

## Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations

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While the TRIPS Agreement provides for the patenting of drugs, it also provides for compulsory licensing as a mechanism to check the abuse of patent rights that might flow from such a rigid patent regime. However, it was only after the subsequent Doha Declaration that the developing nations could use this provision of compulsory licensing to access drugs from the developed world. This article examines international law on compulsory licensing in patents, the extent to which it restricts the scope of developing countries in taking advantage of technology in the developed world, the space it leaves open for them to further promotion of public health and the manner in which it has been used in some developing countries. It argues that although there are a number of obstacles placed through the new patent law regime mandated by TRIPS, there is still immense scope left for the developing countries to exploit. Careful planning and policy making can enable an effective balancing of the conflicting interests of protecting patent rights and making essential drugs accessible to all.

**Keywords:** Patent, compulsory licensing, TRIPS, Doha Declaration, access to drugs

Patents vest monopoly rights in the creator to manufacture, use and sell a product. Monopoly is often coupled with possibilities of abuse of patent rights. With the implementation of the TRIPS Agreement and inclusion of pharmaceutical products within the ambit of patentable subject matter, fears about the abuse of patent rights on drugs has grown, including whether drugs would be available and affordable, especially in the developing countries.

One of the ways TRIPS answers this concern is by incorporating a provision on compulsory licensing, that is, the state can issue licences to manufacturers other than the patentee to produce, use or sell the product, without the consent of the patentee. Doha Declaration further enables developing countries to take benefits of the technology in developed nations through the mechanism of compulsory licensing. With the developed and developing countries taking opposite stands on the issue of patentability of life-saving drugs, these international instruments are seen as an attempt to create a balance.

This article examines the international law on compulsory licensing in patents, the extent to which it restricts the scope of developing countries in taking advantage of technology in the developed world, the space it leaves open for them to use to further the

interest of promotion of public health, and the manner in which it has been used in some developing countries of the world. It argues that although there are a number of obstacles placed through the new patent law regime given by TRIPS, there is still immense scope left open for the developing countries to exploit to their own advantage. Careful planning and policy making can enable an effective balancing of the conflicting interests of protecting patent rights and making essential drugs accessible to all.

### **The Access to Drugs Debate and Compulsory Licensing**

A patent is an exclusive right granted to a person who has invented a new and useful product or process or has improved an existing product. It is a monopoly right preventing others from exploiting the invention, the rationale being that rewarding the inventor for the effort, skill and resources expended will encourage innovation.

Conferring monopoly rights over life-saving drugs is highly contentious. Many argue that pharmaceuticals should be excluded from the purview of patent law, due to the possibility of abusing monopoly rights and taking unfair advantage of the absence of competition that results from the grant of patent. This gets especially problematic in case of medicines, since it is possible that the inventor raises

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price of the patented drug making it inaccessible to the poor. On the other hand, proponents of patent law justify patents on drugs by arguing that removing or limiting patent rights will drastically affect research and development in the pharmaceutical sector.

Compulsory licence is a method to check the abuse of patent rights, while not defeating the law itself. Compulsory licences are 'involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state.'<sup>1</sup> The State, under some conditions, may grant licence to an applicant to produce or use the patented product and sell it in the market even without the consent of the patentee. Both Indian Patents Act, 1970 and the TRIPS have provided for the conditional grant of compulsory licences.

The TRIPS Agreement aims to promote global competition in trade and thus, tries to establish a strong global patent regime. However, this puts at a disadvantage countries with a poor capacity to manufacture essential drugs. Before the TRIPS regime, product patents (including drugs) were not granted in India. The generic industry in India, therefore, flourished through reverse engineering, inspite of the strict patent regime in developed countries. Now, since drugs can be patented in India too, generic versions cannot be produced. Such a patent regime allows the patentee to exercise a larger control over both availability and accessibility (in terms of price, quantity, etc.) of the life-saving drug. On the contrary, limiting patent rights can help in bringing down prices by facilitating the entry of generic products. For example, adoption of price controls and a process-only patents regime in India transformed Indian drug prices from among the highest in the world to among the lowest.<sup>2</sup>

### **Compulsory Licensing under TRIPS and Subsequent Developments**

Article 27 of TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology. However, Article 27(2) allows members to exclude inventions from patentability to protect public order or morality, including to protect health. TRIPS attempts to strike a balance between the short-term objective of providing access to life-saving medicines and the long-term objective of providing incentives to the pharmaceutical industry for the development of new medicines. Hence, it also imposes certain restriction on the rights of the patent holder, including compulsory licensing.

Article 8 of TRIPS allows member countries to adopt measures, consistent with the TRIPS Agreement, necessary to protect public health and nutrition. It also allows states to take measures to prevent the abuse of intellectual property rights or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 30 is a broad provision which allows the member countries to provide limited exceptions to patent rights. When TRIPS was originally negotiated, Article 30 was seen as a mechanism similar to 'fair-use' of copyrighted materials.<sup>3</sup> It allows limited exceptions provided that they do not unreasonably conflict with normal exploitation of the patent nor prejudice the legitimate interests of the patent owner; taking account of the legitimate interests of third parties.

Article 31 of the TRIPS Agreement deals with compulsory licensing in case of patents, although TRIPS phrases it as 'other use without authorization of the right holder'. It allows such authorization under certain conditions, like prior efforts to obtain authorization from the patentee (however, this requirement may be waived in case of national emergency, extreme urgency or public non-commercial use); non-exclusive and non-assignable use; payment of adequate remuneration to the patentee, etc.

The most significant clause here is subparagraph (f) of Article 31 which says that 'such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'. This provision effectively limits the benefits of compulsory licensing to member countries having a good manufacturing capacity only. By requiring licensees to supply a predominant part of their production to their domestic market, it limits the licensee's ability to export medicines to countries with public health needs, thus barring nations with insufficient or no manufacturing capabilities from deriving benefits from this provision, except when necessary to remedy anti-competitive practices. As most countries needing to make use of the patent exceptions are economically troubled nations with insufficient or no manufacturing capabilities, the exceptions in TRIPS failed to satisfy the needs of those countries that the exceptions were designed to benefit.<sup>4</sup> The Doha Declaration, however, made some amends as discussed below.

TRIPS in the process has become a platform for heated debate. Developing countries want a relaxation of the law as they argue that patent protection prevents millions of people from accessing life-saving drugs, forcing these countries to devote their limited resources to development of such drugs. They also argue that increased patent protection will lead to higher pharmaceutical prices. On the other hand, developed countries are arguing for a stronger protection in order to promote development of the pharmaceutical industry.

#### **Doha Declaration**

The Doha Declaration in 2001 sought to resolve the issue of use of compulsory licensing to export drugs to developing countries. The Declaration lays down certain general principles and confers certain rights. It recognizes the need to address public health problems afflicting many developing countries. The TRIPS Agreement should be interpreted and implemented in a manner supportive of countries' right to protect public health and to promote access to medicines for all. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. Each member has the right to determine what constitutes national emergency or extreme urgency and public health crises.

Paragraph 6 of the Declaration recognizes that nations with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, and instructs the Council for TRIPS to find an expeditious solution. In 2003, the WTO announced its decision to implement Paragraph 6, allowing for a waiver of the Article 31(f)'s 'domestic market' restriction on compliance with certain conditions. It allowed any Member country to issue compulsory licence to produce generic drugs for export to least developed countries and other countries which establish that they have insufficient or no manufacturing capacities in the pharmaceutical sector.

#### **Obstacles Created by the Present Compulsory Licensing Law**

Even after the clarification issued during Doha Declaration and the subsequent decision, law on compulsory licensing suffers from many drawbacks, preventing the effective use of this law for access to drugs.

#### **Disincentives Against using Compulsory Licensing by Developing Nations**

At times, it has been observed that developing nations themselves may not want to avail benefits arising from compulsory licensing provisions due to political reasons. Amir Attaran argues that for attracting future investment and technology, many developing nations choose not to issue compulsory licences since it could be perceived as indifference towards intellectual property rights and consequently weaken trade relations or scare off investors.<sup>5</sup> Past history, shows that some low-income nations like Thailand, Colombia and South Africa have even been pressurized by developed nations like the US to adopt more rigorous intellectual property laws.<sup>6</sup>

#### **Practical Difficulties**

Developing countries have to pass through maze of rules and procedure to procure drugs from developed countries. This is against the very purpose of Doha Declaration to provide easy access to medicines to all. Many developing countries may simply lack coordinated mechanism within the government to undertake such steps.<sup>7</sup>

#### **Heavy Reliance on the Will of the Exporting Country**

A major problem is the heavy reliance on countries with manufacturing capacity to first issue compulsory licences. Developed countries following a strict patent regime may not be amenable to granting compulsory licences. Nations with good manufacturing capacity have no incentive to issue compulsory licences for export. Besides, in a scenario where even the developing countries are reluctant to issue compulsory licences due to the above-mentioned disincentives, it is even less likely that the developed nations will use this measure for the benefit of other nations.<sup>6</sup> There have been very few cases of grant of compulsory licences for exportation.<sup>8</sup>

Further, since TRIPS leaves a vast scope for nations to legislate according to their own needs, a lot depends on the country where the product is patented. For example, Canada has a better-developed and more liberal law on compulsory licensing than US which follows a strict patent regime.

It is also possible that developed nations use the threat of compulsory licensing to make companies voluntarily take measures to make their drugs accessible, without actually issuing the licence. Some nations have lowered prices while others have offered voluntary, royalty-free licences.<sup>6</sup> In 2001, US used

such threat to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.<sup>9</sup> Although such measures might be beneficial for the patenting country, it serves no purpose to nations which need to import such drugs.

### **The Way Ahead for the Developing Nations**

In spite of the above-mentioned obstacles, there still is adequate scope in the present regime of patent laws and compulsory licensing which developing nations can exploit. There is a need of a balance between protecting patent rights to encourage innovation and providing access to medicines to all. A careful analysis and application of the provisions show that such a balance is possible.

### **The Need for Innovation**

At the outset, it is important to understand that effective use of compulsory licensing provisions or otherwise limiting patent rights will not completely curb innovation. Like developed nations, it is the goal of developing nations not to prevent but to promote the development of a flourishing pharmaceutical industry.

Facilitating entry of generic products has in fact a positive impact on the development of domestic pharmaceutical industry in developing nations. Since technological demands of producing an already patented product are substantially less than undertaking research to create the patented product, less technologically sophisticated enterprises are able to produce generics. This provides an opportunity for fledgling companies in the developing world with sufficiently large domestic markets. For example, India, Argentina and Turkey have developed flourishing domestic pharmaceutical industries in the last three decades, due to policies of granting no pharmaceutical product patents (Argentina and Turkey) or imposing significant limits (India). Even in Brazil, lower patent protection facilitated industrial development.<sup>10</sup> Compulsory licensing allows generic manufacturers to lower their marginal costs by expanding their demand pool, that is, by selling in other countries. Compulsory licensing schemes can be utilized in many third world countries for a common market approach. For example, East African nations could develop an integrated compulsory licensing and generic drug manufacturing and marketing approach. Third world countries not adopting strict patent policies have proven more innovative than others who have. It was through imitation that virtually every

industrialized country built up its technological capacity. For promotion of research and development, third world countries require a science and technology infrastructure—a national system of advanced education and research—which a patent system cannot provide. Many industrialized countries developed pharmaceutical industries in the absence of patent protection.<sup>2</sup>

Besides, development of a sound domestic industry is much more beneficial than relying on multinationals. Domestic companies are more likely to adapt and modify technologies for local use. They promote local technological infrastructure development and favour generics. Profits accumulated by domestic companies stay within the country.<sup>2</sup>

### **A Liberal Construction of Compulsory Licensing Provisions**

Due to the non-specific language employed in international instruments, national legislations decide the degree of flexibility in the conditions for compulsory licensing. Many terms have been left undefined, for example, 'public non-commercial use', 'national emergency', 'extreme urgency', 'adequate remuneration', etc. which can have varied interpretations. TRIPS provides no clear guidance on how nations are to implement these provisions. For example, while TRIPS specifies that remuneration shall be determined taking into account the economic value of the authorization, it nowhere defines 'economic value' nor prescribes a method to calculate it. TRIPS does not specify at what level a compulsory licence can or should be authorized.<sup>8</sup> According to Bryan Mercurio, four main areas which are not satisfactorily resolved are: (i) the scope of diseases and products covered under the exception; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other markets.<sup>11</sup>

The ambiguity in the provisions can serve as a tool to promoting access to drugs and can enable experimentation with different patent schemes to serve this cause.

Under TRIPS, it is possible for developing countries to define the content of the standards imposed, the singular requirement of international law being that this is done in good faith.<sup>12</sup> Developing countries should utilize this opportunity to tailor domestic legislation in a way that promotes local inventiveness by, for example, permitting lower standards of inventiveness, preventing broad claims,

protecting improvements as separate inventions, employing a liberal test for non-obviousness, etc.<sup>10</sup> Undefined words and phrases may be interpreted according to local requirements and may be flexibly applied.<sup>13</sup> For example, Thailand authorized compulsory licence for the drug Plavix under the provision for 'public non-commercial use,' under Article 31 of TRIPS, rather than the provision on 'national emergency or other situation of extreme urgency.'<sup>14</sup> Developing countries should craft domestic legislation in a way that benefits their immediate societies.<sup>10</sup>

The fact that these loopholes can be exploited to the advantage of the developing countries is also evident from the pre-TRIPS situation. The heavy dependence on protection afforded by national legislation pre-TRIPS resulted in a number of disparities, but they actually benefitted the developing nations. They not only allowed for the possibility and right to tailor the patent system as per respective needs of the state, but also facilitated access to technology.<sup>10</sup> Hence, a balancing act is possible through a careful policy making on administering price controls, setting royalties in compulsory licensing system, or determining length of domestic patent protection.<sup>2</sup>

#### Other Alternatives

Articles 8 and 30 of TRIPS Agreement provide other viable alternatives apart from Article 31 route of compulsory licensing.

Article 8(1) allows the nations to adopt measures necessary to protect public health, subject to the provisions of TRIPS. Read along with Article 27, this provision can be used and domestic patent policy can be tailored accordingly. Recently, the Indian subsidiary of Swiss drug-maker, Novartis's cancer drug, Glivec, was denied a patent by Intellectual Property Appellate Board (IPAB).<sup>15</sup> It cited Section 3(d) of the Indian Patents Act, 1970, which makes therapeutic efficacy a prerequisite for grant of patent under specific conditions.<sup>16</sup> This is an example where available flexibility in the TRIPS regime was used to lay down the principles to be followed for subject matter analysis.

Similarly, the broad language of Article 30 can be exploited to promote public health interests. Articles 30 and 31 determine the outer limits of the scope of initiative that developing countries may legitimately rely upon. The need to provide pharmaceuticals or combat shortages arising from outbreaks of disease or

other national emergencies would clearly fall under these provisions. In addition, availability of pharmaceutical goods at affordable rates should constitute a valid ground for invoking the exceptions under the TRIPS Agreement.<sup>10</sup> Article 30 does not limit the purposes for which a country may make exceptions to the Agreement. The three limitations under Article 30 are not self-defining and these limitations may reasonably be interpreted to preserve a broad range of exceptions under Article 30, and hence a broad range of pharmaceutical patent policy alternatives for developing nations.<sup>2</sup>

#### The Need to Create a Favourable Paradigm

The developing nations must themselves take the initiative to protect their interests. They need to create an environment favourable for restricting the scope of patent rights in the larger interests of public health and for issuing compulsory licences and adopt measures to replace the paradigm of strict patent regimes. This involves providing for effective domestic legislations incorporating the required compulsory licensing provisions and creating smooth administrative procedures to avoid red tapism.

Those developing countries which have developed a strong pharmaceutical industry today as a result of their past policies must play an important role. For example, India has developed a strong industry and is one of the main suppliers of drugs to under-privileged countries.<sup>8</sup> By allowing easier policies towards nations which need drugs from India, such a favourable atmosphere can be created. A positive outcome results, if countries with the ability to manufacture drugs recognize and respond to the needs of other countries. Canada has set an example by introducing legislation to amend its Patent Act in 2003 to facilitate access to pharmaceuticals and address public health problems in developing countries.<sup>17</sup>

After the Doha Declaration and subsequent developments, Section 92A was added to the Indian Patents Act, 1970 in 2005 providing for export of pharmaceutical products to countries with no or insufficient manufacturing capacity in pharmaceutical sector. In this context, the case *Natco v Pfizer*, pending before the Delhi High Court is significant.<sup>8</sup> In this case, a Hyderabad-based generics manufacturer, Natco Pharma Ltd, filed an application for a compulsory licence to export to Nepal, Erlotinib, patented by Swiss firm, Roche in India. Natco contends that the generic versions can be

manufactured at one-fifth the cost of production by the innovators. Since Nepal is a least developed country, TRIPS permits the export of drugs to the country under the compulsory licensing system. The decision of the case is eagerly awaited as it would be significant in determining what line India takes.

Since the use of compulsory licensing is dependant on the exporting country, creating such a paradigm worldwide may help pressurize the developed nations to themselves adopt liberal measures.

### **Compulsory Licensing of Pharmaceuticals in Asia: Some Examples**

The use of compulsory licensing provisions in certain countries like, Malaysia, Indonesia and Thailand demonstrate how TRIPS flexibilities can be utilized to benefit public health. In these three countries, compulsory licensing was effectively used to significantly bring down the prices of essential HIV antiretroviral (ARV) drugs.

#### **Malaysia**

In 2003, Malaysia became the first Asian country to implement a compulsory licence after the Doha Declaration and Council Decision. Section 84 of the Malaysian Patents Act, 1983 provides for issue of such licence in case of national emergency or in public interest. Based on this provision, Malaysia issued a compulsory licence to import generic versions of patented HIV antiretrovirals (ARV) from India. This measure helped bring down the cost of treatment substantially.<sup>18</sup>

#### **Indonesia**

The Indonesian government also used compulsory licensing to overcome the high cost of ARVs. Unlike Malaysia which imported generic versions of the drugs, Indonesia used the compulsory licensing to appoint a local manufacturer to produce the drug. After the use of compulsory licensing, the price of drug dropped considerably.<sup>19</sup>

#### **Thailand**

In 2006, Thailand issued a compulsory licence for the domestic manufacture of the patented HIV drug Efavirenz in accordance with Section 51 of Thailand's Patent Act of 1979, which, *inter alia*, provides for the issue of such licence in order to carry out any service for public consumption or to prevent or relieve a severe shortage of food, drugs or other consumption items for any other public service. The government issued a compulsory licence for use in

public health services. The law in Thailand further facilitates the use of the TRIPS flexibility of compulsory licensing by minimizing red-tapism. The law allows any ministry, bureau or department of the government, by itself, to exercise compulsory licensing. Thus, Thailand implemented the licence domestically much faster than countries like Malaysia and Indonesia.<sup>20</sup>

### **Conclusion**

Although the TRIPS regime attempts to create a strict patent regime, it also contains provisions like those regarding compulsory licensing, which gives some consideration to developing nations' concern about access to drugs to address their public health needs. However, these concessions offered by TRIPS regime limit the extent to which compulsory licensing can be utilized to access drugs from the developed nations. But a careful analysis shows that there is still enough leeway for the developing nations. The primary concern of a rational drug policy for the developing nations should be to disseminate useful drugs widely and cheaply, and encourage research and development of products to address local illnesses. Within the realm of patent policy, the best means of providing drugs widely and cheaply is to promote generic production. This can be effectively done if the TRIPS Agreement is intelligently applied and compulsory licensing provisions are enforced in a manner beneficial to the public health interests. The fact that TRIPS flexibilities can be used to benefit public health has already been demonstrated by some South-East Asian countries, including India. By careful planning and policy making, the third world can work towards protecting the interests of the public, while still complying with the TRIPS patent regime.

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