# The pitfalls of compulsory licensing in India

Compulsory licences can mitigate the impact of exclusive rights. However, the compulsory licensing provisions must be used sparingly to avoid stifling innovation

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According to the World Trade Organisation (WTO) Media Relations Division: "Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property – the TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement."

The introduction of TRIPs brought unprecedented changes to IP law. The adoption of the Uruguay Round in 1994 led to the expansion of IP rights into new fields and the strengthening of rights holders' legal positions. The powers conferred on title holders have been enhanced, raising unprecedented concerns in developing countries such as India as to the extent to which the essentially commercial interests protected by IP rights – particularly patent rights – may be given primacy over other societal interests (eg, public health).

Patent rights are not absolute and national laws have identified certain situations in which exceptions to such rights apply. Compulsory licences limit the exercise of patent rights, but do not work in the same way as exceptions. However, compulsory licences are one of the tools that can mitigate the impact of exclusive rights – an issue which has been receiving growing attention.

## Background

The concept of a compulsory licence is linked to an obligation introduced by the UK Statute of Monopolies 1623 (the first statutory expression of English patent law), which stated that grants should not be "mischievous to the State" or hurt trade. However, compulsory licensing became an official proposal only in the early 19th century. European countries popularised compulsory licensing as part of anti-patent movements in the 1850s. The United Kingdom recognised compulsory licensing in terms of non-use and set down rules to prevent patents from sitting idle. Thus, compulsory licensing has always formed part of international conventions and statutes, whether in the Paris Convention or in the laws of countries such as the United Kingdom, Canada, Australia and India (see Table 1). In *Bayer Corporation v Union of India*, an appeal against the grant of a compulsory licence for Nexavar in India, the Intellectual Property Appellate Board rightly observed that: "Compulsory licence (CL) is not an unmentionable word. It is found in our Patents Act."

TRIPs envisages a number of conditions for issuing compulsory licences under Article 31, "Other use without the authorisation of the right holder". In particular, before applying for a compulsory licence, the person or company must have made efforts to obtain a voluntary licence from the patent holder on reasonable commercial terms and conditions, and such efforts must have been unsuccessful within a reasonable period. TRIPs states: "Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."

When a compulsory licence is issued,

Table 1. **Compulsory licence activity**

| Country | Period | Statistics |
|---|---|---|
| Canada | 1935-1970 | Fifty-three applications submitted under Section 65 of the Patents Act, which provided for licences for inadequate or lack of working and refusal to deal. |
| | 1970-1989 | Forty-three applications for compulsory licences, six of which resulted in licences being granted. Of the 25 withdrawn or abandoned applications, the parties reached voluntary agreements in four cases. |
| | 1923-1969 | For compulsory licences relating to medicines, 49 were applied for and 22 were granted. |
| | 1969-1992 | A total of 1,030 applications were submitted with a view to importing or manufacturing medicines, and licences were granted in 613 cases (Canadian law was amended in 1969 and compulsory licences for the import of medicines were allowed). |
| United States | August 1941-January 1977 | In 125 decisions, patent rights were restricted. In a single case – *US Manufacturers Aircraft Association Inc* – about 1,500 patents were compulsorily licensed. |
| United Kingdom | 1950-1972 | Seventy-six compulsory licences were applied for under Section 41 of the Patent Law, 25 of which were granted. |
| | 1988-1990 | Nine compulsory licence applications were filed. |
| | 1985-1989 | Licences of rights established by the Patent Act 1977 were applied for in 77 drug cases. Over 100 applications for such licences were reported until they were abolished in 1988. |
| Germany | 1961 | Since the establishment of the Federal Patent Court in 1961, 12 compulsory licence proceedings have been initiated. |
| Israel | 1995-1997 | A compulsory licence for the manufacture of the hepatitis B vaccine under a Biogen patent was granted by the registrar of patents, designs and trademarks in 1995 and upheld by a district court in 1997. |
| Australia | | In at least two cases, the Trade Practices Act 1974 was applied in relation to refusals to deal. |
| South Africa | 1993 | There were two applications for compulsory licences, but both were eventually rejected. |
| India | | Under the Patents and Designs Act 1911, 59 applications for compulsory licences were filed, of which 20 were granted. |
| | 1972-May 2013 | Under the Patents Act 1970, eight applications for compulsory licences were filed, of which four were granted, two were withdrawn, one remains pending and one was refused on the grounds that the patent term had expired. |

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the patent owner must receive adequate remuneration in each case, taking into account the economic value of the authorisation.

TRIPs states that: "The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." However, it does not define 'adequate remuneration' or 'economic value'.

Further, compulsory licensing must meet certain additional requirements:

- It cannot give exclusivity to licensees (eg, the patent holder can continue to use the patent); and
- It should be subject to legal review in a given country.

The Paris Convention for the Protection of Industrial Property 1883 (as amended), administered by the World Intellectual Property Organisation (WIPO), addresses the compulsory licensing of patents in Article 5(A) under the heading "Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses". However, it deals only with compulsory licences granted for failure to work.

In India, the compulsory licensing provisions can be traced back to the Patents and Designs Act 1911. Under the existing law (the Patents Act 1970), a compulsory licence can be granted under various provisions of the act (see Table 2).

**Recent compulsory licences granted under Section 84 of the Patents Act**

In the high-profile *Bayer Corporation v Union of India* case, the Intellectual Property Appellate Board made the following observations:

- The term 'patented invention' can mean only what the patentee or its licensee markets, nothing else.
- The law is clear that the requirements and conditions for the grant of a compulsory licence must be decided with reference to the patentee alone and not a party whose presence is litigious. Therefore, when deciding on the conditions of Section 84, the presence of the infringer shall not be taken into account.
- The Patient Assistance Programme does not satisfy the working requirement – Section 84 is concerned only with the price at which the drug is made available to the public.
- Nothing prevents the patentee from lowering the price and making its invention available to the public after a compulsory licence application has been filed.
- The patentee must show why a patent could not be manufactured locally. A mere statement to that effect is insufficient. 'Working' could in some cases mean only local manufacture or in other cases could mean only importation – it depends on the facts and evidence in each case.

**Ripple effect**

Following the *Bayer* decision, the Health Ministry suggested invoking Section 92 of the Patents Act for three medicines: Trastuzumab, owned by F Hoffmann-La Roche AG, and Ixabepilone and Dasatinib, both owned by Bristol-Myers Squibb. As shown in Table 2,

Table 2. **Compulsory licensing provisions in the Patents Act 1970**

| Section | Time limit | Grounds | Applicants |
|---|---|---|---|
| Section 84 | Any time after three years from the date of grant of the patent. | • Reasonable requirements of the public with respect to the patented invention have not been satisfied.<br>• The patented invention is unavailable to the public at a reasonably affordable price.<br>• The patented invention is not worked in the territory of India. | Any interested person. |
| Section 92 | Any time after grant of the patent. | • A national emergency.<br>• Circumstances of extreme urgency.<br>• A case of public non-commercial use. | Upon declaration by the central government, any interested person. |
| Section 92A | At any time after grant of the patent. | In certain exceptional circumstances (in line with Paragraph 6 of the Doha Declaration on TRIPs and Public Health), a compulsory licence can be granted to manufacture and export patented pharmaceutical products to a country with insufficient or no manufacturing capacity in the pharmaceutical sector in order to address public health issues. | |

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this provision allows the government to grant a compulsory licence in cases of national emergency, extreme urgency or public non-commercial use. Once the government has invoked this provision, generic drug manufacturing companies can directly apply to the Patent Office for permission to manufacture and sell these drugs at the lowest price, provided that the patentees derive a reasonable advantage from their patent rights.

In the meantime, Indian generic company BDR Pharmaceuticals has also applied for a compulsory licence to sell a generic version of Bristol-Myers Squibb's cancer drug Dasatinib.

**What next**

**Discouraging foreign direct investment**

Decisions issuing compulsory licences will further cement the view that India has a weak IP regime. Innovator companies will continue to feel insecure investing in a country where their extensively researched products, incurring high R&D costs, could be subject to compulsory licences. Because foreign direct investment is an important source of economic growth for developing nations, the loss of such investment due to compulsory licensing can outweigh the benefits of cheaply accessing foreign patented innovation.

In 2001 the US ambassador to Egypt stated that: "Egypt's ability to attract foreign investors in many fields will hinge on adequate protection of copyrights, patents and other intellectual property, and may be a precondition for any free trade agreement between Egypt and the United States."

**Discouraging R&D**

The limitation of exclusive rights by the grant of compulsory licences can weaken economic incentives to invent, and consequently will significantly curtail future pharmaceutical research. Because the level of research expenditure directly corresponds to the creation of new pharmaceuticals, a reduction in research expenditure can lead to a reduction in new pharmaceutical entities. Moreover, the grant of compulsory licences to Indian generic companies may discourage them from investing in R&D, thus reinforcing the copycat image of the Indian pharmaceutical industry, and will be detrimental to economic growth.

**Encouraging price wars and anti-competitive behaviour**

The grant of a compulsory licence in *Bayer* has already led to price wars among generic companies. For example, Cipla Limited has reduced the price of Nexavar to almost 60% of the price offered by the compulsory licensee, and consequently fixed by the Patent Office. Thus, an anti-competitive environment cannot be ruled out.

**Comment**

Innovation should be encouraged, rather than stifled, for the long-term benefit of the public. Bearing in mind the spirit of IP legislation and international conventions, it is also important to define and balance the rights and duties of rights holders, the public and the government for the wellbeing of citizens worldwide. After all, it is the state's duty to provide better healthcare facilities, including specialist

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government hospitals and doctors, to its citizens without compromising on the interests of innovators. In practice, the availability of affordable medicine becomes important only when affordable specialist hospitals and doctors are made available.

The mechanism to make patented drugs available through public or private insurance must be strong and well established. In addition, it is important that the government operates its own specialist healthcare programmes, rather than making the pharmaceutical industry absorb the costs alone. It would be a welcome move for the Indian government to introduce facilities such as health insurance for all citizens at a subsidised cost so that all classes of citizen can afford and benefit from innovation-based medicines.

The government should also consider making the specialised healthcare system strong and effective at all levels, including the lowest level of administration in India (ie, the *panchayat*), in order to ensure better accessibility to medicine. Specialised government hospitals and doctors would be the first step towards doing this.

Another major step forward would be the creation of research-based databases for recording the number of citizens suffering from diseases which require specialist treatment, and making such treatment available to the pharmaceutical industry, hospitals and non-governmental organisations with a presence in India. This would aid in understanding of target patients and the needs of the Indian people.

The compulsory licensing provisions must be used sparingly. The discretion provided by the law should not lead to arbitrary action under the garb of public interest. To ensure the enhanced presence of innovators' products in the market, it is also essential to make the enforceability of IP rights, including patent rights, effective. This would also allow innovators to explore the market fully and to consider how different strata of people can benefit from their products. It is also important to understand that the presence of infringing products in the market only curtails the availability of innovation-based products.

Taking steps in the right direction, with a positive mindset and an understanding of the respective rights and duties, would result in the balancing of interests, without losing the benefits of innovation-based products and a better healthcare system in India.

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