Compulsory License - A Tool To Enable Availability Of Affordable Medicines

Introduction:

The Indian Constitution guarantees the right to health as a part of the right to life under Article 21. Article 47 of the Indian Constitution declares the state's obligation to improve public health as one of its primary duties. Internationally, the states have an obligation to facilitate the right to health under Article 12 of the International Covenant on Economic, Social & Cultural Rights (ICESCR) which has been adopted by India. The provision of medicines that are necessary to satisfy the priority healthcare needs of a country's population forms a core component of the state's obligations towards right to health. The State must respect, protect & fulfil individual's right to access medicines, which requires medicines to be available and affordable.

One of the factors which interfere with the enjoyment of this right to health is protection for patents granted to medicines. Patents provide right holders with the right to prevent third parties from making, using, offering for sale, selling or importing the patented product. In other words, patent protection gives the patent holder the exclusive right to prevent other companies from manufacturing cheaper versions of the drug.

There are two types of patents:

- **Product Patent**: A product patent protects the product that has been synthesised or made by the inventor. Only the inventor and no one else can make the same product. For example, a patent over Aspirin would imply that no other person except the patent holder can make, use, offer for sale, sell or import Aspirin.

- **Process Patent**: A process patent protects only the method that the inventor has developed to make the article/product. Only the inventor can use that method to make that particular article/product. But others can make the same article/product using different processes. For example, a patent over the process to make Aspirin would imply that no other person except the patent holder can use that particular process to produce Aspirin. But other persons can make Aspirin using different processes other than that patented.

When patents are granted on medicines, they are highly priced limiting its access, mainly because as a single entrant in the market the patent holder can price the patented product according to his discretion and in most of the cases, patent holders, such as large multi-national pharmaceutical companies, abuse patent monopolies by charging exorbitant prices for medicines and by preventing products from being made widely available. In the absence of competition the patent holder enjoys market domination. The availability and high prices of medicines are key indicators of access to treatment. Patents negatively affect access, particularly the affordability of essential medicines.

Compulsory License as a mechanism is allowed by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) - the international agreement which establishes intellectual property rights, including patent rights. Patent protection can be overcome through the use of Compulsory Licenses, which enables other companies to produce a patented product without the permission of the patent holder. A compulsory license creates an exception to the monopoly created by patent protection and acts as a legal counterweight to combat the adverse effects of patents. TRIPS empowers the State to make use of Compulsory License according to its own discretion. Thus, the State can rightfully resort to the use of Compulsory License in order to meet health requirements of the country's population.

On 9th March 2012, India issued its first compulsory license to a local generic pharmaceutical company, Natco, to produce a generic version of the patented drug sorafenib tosylate, (Brand name-Nexavar), used for the treatment of kidney and liver cancer. The compulsory license allowed the generic company to manufacture and sell the drug at a fraction of the cost of the patented version. The move has been praised by access to medicines advocates both within India and internationally. Not only will the Compulsory License make sorafenib tosylate more accessible and affordable, but hopefully it will set a precedent for the grant of licenses for other life-saving medicines in the future.

This newsletter examines the role Compulsory Licenses to ensure access to affordable medicines and in light of expansion of the patent regime, developing and least-developed countries have issued Compulsory Licenses to help improve accessibility to affordable medicines. Further it also discusses the obstacles against the use of Compulsory Licenses in developing countries.
India’s First Compulsory License

India’s first Compulsory License was granted by the Patent Office to Natco Pharma Ltd. for producing generic version of Bayer Corporation’s patented medicine, sorafenib tosylate used in the treatment of liver (Hepato cellular carcinoma [HCC]) and kidney cancer (Renal cellular carcinoma [RCC]) at advanced stages. Bayer was granted a patent for sorafenib tosylate in the year 2007. Bayer marketed this medicine in India by pricing it at Rs. 2,84,000 per patient per month.

On 6th December, 2010 Natco had requested Bayer for a voluntary license to manufacture and sell Bayer’s patented drug Nexavar in India at a price of less than Rs.10,000/per month of therapy as against the price of Rs.2,80,428/per month that was being charged by Bayer. As Bayer denied to grant a voluntarily license to Natco and rejected Natco’s request, Natco made an application to the Patent Controller requesting the grant of a compulsory license i.e. without Bayer’s consent, to manufacture and sell Bayer’s patented drug sorafenib tosylate in India.

Under section 84 of the Indian Patents Act, 1970 any person interested, may make an Application for the grant of Compulsory License after 3 years from the date of grant of Patent on the grounds that

a) the reasonable requirements of the public have not been satisfied, or
b) the patented invention is not available to the public at reasonable affordable price, or
c) the patented invention is not worked in the territory of India

As per section 84(6) of the Act, the application for Compulsory license should be preceded by an attempt made by the applicant to obtain a Voluntary license from the Patentee on reasonable terms & conditions. Only upon failure of Applicant’s such attempt, can he apply for Compulsory license under section 84 (1).

Thus, Natco’s application under section 84 for Compulsory License was considered by the Patent Controller. Under section 84, while any one of the above three grounds can suffice for the grant of Compulsory License, the Patent Controller decided against Bayer on all the three grounds.

Reasonable requirements: Bayer submitted that, in India, only 4004 patients are with kidney cancer in the terminal stage and 4838 patients liver cancer in the terminal stage required sorafenib tosylate for treatment. But the Patent Controller pointed out that in the year 2011, Bayer had supplied only 593 boxes of Nexavar (which could suffice 200 patients only), thus falling short to cater to its own figure of 8842 patients comprising the total requirement. Thus, the Patent Controller concluded that Bayer had been able to supply sorafenib tosylate to only a little above 2% of the patients in India since 2008 i.e. after 3 years of grant of the Patent in India and as such Bayer had not met the demand for sorafenib tosylate to an adequate extent and failed to meet the reasonable requirements of the public.

Not available at affordable price: As noted Bayer was selling sorafenib tosylate at Rs. 2,80,000 (USD 4559) per patient for a month’s treatment. Bayer insisted they had offered reduced prices under its Patient Assistance Programme (PAP). It is pertinent to note that Bayer had initiated PAP in India only subsequent to the CL application proceedings. Moreover, in order to avail the benefit of the reduced prices under PAP certain eligibility criteria had to be fulfilled by the patients such as recommendation from a physician, these eligibility criteria left many patients out of the PAP. Hence, PAP did not offer unqualified price to the public at large. In contrast, Natco offered to make sorafenib tosylate available to all the patients at about Rs.8800 (USD 144)(i.e. 3% of what was charged by Bayer).

Worked the patent: Since Bayer imported sorafenib tosylate into India and could not provide substantial reasons for failing to produce sorafenib tosylate in India despite having manufacturing facilities for other drugs in India, the Patent Controller held that Bayer had failed to work the invention in the territory of India.

Bayer was awarded 6% royalty by the Patent Controller to be paid by Natco pharma. Further under the compulsory license Natco would manufacture and market the generic version of sorafenib tosylate at the price of Rs.8,800 per patient per month only in India i.e. 97% lesser than Bayer’s price for sorafenib.

Aggrieved by the Controller’s decision, Bayer moved the Intellectual Property Appellate Board (IPAB) alleging that the grant of Compulsory License was illegal and unsustainable. The Appellate Board rejected Bayer’s appeal.

The Appellate Board’s Hon’ble Chairperson Prabha Sridevan on 4th March, 2013 upheld the Controller’s decision for grant of Compulsory License on Bayer’s patented drug sorafenib tosylate. However the royalty rate was increased by 1% as awarded by the Patent Controller.
Bayer challenged the Patent Controller’s decision and the IPAB’s order through a Writ Petition in the Bombay High Court. The Bombay High Court dismissed the Writ Petition by its Order dated 15th July, 2014 stating that it found no reason to interfere with the Patent Controller’s as well as IPAB’s orders and has thus, upheld India’s first Compulsory license for sorafenib tosylate. As of date no petition by Bayer challenging the Compulsory license has been filed in the Supreme Court.

This case makes it evident that Compulsory License can thus ensure greater access to medicines by introducing an alternative supplier in the market thereby giving the public a choice other than drugs of the patentee and also increasing the quantity of the same drug to meet the treatment demands. Compulsory License also helps in making the patented drugs more affordable for the general public. It is a step forward in the right direction towards utilization of TRIPS flexibilities to address public health needs.

The advent of TRIPS and India’s accession to TRIPS

During the 1980’s the developed countries sought to establish a new global trading system with the intention to maximise the profits for their multinational companies (MNCs) and thus, insisted on the inclusion of Intellectual Property Rights under the ambit of international trade rules during the Multilateral Trade Negotiations, known as the Uruguay Round, which got underway in 1986.

It resulted in the formation of the World Trade Organization³, which incorporated a new, comprehensive and relatively elevated set of international minimum standards of patent protection into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). India was an original signatory to WTO which came into being on 1 January 1995. Under the terms of the WTO-mandated TRIPS Agreement, India was obliged to make patent protection available for process as well as products for inventions in all fields of technology⁴. Previously, India provided patent protection only for process. Protection for product patents was excluded for pharmaceuticals under the then Act. Thus, India could no longer exclude pharmaceuticals and agro chemicals from patent protection. Further, the minimum term of patent protection required under TRIPS is twenty years, thus drastically extending the term of protection of seven years that India provided to process patents on medicines during the pre-TRIPS era.

Compulsory License as TRIPS flexibility

There is no compulsion under TRIPS for the developing countries to follow the liberal patent standards of developed countries. Rather TRIPS required member nations to provide minimum standards of patent protection. Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are “new, involve an inventive step and are capable of industrial application”. TRIPS however does not define these terms. This provides some flexibility.

Article 31 of TRIPS dealing with compulsory licensing does not place any restriction on the grounds under which a compulsory licenses can be granted. TRIPS does not use the term “compulsory license.” However, Article 31 refers to “use without authorization of the right holder,” and includes, both, use by third parties (what is usually referred to as compulsory licenses) and use by government. The member countries can use this provision on grounds of public interest, abuse of patent or anti-competitive conduct, public non-commercial use, under national emergency and circumstances of extreme emergencies. Thus, TRIPS provides for some flexibilities to member countries of WTO to take action to tackle the negative consequences of patent protection. India agreed to adopt TRIPS on account of these flexibilities.

WHO and WTO point out that compulsory licensing is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs.

Compulsory License under Indian Patent Law provisions

The Patents Act, 1970 amended in 2005 has elaborate provisions on compulsory licensing in Chapter XVI (Sections 82 to 94). These provisions along with rules elucidates the grounds and procedure to be followed by applicants seeking compulsory license, the grounds available to apply for compulsory license, the due considerations and procedure to be followed by patent office while deciding the compulsory license grant, grant of compulsory license under extreme and emergency situations, for purpose of exporting generic medicines and the power vested with the government to use the patented invention for its own use.

Procedure for grant of compulsory license under section 84:

Prior to making an application for Compulsory license under section 84, the applicant should attempt to obtain a voluntary license from the patent-holder in order to make, use, offer for sale, sell or import the patentee’s invention. It is only when patent holder refuses to consent and grant a voluntary license on reasonable terms and conditions resulting in failure of applicant’s attempt to obtain a voluntary license, the applicant can then apply to
the Patent Controller for a compulsory license on anyone of the grounds enlisted under section 84 (1).

The procedure for grant of compulsory license before the Patent Controller sets out a two-step procedure. Firstly, the Controller examines the application for a compulsory licence to determine if the application indeed discloses sufficient facts and incidents which are able to support the grounds raised therein for the grant of compulsory license i.e. whether a *prima facie* case has been made out for issuing a compulsory licence.

The procedure is open-ended without any time limit imposed for the grant of compulsory licenses. Thus, the patentees can oppose the grant of compulsory license and if granted, appeal against such decisions and indefinitely delay or prevent the actual use of compulsory license.

Applicant should negotiate with patent holder to obtain a Voluntary License

| Applicant can apply u/s 84 (1) to Patent Controller for a Compulsory License |
| The applicant can use any one of three grounds u/s 84(1), namely: reasonable requirements or affordable price or working of the patent in India |
| *if prima facie case has been made out* |
| *if prima facie case is not made out* |
| Controller is to notify the applicant |
| Controller to grant hearing to the Applicant upon request made by the Applicant within one month OR refuse the compulsory licence application |
| The Compulsory Licence Application also needs to be published in the official Patent Journal |
| Notice of Opposition to be given by Patentee or any other person interested in opposing the Compulsory Licence application, to the Patent Controller |
| The Controller shall notify the Applicant about any such Notice of opposition |
| The Controller will decide only after hearing the Applicant and the Opponent |
| The Compulsory The Compulsory License granted by the Controller can be challenged by an appeal before the Appellate Board |
| No waiting period: Once such a declaration is made, an application for compulsory licence can be filed at any time. The three-year waiting period from the date of grant of patent does not apply as in case of an application for Compulsory license made under section 84 |
| No requirement for prior negotiations of voluntary licence: As set out earlier, the Controller need not consider if the applicant has entered into prior negotiations for a voluntary licence. |
| Dispensation of hearing: If the Controller is satisfied that in the cases listed above, including in case of public health crises, including AIDS, HIV, TB, malaria or other epidemics, the Controller shall not follow the procedures for hearing. The Controller is only required to inform the patentee, as soon as may be practicable, of the application for non-application of the hearing procedure. |
| Attempt to endeavour lowest prices: The Controller is further required to endeavour, while settling the terms and conditions of the compulsory licence, that the product shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. |

Use of Compulsory License in circumstances of national emergency, extreme urgency, or public non-commercial use:

The other key provision is **section 92**. This provision allows grant of compulsory license at any time by the government under circumstances of *national emergency* or in circumstances of extreme urgency or in case of public non-commercial use. The government may in this respect either make a declaration or issue a notification in the official gazette. The procedure mentioned above for the grant of compulsory licenses will have to be followed for these applications too, except that the applicant is not required to approach the patentee for a voluntary license.

The main advantages of issuance of compulsory license through government notification are

- No waiting period: Once such a declaration is made, an application for compulsory licence can be filed at any time. The three-year waiting period from the date of grant of patent does not apply as in case of an application for Compulsory license made under section 84
- No requirement for prior negotiations of voluntary licence: As set out earlier, the Controller need not consider if the applicant has entered into prior negotiations for a voluntary licence.
- Dispensation of hearing: If the Controller is satisfied that in the cases listed above, including in case of public health crises, including AIDS, HIV, TB, malaria or other epidemics, the Controller shall not follow the procedures for hearing. The Controller is only required to inform the patentee, as soon as may be practicable, of the application for non-application of the hearing procedure.
- Attempt to endeavour lowest prices: The Controller is further required to endeavour, while settling the terms and conditions of the compulsory licence, that the product shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

Though the usual procedure is not applicable, however, the decision of the Patent Controller can be challenged and referred to the Appellate Board. The requirement of TRIPS that any Compulsory Licensing decision would be subject to review does not mean that the actual use should be held up till all disputes are settled. TRIPS does not require Government to grant relief to patent holders by way of granting injunction upon the use of a compulsory license. Any opposition to the proposed royalty rate would satisfy
the requirement of the review of the Compulsory Licensing decision.

**Use of Compulsory License by the Government:**

The Indian patent law also provides for government use of patents under section 100 of Patents Act, 1970. The Central government or State government or government undertaking may acquire a patented invention for its own use, make, exercise or vend on payment of adequate remuneration or compensation (Sections 99 to 103). The Central Government is required to notify the patentee as soon as practicable of the use of the invention and furnish information about the extent of the use of the invention, from time to time, as the patentee may reasonably require. However, this requirement of notification as soon as practicable is not required to be complied with in case of national emergency, extreme urgency for public non-commercial use. The patent owner however can challenge such a use or the terms of such use. Any such disputes are required to be judicially settled.

Specifically, under section 102 the Central Government may acquire a patented invention for a public purpose. In such a case of acquisition of the patented invention by the Central Government, the rights of the patentee come to be vested in the Central Government. Whereas, in case of compulsory license for Government use, the patentee retains his patent rights. The patent holder is still the owner of the patented invention even after the issuance of compulsory license for Government use. While in the case of acquisition of the patented invention by the Government for public purpose, the patent owner loses all rights in the patent to the Government. The patentee is to be notified of such acquisition and is entitled to compensation. The patentee can seek to determine the quantum of compensation by approaching the High Court but cannot challenge such acquisition of its patented invention by the Government.

**Enlarging the scope of Compulsory License through the Doha Declaration**

Under TRIPS agreement a member country with pharmaceutical manufacturing capacity can resort to Compulsory Licensing to manufacture patented drugs to meet public health needs. But under Article 31(f) this flexibility has a limitation, by which production under a Compulsory License has to be predominantly to supply only for domestic market. This implies that member countries manufacturing the patented medicines under a Compulsory License cannot export these medicines to other countries. Thus, countries with no manufacturing capacity trying to meet the health requirements by importing the patented medicines would face a stumbling block due to Article 31(f) which restricts the manufacturing countries from exporting the required patented medicines produced under a Compulsory License.

The Declaration on TRIPS Agreement and Public Health adopted during the WTO Ministerial meeting held in November 2001 in Doha (referred to as the Doha Declaration) in its paragraph 6 addressed this major lacuna in TRIPS. It instructed the TRIPS Council to find an expeditious solution to this problem and to report the General Council before end of 2002. However, no consensus could be reached by December 2002 due to the differences between the developed countries and developing countries over the scope of the solution, including the diseases and medicines to be covered, countries to be eligible to import, and the procedures to be followed. Ultimately, a compromise was reached on 30 August, 2003 which proposed a waiver of the obligation under Article 31(f) of TRIPS that Compulsory License can be granted predominantly for the supply of domestic market.

The Decision of 30 August, 2003 permits countries producing patented drugs under Compulsory License to export to countries with less or no manufacturing capacities. However, if any developed country opposes the action taken by a developing country in support of its right to take measures to protect public health, such developing country can rely on the Doha Declaration in the WTO dispute settlement body.

Accordingly, Section 92-A was inserted in the Indian Patents Act, 1970, alongwith the other amendments in 2005, enabling the grant of Compulsory license for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity w.r.t the patented pharmaceutical product in order to address “public health needs”.

One such example is the case of Rwanda and Canada.

Rwanda was the first country to use the system under the 30 August Decision, 2003.

In 2007 Rwanda notified WTO Council of its intention to use this system to import ARV fixed dose combination of zidovudine, lamivudine and nevirapine (TriAvir) from a Canadian generic company Apotex. Being a LDC Rwanda did not have product patent regime. It was not required to issue a compulsory license to import these FDCs.

In order to implement the Decision of August 30, Canada amended its Patent Act and Food & Drugs Act to allow for
export of patented medicine, it is generally referred to as “Canada’s Access to Medicines Regime” (CAMR). Since the patent was granted in the exporting country Canada, according to the requirements under CAMR, Apotex, a Canadian pharma company, had to negotiate for a voluntary license with patent holders within the 30 day period. Since the negotiations did not result in a voluntary license Apotex then applied for compulsory license with Canadian Intellectual Property Office to export ARV FDC of zidovudine, lamivudine and nevirapine for a quantity of 15.6 million tablets. After the grant of compulsory license by the Canadian Patents of Commissioner, Canada notified WTO council of its intention to export the generic version of TriAvir to Rwanda. In the fall of 2008, the first shipment of ARV medicines were exported from Canada to Rwanda under the 30 August 2003, decision.

However the entire process was lengthy and the requirements under the August 30 system and under domestic laws created obstacles instead of facilitating early and easier process to export patented medicines to needy countries. These included, firstly, the requirement of notifying to WTO Council by the importing and exporting country under 30 August system. Secondly, requirement of negotiating with patent holders for voluntary license before seeking compulsory license under domestic laws of countries such as Canada, Europe. Thirdly, a condition to establish by the importing country as LDC or it lacks pharmaceutical manufacturing capacity. Fourthly, restricted timelines on the duration of the compulsory license under domestic laws issued under 30 August system makes it financially non-viable for generic companies. The restriction in the CAMR of Canada with only two years’ duration of compulsory license extendable for another two years but only for producing approved quantity of drugs has failed to create incentives for generic companies.

All these factors have discouraged both Member countries and generic companies to utilize 30 August decision system, to enable supply of affordable generic copies of patented medicines to LDCs and resource poor countries. There is an urgent need to renew this system.

**Use of Compulsory License Mechanism by Developing Countries:**

Many developing countries such as Thailand, Indonesia, Malaysia, Eritrea, Ecuador, Zimbabwe, Rwanda, and Mozambique have issued compulsory licenses on essential life saving medicines such as anti-retrovirals, cancer drugs which are patented in their respective countries. The details of few of these licenses issued in developing countries have been tabulated as below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Drug/ patentee</th>
<th>Cost of drug before CL</th>
<th>Year when Compulsory License issued</th>
<th>Royalty paid</th>
<th>Price reduction post CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>Efavirenz (anti-retroviral) / Merck, Sharp &amp; Dohme</td>
<td>US$ 1.59 per dose</td>
<td>2007 operative till 2012</td>
<td>1.5 %</td>
<td>US$0.72 per dose</td>
</tr>
<tr>
<td>Ecuador</td>
<td>Lopinavir/ritonavir / Abbot</td>
<td>US$1,000 per person per year</td>
<td>2010 operative till 2014</td>
<td>4%</td>
<td>US $478 per person per year</td>
</tr>
<tr>
<td>Ecuador</td>
<td>Abacavir/lamivudine (anti-retroviral FDC)/ Glaxo group</td>
<td>US $753 per month</td>
<td>2012</td>
<td>5%</td>
<td>75% price reduction</td>
</tr>
<tr>
<td>Thailand</td>
<td>Efavirenz (anti-retroviral) / Merck, Sharp &amp; Dohme</td>
<td>1,400 Baht per month</td>
<td>2006</td>
<td>0.5%</td>
<td>650 Baht per month</td>
</tr>
<tr>
<td>Thailand</td>
<td>Lopinavir/ritonavir (anti-retroviral) / Abbot</td>
<td>12,000 Baht per patient per year</td>
<td>2007</td>
<td>0.5%</td>
<td>80% price reduction</td>
</tr>
<tr>
<td>Thailand</td>
<td>Clopidogrel (anti-platelet drug)/ Sanford, Aventis</td>
<td>75 Baht per day</td>
<td>2007</td>
<td>0.5%</td>
<td>7 Baht per day</td>
</tr>
</tbody>
</table>

Even the United States of America has granted compulsory licenses extensively, particularly under its antitrust legislation, to remedy anticompetitive practices. Under its patent law, USA has also made extensive use of compulsory licensing to facilitate public non-commercial uses by the government and those authorized by it. While most of these pertain to national defence, this legal tool has also been used to bring down prices of medicines.

Under 28 USC Sec 1498 of the US patent law, the US government can use a patent or authorize third parties to use patents for virtually any public purpose and the government has actually made good use of it. In late 2001, when there were a series of Anthrax attacks and it was feared that an Anthrax epidemic may start, USA did not hesitate to initiate action to make the drug more affordable to deal with the crisis. Bayer, the German MNC, held the product patent for the antibiotic (Bayer’s brand, Cipro) prescribed for treating patients. Bayer was threatened that Compulsory Licenses would be issued unless it reduced its price. Such a threat worked and Bayer reduced its price substantially benefitting the people in the country.

These examples from various countries demonstrate the importance of compulsory license as a key policy tool which is an efficient mechanism to regulate the prices of patented medicines and can also be used to curb anti-competitive practices among patent holders in developing countries.

Though this TRIPS flexibility should be used and implemented by developing countries to address public health goals, the increased pressure by developed nations...
at the behest of multinational pharmaceutical companies (MNPCs) continues to thwart the use of compulsory license and government use provisions. In contrast to what US did during the anthrax crisis, the US government has been aggressively indulging in activities to stop and deny the same freedom to the developing countries to tackle their public health crisis.

**Current obstacles and practices undermining CLs:**

**International and National Pressures at Play!**

With the foregoing explanation it is also important to highlight various barriers which disallow use of compulsory license to enable access to patented medicines by developing countries. The MPNCs see the use of CL as a threat to their patent monopoly and insist government should use compulsory license as a ‘last resort’. USA has systematised the threat of unilateral trade pressures through section 301 of the United States Trade Act of 1974. Under section 301, the USTR issues a yearly report threatening the foreign countries with unilateral trade sanctions for not adequately protecting the intellectual property rights of the US companies. The threat of trade sanctions has a chilling effect and discourages the developing countries from the use of compulsory license. For example, Thailand was placed on USTR 301 Report Priority Watch List for issuing government use compulsory license in 2006-2007.

The developed countries are constantly striving to strengthen the IP regime while the developing world pushes for policy tools such as use of CL to ensure access to affordable medicines. It is important to strike a balance between private patent rights and public health. While patent holders promote the idea of voluntary licensing in place of CL, low and middle-income countries have constantly pushed the public health rights agenda.

**Litigation Costs:**

Generic companies usually refuse to seek compulsory license due to the extensive litigation cost involved in the process. Once a compulsory license is issued it can always be challenged in the higher courts by the patentee, to produce and market the drug the licensee (generic company) will have to contest the case in court. Therefore licensees will have to incur high litigation cost and this also involves considerable amount of time and a level of uncertainty. This is seen as one of the key factors which discourage generic companies’ especially small players in exploring this option.

**Bilateral and Regional Trade Agreements:**

Developed countries engage with developing countries and negotiate free trade agreements (FTAs). These FTAs usually include extensive provisions on protection of intellectual property rights and impose obligation on negotiating parties to include maximum protection and enforcement of IPR than is required under TRIPS Agreement. They are designed to negate the use of TRIPS flexibilities including use of compulsory license. For example inclusion of provisions such as data exclusivity (a provision which will restrict drug regulatory authorities to rely on clinical trial data submitted by innovator companies to approve a generic versions) in a bilateral trade agreement will disallow use of innovator company’s clinical trial data for a period of 3 to 5 years by the drug regulator to approve the marketing of generic medicines. In such instances, even if a compulsory license is granted to a patented medicine, generic company will be unable to market the medicine due to absence of marketing approval, this will render the issued compulsory license ineffective.

**United States political pressure:**

The trade negotiation history reveals how United States has been in the forefront in achieving the agenda of their industries in particular pharmaceutical companies and has aggressively promoted and pushed for protection and promotion of IPR. Apart from using multilateral and bilateral forums, US also exerts pressure on developing countries through unilateral measures to advance their IP agenda. In 2009, when Ecuador government decided to introduce procedures for compulsory licensing of pharmaceutical patents and issued Decree 118 to grant compulsory license, US government including multinational pharmaceutical companies tried to influence and veer off the efforts of Ecuador government. It was also reported that after the Ecuador President issued Decree 118, the US mission in Quito tried to pitch against Ecuador policy. These details were disclosed to public through wiki leak in 2011. From the time India issued its first ever compulsory license for the cancer drug sorafenib, MNPCs are lobbying with US government to put pressure on the Indian government. US trade department is backing their industry stand and have repeatedly and constantly alleged India has failed to comply with the TRIPS agreement and the investment climate in India is not supportive and conducive for their industry players to continue to stay
invested in India. The various investigations initiated by various departments of US government against India have affected the decision of the Indian government to issue a government use license for other key cancer drugs. Though India has stood its ground and vehemently opposed US government stand on the issue of use of compulsory license the recent decision of the government is reconsider their decision on use of government use compulsory license for key cancer drugs is a cause of concern. These unilateral actions and threats by U.S. have considerably slowed down the process of utilizing compulsory license and government use provisions by Indian government.

Conclusion:

Developing countries should adopt expansive interpretation of public health to enable use of TRIPS flexibilities to protect, promote and advance access to affordable medicines.

As a way to enhance and enable access to affordable medicines developing countries, specifically Brazil, Russia, India, China and South Africa (BRICS) should collaborate and create a platform on South-South cooperation. BRICS should push for utilization of TRIPS flexibilities such as compulsory license on public health grounds.

Further developing countries should learn from each other and emulate lessons countries for the use of compulsory license to make available patented medicines at affordable price. For example India could follow the footsteps of Thailand in utilizing the TRIPS flexibilities. India should make effective use of compulsory licensing to ensure transfer of technology to India and to check abuse of patent rights like excessive pricing of patented medicines.

Developing countries should reject FTAs with riders which mitigate compulsory license provisions and resist inclusion of restrictions which would undermine the use of compulsory license by developed countries.

Contributions: Viveka Truman & Ramya Sheshadri

2. Bayer Corporation Vs. Union of India & Others (Writ Petition no 1323 of 2013) http://bombayhighcourt.nic.in/generatevivash.htm?auth=CGFoaD0uL2RhdbGtcy1vY2ZvZ2ZvZ25vcj8yMDMDEly2bnBmZ2ttL0tleUM0NTMzLmFwZi90aGxlLkJidXRwMlRjYjExLkNub2RlLWlvdXIucG9zaXplLXNpaWUucG9zaXplLXNlbmNvZGluZw==9Tg
4. TRIPS Article 27.1
7. Day-to-day work is handled by the General Council where all the member countries are represented. The TRIPS Council, the Goods Council and the Services Council deal specifically with the three main Agreements, which includes TRIPS, and report to the General Council

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