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## Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance

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Dear Readers,

*When the Editor Mrs Madhu Sahni invited me to be the 'columnist of the 'Global IP Debates' from 2012, I thought it would be a wonderful idea to have the column. This column should be a forum to stimulate thinking, provoke thoughts and encourage arguments rather than a setting to decide what is right or wrong, as there are so many grey areas in IP and the right or wrong is not easily justified.*

*With the above in mind, in each column, I shall follow exactly the same structure to allow style consistency and readability. In other words, each paper will start with a case or cases to open up debates followed by some clarification of concepts and brief account of the history relevant to a particular topic. Subsequently, the focus will be on reasoning and extensive discussions on relevant debates, concluding with proposed alternative solutions.*

.....Deli Yang

Ever since compulsory licensing has emerged as a statutory obligation, it has been debated around the balance of interests between the general public and IP right holders. After opening two cases relevant and typical to the debate, this column clarifies compulsory licensing within the licensing contexts, and gives a brief account of its history. The focal point then centres on the main issues of compulsory licensing grants for national emergency, non-working, anti-competitive practice, non-commercial use and relevant international issues. In the end, some potential solutions are proposed.

**Keywords:** Compulsory licensing, non-working patent, anti-competitive practice, non-commercial patent use, non-voluntary licensing

### Opening Cases of Compulsory Licensing

Compulsory licensing refers to the grant of IP licences, particularly copyright or patent licence by a national government without the owner's consent for the purpose of wide utilization of the protected right. The grant of such a patent licence tends to fulfill one of the three purposes: massive production of patented products (e.g. patented drugs) to cure a disease, anti-trust act to allow fair competition (e.g. between firms), and non-commercial use (e.g. by the government) in the interest of the general public. Two relevant cases illustrate the purposes of compulsory licensing practice, its international impact and emerging issues.

In late 2006 and early 2007, the Thai government authorized three compulsory pharmaceutical licences -

*Plavix* (owned by Sanofi, Aventis and Bristol, Meyers Squibb) for heart disease, *Kaletra* (Abbott) and *Efavirenz* (Merck); both drugs against AIDS.<sup>1</sup> Under compulsory licensing, the economically manufactured drugs could only supply local market and be distributed to the poor. For example, under the compulsory licensing of a five-year contract for Efavirenz, the drug would be manufactured within Thailand with 50 per cent cost reduction (i.e. approximately US\$ 28 millions per year). In return, the patent owner, Merck would receive 1 per cent of sales in Thailand.

Using compulsory licensing as a tool against unfair competition is the other case on focus and has been a long-term strategy for the US. Although the US Code Title 35 – Patents, has not mentioned a word about compulsory licensing, the practice of compulsory licensing in the US seems to go back to the 1940s.

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According to incomplete statistics, the US issued tens of thousands of patent-related compulsory licences involving over 100 cases till the end of the 20<sup>th</sup> century.<sup>2</sup> One of the earliest cases that had world-wide impact was the consent decree of the Federal Trade Commission (FTC) against Xerox settled in July 1975 (ref. 3). In 1973, the FTC filed complaints against Xerox for engaging in the unfair practice of preserving monopoly by recreating and maintaining a patent structure of great size, complexity, with obscure boundaries and for using its position to access technologies owned by other competitors. Under the compulsory licensing decree, Xerox was to license all office copier patents, including patents owned by its foreign subsidiaries. A licensee was to have up to three patents licensed free of royalty and the rest at a royalty rate less than 0.5 per cent of the net revenues with an accumulated royalty of 1.5 per cent.

Relevant to the above two cases, the debates surround wide use of patents versus patent owners' interests. Three issues are particularly salient: (1) Is it fair to give 1 per cent royalty or royalty-free to the owner? (2) Could the local supply be guaranteed not to create grey market globally? (3) Would the grant dishearten owners against further innovative activity, and/or hurt the motivation of innovation leaders? These controversies lead to the focus of this column: how should the compulsory licensing system be operated to balance all the stakeholders' interests. The balance of interests seems to form the thread of all debates on compulsory licensing.

### Concepts and History

Before debating the issues of compulsory licensing, the column first focuses on the conceptual clarification and its origin to understand the background. Licensing agreement for IP can be voluntary or compulsory depending on the licensor's willingness. While voluntary licensing is more common a form to authorize use, make patented or copyrighted right for commercial purpose, there are occasions when licensors are not willing to authorize the use to a potential licensee. When this occurs, government organizations may intervene and enforce a licensing relationship under certain conditions without the licensor's consent. Previous research has more orientation towards the study of voluntary licensing, only sporadic scholarly research has examined compulsory licensing. In reality, compulsory licensing is much more prevalent in statutory terms than in practice.

As a stipulation, compulsory licensing can be traced back to the UK Statute of Monopolies in 1624, which ruled out monopolies associated with patent, and stated that grants should not be 'mischievous to the state' or hurt trade. However, compulsory licensing only became an official proposal in the early 19<sup>th</sup> century.<sup>4</sup> Countries in Europe (e.g. the UK) popularized compulsory licensing under its anti-patent movements in the 1850s. The UK recognized compulsory licensing in terms of non-working and stipulated rules to prevent patents from non-working (e.g. the Patent Act of 1883, Section 22). Subsequently, the Paris Convention in 1883 stipulated the 'working requirements' for patents to 'prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work' (Article 5), and added compulsory licensing as the means of exploiting patents in its Hague 1925 revision. Since then, compulsory licensing has gradually become part of legal obligation for countries. Since the 1990s particularly, after signing of the TRIPS Agreement in 1995, compulsory licensing stipulation has become an obligation for nations to deal with non-working issue, consider public interest, and handle non-commercial use and unfair competition. Further to this step, it was the Doha Declaration which paid detailed attention to patented drugs that could cure widespread fatal diseases. As an action, the European Commission announced the Doha Declaration's legal effect in the European Union in 2006 (ref. 5). In consequence, compulsory licences could be issued in developed countries to manufacture patented drugs on conditions for export to least developed countries to treat epidemic diseases.

Compulsory licensing tends to be imposed by governments for their own or third parties' use in national interest, and also to aid the wider utilization of a patented invention. Wide discussions and practice tend to focus on compulsory licensing of patents for pharmaceuticals to combat national emergency. However, compulsory licensing may also be issued by a government for non-commercial public use or as a remedy to anti-competitive practices.<sup>6</sup> Since 1995, it has been mandatory for WTO members to include compulsory licensing as part of their patent law stipulations. Thus, TRIPS members' patent laws must stipulate the conditions in which patents can be authorized for use without the owner's consent. The purpose of such mandatory stipulation is to ensure balancing of public interest and wide patent utilization with owners' benefits.

A compulsory licence may be granted by a national judicial review body when they believe the request has met the following conditions in the law based on the TRIPS Agreement (Article 31): Emergency and extreme urgency; anti-competitive practice; public non-commercial use; or dependent patents. These conditions to grant a compulsory licensing are not detailed, requiring case-by-case assessment. TRIPS does indicate that a prior request to the patent holder was first attempted on reasonable commercial terms but failed (this does not apply when a nation faces national emergency, e.g. disease pandemic or national disaster and the patent can help immensely to alleviate the national situation). In addition, compulsory licensing grant should also consider working requirements, compensation based on the economic value of the licence, non-exclusive and non-assignable deal with termination clauses included. As for working requirements, the patent must have been granted for a period of time (TRIPS has not stipulated that, but the patent law survey by the author shows that most countries stipulate non-working if the patent holder fails to fulfil the work requirements within three years upon grant or four years upon application).

Compulsory licensing is easier said than done, and this can be seen in both the historic and contemporary context. In 1769, James Watt was granted a patent for his tremendous improvement of steam engine technology that led to the wide use of efficient steam power across many industries, and in fact became absolutely fundamental to the industrial revolution. However, controversies about him remain<sup>7</sup>: Whether Watt was the sole inventor of some patents is still a question mark. Watt monopolized his invention and prevented others - notably William Murdoch (his employee) and Jonathan Hornblower (a rival inventor) - from further developing steam technology. Watt patented the application of the sun and planet gear to a steam locomotive respectively in 1781 and 1784. However, there were claims that William Murdoch was the inventor. It has been suggested that, had Watt's patent been compulsorily licensed, society would have benefited from efficient steam engines at least ten years earlier than it did.

While many countries have included compulsory licensing clauses in their patent laws - the author's examination of legislation in 193 countries finds that more than 90 per cent of them include the relevant stipulations - it nevertheless seems difficult to implement a compulsory licence - or, at least, the

right to do so is still very much under-used. In Canada, for example, there were only 86 applications for compulsory licensing between 1935 and 1989 (of which 17 were granted and 15 rejected, the remainder being withdrawn, abandoned or not pursued for other reasons) while since the 1990s, Canada has virtually stopped using the provision.<sup>8</sup> As far as developing countries are concerned, only a few have authorized compulsory licences.

### **Controversies Surrounding the Stipulations and Action of Compulsory Licensing**

Stipulating compulsory licensing in IP laws is not a daunting task for policy makers, but the challenge lies in having provisions that leave little room for controversy or varied interpretation, and practising compulsory licensing in a way that it balances all the stakeholders' interest. The reality is that, compulsory licensing stipulations being specified, the long-term task is to balance the interest between the authorizer (the government) and the compulsory licensee (e.g. government, organization, or firm) on one side, and the IP owner (who becomes the unwilling licensor) on the other. The difficulty also lies in the unpredictability of compulsory licensing given it concerns with the future production and sales of a patented product, its remuneration to the holder, and innovative activities.

The example of Thailand in the opening case demonstrates how compulsory licensing is more easily said than done. The action of the Thai government caused a storm of controversy because of the conflicts of interests between the Thai government, the users of the drugs and their supporters (developing country governments, and health activists), and the three drug companies and their supporters (developed country governments). The Thai government argued that the purpose of the compulsory licences was to bring down the market prices and thus allow sufferers access to the drugs, and that their action was intended to contribute to social well-being in Thailand where (according to WHO estimates) 600,000 people are HIV positive. Without this move, the drugs provided by these companies were too expensive, and their price structures undermined the Thai government's commitment to effective health care for its citizens. Non-governmental organizations, such as the Aids Access Foundation, Oxfam and Médecins Sans Frontières offered strong support for the broad

principle of compulsory licences, on the grounds that such licences could benefit many people, and their use would establish the example for other countries to use compulsory licensing for social welfare.

On the other hand, both opening cases present a stiff challenge to the R&D based developed-country companies. Multinational patent owners feel their patent security has been threatened and their R&D achievements have been undermined. Abbot Laboratories responded to the Thai action by saying it would no longer license any new drugs for sale in Thailand. The companies also argued that they should have been at least consulted before any compulsory licensing was issued. In this case, Merck alleged that there had been no previous voluntary licence application, and they only learned about the decision two days before it was announced. One of the firms retaliated by withdrawing six drug patent applications in Thailand.

The controversy has developed into a heated debate between the developed and developing country camps. The US Trade Representative elevated Thailand to the Special 301 Priority Watch List due to its weakened respect for patents.<sup>9</sup> *The Wall Street Journal* criticized that it was barely epidemic, as the AIDS incidence was only 1.5 per cent of the population; the same holding for heart disease. The European Commission warned the Thai government that such actions would have repercussions in the long run for new drug development. The US demanded Thailand cancel the compulsory licences unless they could clarify their scope in using them. The Thai government and the developing country counterparts argued that issuance of compulsory licences conformed to TRIPS stipulations. The WHO endorsement at the annual meeting of the 193 member states in May 2007 appeared to have temporarily halted the debate. The WHO showed its official stance on this issue, promising a commitment to the technical and policy support for using compulsory licensing to access medicines. However, this may only be a temporary 'ceasefire', as the conflicts of interests remain unaltered.

In addition to the broad debate between the two camps of developed and developing countries, controversies also lie in some stipulating and operational issues associated with compulsory licensing. Firstly, 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use' (TRIPS Article

31 9F) could potentially create grey markets in two different ways. One is the grey market created across borders where countries with expensive patented products import from a country with less expensive offering. Nations may have bilateral agreements on preventing the existence of such grey markets, but they still cannot prevent individual consumers from bringing such products into the country (the other way of creating grey market). Both grey markets consequently affect the global sales of the patented products. Although in 2003, the WTO decided to allow generic produce under compulsory licensing to be exported in all member states, 33 countries decided not to be part of the import and other 11 nations decided to only use the system under national emergency or extreme urgency.<sup>10</sup>

Secondly, 'national emergency' and 'public non-commercial use' (government use) are terms that leave a large room for interpretation. Basically, 'public non-commercial use' is a superfluous, open-ended term with no internationally standardized definition. Any country can exercise its power to declare a non-commercial government use of a patent that is not necessarily a national emergency or urgency (e.g. the case in Thailand), but in national interest (e.g. defence). For example, the Thai government subsequently issued four more compulsory licences in 2008 on the ground of public non-commercial use. Exercising such use quite often can hurt bilateral relations between the patent owner's country and the compulsory licensing issuing state.

Thirdly, 'adequate remuneration' and 'economic value' are unclear terms. The WTO interpretation is that adequacy is decided based on the nation concerned and the patent owner has the right to appeal.<sup>11</sup> However, it is widely known that patent value tends to be seriously considered and evaluated when mergers and acquisitions take place. Would compulsory licensing authority seriously assess the economic value, and provide the patent owner with a payment that is deemed fair and adequate? Due to the enforced nature of the licence, it can be difficult to agree on a royalty rate, although according to the stipulation, it should be negotiable. In practice, probably the owner has little bargaining power.

Fourthly, states have the flexibility to issue compulsory licenses that often involve the interest of other countries. As discussed earlier, the nature of global business has made compulsory licensing not a business of one nation only. This is usually the case

when the patent is not originally from the compulsory licensing issuing nation, but from the country of the patent holder and any other countries that have granted or have shown interest in the patented production. These countries may feel that their economic gain might be undermined under the licensing conditions.

Fifthly, would such compulsory licensing act as a positive influence on innovative motivations? The best test would be empirical evidence. However, this is an area with little research being done. A study of 70 firms subject to compulsory licensing<sup>2</sup> shows a significant increase of R&D expenditure in comparison to firms under no influence of compulsory licensing. This is probably due to the fact that firms under compulsory licensing obligations feel the intense pressure to continue innovating so that they can be ahead of their competitors. However, this evidence is only based on 70 firms, and future research may further examine the positive and negative impact of compulsory licensing on innovative activities.

Finally, the royalty-free practice of compulsory licensing has given rise to controversies as to the fairness to the unwilling licensor. On the one hand, the royalty-free grant of compulsory licensing certainly helps to widen the utilization of patented inventions so that compulsory licensee can produce or manufacture inexpensively; on the other hand, in the author's view, the patent owner deserves the right to be paid for its effort to invent something new. Referring back to the Xerox case, the royalty-free grant of compulsory licenses opened up opportunities for competitors to invent around. This, as a result, may be beneficial to society in order to enjoy related products on the market with the acceleration of commercializing patented inventions. Nonetheless, patent owners deserve certain payment for their inventive work.

### Proposing Solutions

To resolve these conflicts of interests, it is argued that some fundamental issues must be determined, although perfect solutions can never be found given the difficulties of balancing interests. This argument is proposed on the basis of the reality that nations all have an intention to harmonize and integrate with the rest of the world. This means that both WIPO and the WTO shall play a crucial role in conflict resolutions. First, compulsory licensing as a legal stipulation

requires detailed clarification, particularly regarding the conditions to grant compulsory licensing. The TRIPS Agreement stipulates that a voluntary licence must be negotiated first with the patent holder on 'reasonable' commercial terms, who will receive 'adequate' remuneration decided by relevant authorities in the 'country concerned', with the 'economic value' of the patent taken into account. What is considered reasonable, adequate can be understood differently in the country concerned from other stakeholders (e.g. patent owner's country of origin). This is how conflict of interest evolves. For example, national organizations responsible for issuing compulsory licensing should allow potential compulsory licensing parties to negotiate a term of compensation rather than impose a royalty or royalty-free deal. This means that the WTO should regulate that national government proposes a range of royalty payments so that licensors and licensees have a base licensing fee to work on when they start their negotiations.

Another point is that according to TRIPS, licensors should be informed 'as soon as practicable' about any compulsory licensing procedures that affect them could be replaced by a specific duration, such as up to three months unless it is national emergency. The WTO also needs to clarify what constitutes 'national emergency' and what is considered 'public non-commercial use'? Coming back to the compulsory licensing case in Thailand, both stakeholders used TRIPS as their argument tool: the Thai government emphasized that TRIPS allows countries to interpret and implement the compulsory licensing stipulations in support of their national interests and to promote access to medicine. The drug companies argued that compulsory licensing should be authorized only if licensees fail to obtain consent from the owner or under extreme national emergency, and that the Thai situation could not be so described. Given that TRIPS is a broad framework that allows countries to freely stipulate the details of their own policy, both sides of the arguments appear to have some strength. However, when the compulsory licensing involves parties from different countries, which was exactly the case in Thailand, the complexity of the problem increases. Despite the WHO's stance, the implication is that the WTO needs to specify more clearly what can be compulsorily licensed, when, and how.

Second, balancing the interests of all stakeholders when considering compulsory licensing is important.

Looking back, the Thailand compulsory licensing case has not only caused controversy, but also both increased the pressure to find acceptable resolutions to such matters, and encouraged other countries (e.g. Brazil) towards the wider application of compulsory licensing. Another important matter to consider from the government's perspective was the need to attract and maintain good relationships with business interests. At least some negotiations with the relevant companies could have taken place, which would have led to more amicable long term relationships, encouraged multinationals to continue to invest in Thailand and - hopefully - led to some compromises about drug prices and arrangements for further international cooperation.

Third, another important step would be to set up an international system to coordinate the granting of compulsory licences in cross-border situations in a relatively 'standard' or 'consistent' manner and monitor activities to ensure fairness to both licensors and licensees. Such a system would also allow the parties to file any complaints with a designated body, so that disputes could be resolved quickly. While such international efforts may, on the one hand, serve to encourage voluntary licensing, it could also, on the other, reduce international conflicts through effective international coordination.

Without some form of international monitoring system, the compulsory licensing system will be difficult to implement at a wider international level. The difficulties lie in the discrepancies among different national laws, and the vague and imprecise international stipulations as to how compulsory licensing should be understood, utilized to balance the interests of all stakeholders when cross-border activities are involved.

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