate remuneration *'in the circumstances of each case'* (i.e. having regard to the economic position of the country granting the licence). This condition is regarded as one of the most controversial and ambiguous sections of the TRIPS Agreement[2].
- **Judicial review.** Decisions relating to the granting of the compulsory licence and to the remuneration paid to the patent owner must be subject to judicial review.

Additional conditions apply in circumstances where a second patent cannot be exploited without infringing the patent owner's patent.

The Doha Declaration and WTO General Council decision

In the negotiating round on TRIPS, in Doha, Qatar, access to medicines – and the potential limitations imposed by Article 31 on such access – were a central point of discussions. These discussions ultimately resulted in the Doha Declaration on the TRIPS Agreement and Public Health, adopted on November 14 2001(the 'Declaration').

The Declaration makes clear that the TRIPS Agreement does not and should not prevent WTO Members from taking measures to protect public health – including through the grant of compulsory licences. Specifically, the Declaration provides that each WTO member has the right *'to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'*, and the right *'to determine what constitutes a national emergency or other circumstances of extreme urgency'*. The Declaration clarified *'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'*.

The Declaration also instructed the WTO General Council to find an expeditious solution to the problem of those WTO Members with insufficient or no domestic pharmaceutical manufacturing capacities – who would potentially face difficulty in benefiting from compulsory licensing under the TRIPS Agreement given Article 31's requirement that compulsory licences be primarily for use in the domestic market. In response, the Council adopted a Decision on 30 August 2003, allowing any WTO Member to export patented pharmaceutical products that are needed to address a public health problem to any 'eligible importing member' under a compulsory licence[3]. Broadly, the system works by waiving exporting countries' obligations under Article 31(f) of TRIPS to restrict supply to its domestic market. This is provided that the eligible importing country Member notifies the Council for TRIPS of the product it needs, and confirms (unless it is a least-developed country Member) that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question. Further, importing countries' obligations to remunerate the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side[4].

WTO Members agreed in 2005 to make the Decision a permanent amendment to the TRIPS Agreement[5]. This will take effect when two-thirds of Members accept it[6].

Use of compulsory licensing in the context of competition

In the US compulsory licensing is a long-established remedy in the context of mergers that would otherwise violate US antitrust law, and can be a useful alternative to divestiture[7]. It can also be used in non-merger cases where less restrictive remedies would likely fail to prevent alleged anticompetitive conduct.

Among the most recent examples of compulsory licensing in the US anticompetition context is the Federal Trade Commission's (FTC's) February 2007 remedial order in the *Rambus* case[8]. The FTC had earlier held that Rambus had violated the antitrust laws by concealing essential patents it held from an industry-wide standard-setting organisation. To remedy the conduct, the FTC imposed a compulsory licence (rejecting Rambus's assertion that the FTC's remedial power did not extend that far), setting a maximum royalty rate after looking at royalty rates for similar technologies and then adjusting downwards.

In Europe, the 1995 European Court of Justice's decision in *Magill*[9], and the subsequent judgment on infringement of Article 82

EC (the EU Treaty provision that prohibits abusive or anticompetitive behaviour by a company in a dominant position) in *IMS Health/NDC*[10], have established compulsory licensing as a remedy for anticompetitive conduct (albeit it in the copyright context)[11]. Significantly, in those cases the remedy did not apply to the markets in which the company was active, but instead was limited to markets in which the dominant company did not compete. The European Commission's Competition Directorate has indicated that it may be abandoning these limitations, however. In its ongoing case against Microsoft, the Commission has gone beyond previous case law in forcing Microsoft to grant a licence to technology in a market in which it was already active and in which it faced strong competition.

Recent developments

Recent developments in jurisdictions worldwide have caused patent owners to query the expanded use of compulsory licensing. These developments have raised concerns that compulsory licensing is no longer viewed as an exceptional policy tool, but instead is being misused as a means to obtain free/low-cost access to innovations and/or to assist domestic industries. In this section, we explore some of the developments that have given rise to these concerns.

Taiwan

In July 2002, while a case regarding an alleged violation of Taiwan's Fair Trade Act was pending[12], the Taiwanese firm Gigastorage Corp asked Taiwan's IP Office (TIPO) to grant a compulsory licence to produce recordable compact discs (CD-Rs) under patents owned by Philips Electronics. In July 2004 TIPO granted the compulsory licence, which was upheld by Taiwan's Ministry of Economic Affairs two years later, in June 2006.

Philips ultimately lodged a complaint with the European Commission on 15 January 2007, requesting that the Commission seek a ruling from the WTO that Taiwan violated the TRIPS Agreement. Philips asserted, among other things, that Taiwan granted the compulsory licences knowing that the CD-Rs produced would be for export, and despite reasonable efforts by Philips to provide licences on a voluntary basis by offering terms that had proven acceptable to seven of the eight primary Taiwanese CD-R producers.

In March 2007, the Commission announced that *'there is sufficient* prima facie *evidence of a violation of the TRIPS Agreement and of adverse effects on the [European] Community to merit an investigation'* into Philips' allegations, and that the Commission might, among other things, *'decide to initiate international dispute settlement proceedings in the WTO against Taiwan'*. The following month, however, Gigastorage requested that TIPO terminate the compulsory licences (following the company's decision to move its production of CD-R discs to Thailand). Although this appears to bring an end to Philips' immediate problems (aside from arguments that Gigastorage should pay the royalties that are due from previous years), the case creates a worrying precedent regarding Taiwan's willingness to grant a licence on the basis of a domestic company arguing that it could not reach an agreement with a foreign patent owner for a licence on reasonable commercial terms and conditions. This would leave patent owners in a weak position to negotiate compensation.

China

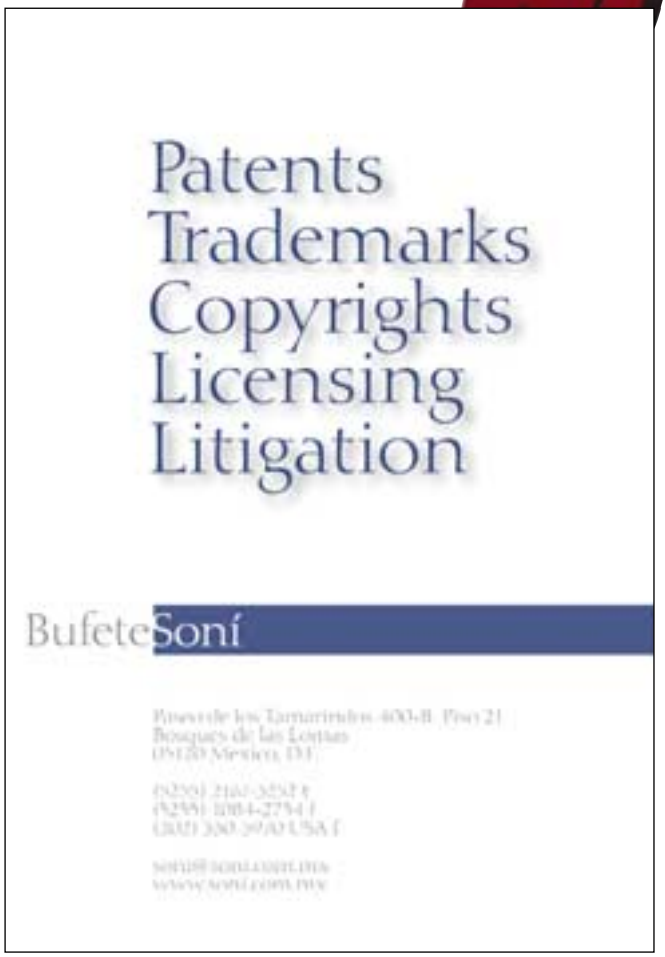
There are concerns the Draft Amendments to the Patent Law of the People's Republic of China, dated 27 December 2006, contain provisions that would broaden the scope of compulsory licensing. Currently, under Chinese law compulsory licences may be granted *'[w]here a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires'*. The proposed amendments would expand the circumstances to include actions taken *'to prevent… epidemic disease'*. Not only is 'epidemic disease' defined fairly broadly by the World Health Organization, but the expression 'to prevent' is likewise very broad and could encompass almost any product or process from simple cleaning apparatus to medicines and vaccines[13].

There are also concerns that amended Article 53, which provides that a compulsory licence is available only if the patent owner has refused to licence the patent on reasonable terms, may not apply to a compulsory licence that is granted in the 'public interest' under Article 49. This amendment is arguably inconsistent with the narrow exceptions permissible under TRIPS Article 31(b), which allows Member States to waive the requirement of prior negotiation in the case of 'national emergency', 'extreme urgency' or 'in cases of public non-commercial use'.

Thailand

In the past eight months the Department of Disease Control within the Ministry of Public Health has announced that it has issued three compulsory licences:

- One for the drug efavirenz (marketed in Thailand by Merck under the name Stocrin), which is used to treat patients with HIV.



- One for Kaletra (lopinavir plus ritonavir), another AIDS drug, produced by Abbott.
- Perhaps most controversially (as it relates to treatment for what is frequently described as a 'lifestyle disease' as opposed to a pandemic), one for Plavix (clopidogrel), a blood-thinning medicine developed by Sanofi-Aventis and Bristol-Meyers Squibb to treat heart disease.

In response, the pharmaceutical sector has raised several concerns – among them, whether the remuneration offered is adequate, as required by TRIPS Article 31(h). In the case of efaverinz, for example, Thailand has committed to pay Merck only 0.5 per cent of revenues from sales of the generic drug as compensation). Merck has since filed a case before the Board of Patents of the Department of IP (the DIP), and Abbott has chosen to stop introducing new products to the Thai market[14]. It has been reported that the Thai government is contemplating issuing compulsory licences for over 11 more drugs[15].

In addition to the controversy over these compulsory licences, there is concern regarding a competition law study commissioned by the DIP that focuses on the pharmaceutical and software industries amongst others. The tone of the project seems to suggest the mere exercise of IP laws causes harm to Thai consumers, and that the ability of rights holders to assert their rights should be restricted in some fashion via the competition law statute. While the study itself does not specifically reference compulsory licensing as a remedy, it is arguably implicit, particularly in light of Thailand's recent activities in the pharmaceutical context. These developments should be watched closely by the affected sectors; if Thailand were to adopt the position outlined in the DIP study into law, for example, it is possible that the refusal to licence, in itself, could give rise to antitrust liability.

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Switzerland

The expanded use of compulsory licensing is not limited to non-Western countries. Switzerland, for example, which as a general rule has a highly effective, well-balanced patent regime, has recently adopted amendments to its patent law that have raised concerns. Article 40(b), for example, provides that anyone has the right to a (non-exclusive) compulsory licence to use a patented biotechnological invention as a *'research tool or accessory'*. Such a broad compulsory licensing scheme appears incompatible with several of the procedural requirements set out in Article 31 of TRIPS, including the requirements of prior negotiation, adequate remuneration and authorisation on a case-by-case basis. Further, the targeted nature of Article 40(b) may also be incompatible with Article 27(1) of TRIPS, which expressly prohibits WTO Members from discriminating in the availability of patents and patent rights based on the patent's *'field of technology'*[16].

A worrying trend

The flexibilities that exist in TRIPS, and that have been affirmed by the Declaration and Decision, were created with the understanding that compulsory licensing can serve important social objectives, including to remedy anticompetitive practices or address national emergencies. TRIPS makes clear, however, that compulsory licences, while permissible, must satisfy certain conditions designed to protect the interests of the patent owner. Countries appear increasingly to be moving beyond TRIPS' limitations, engaging in activity that is of questionable compliance with Article 31. This worrying trend bears close scrutiny.

Notes

1. Paris Convention for the Protection of Industrial Property, Article 5. The Convention imposes certain limitations on compulsory licences based on failure to work the patented invention. *See id*.
2. Daniel Gervais. *The TRIPS Agreement: Drafting History and Analysis*. Second Edition. London: Sweet & Maxwell, 2003: page 252.
3. Such licenses are subject to several conditions. See §2(b) of the Decision, available at www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 25.7.07).
4. §6(i) of the Decision contains a third waiver: exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the Members were categorised as least-developed countries at the time the decision was made. That way, developing countries can make use of economies of scale.
5. See the WTO Document IP/C/41 (6.12.05).
6. In the meanwhile, the EU has enacted a Regulation for implement the Decision. Reg 816/2006 on Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems. The Regulation has been criticised for leaving significant scope for abuse of the system. See Alisa Carter and Maria Isabel Manley. Scope for abuse? *Patent World* 2006; 180: 23-25.
7. For an analysis of early experiences of the US with compulsory licensing as a remedy in antitrust cases, see Moore. A study of compulsory licensing a dedication of patents as relief measures in antitrust cases. *Geo Wash L Rev* 1955; 24: 223-238.
8. *In the Matter of Rambus Inc*, Docket No 9302, Opinion of the Commission on Remedy. 5 February 2007. Available at www.ftc.gov/os/ adjpro/d9302/index.htm (accessed 25.7.07).
9. Case C-241/91P.
10. Case C-418/01.
11. The disputes revolved around copyright in television programme guides in *Magill*, and copyright in a 'brick' structure in *IMS Health*.
12. For more about the complaint to the Fair Trade Commission of Taiwan and subsequent appeal, see Hubert Hsu, Taiwan: Competition – Patent Pools. *European Intellectual Property Review* 2006; 28: 65-66.
13. See comments of International Chamber of Commerce on the Draft Third Amendment at p45. Available at www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Comments_ChinaPatentLaw_1March07_E.pdf (accessed 25.7.07).
14. Abbott says it will not introduce new drugs in Thailand. *World Intellectual Property Report* 2007; 21: 19-20.
15. Supra 15.
16. While Article 27(3) TRIPS allows Members to exclude biological processes from patentability, it does not permit the exclusion of biotechnology tools from patentability, or the weakening of protection of biotechnology tools that have been found patentable and that have actually been patented.