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Debate on compulsory licensing continues..

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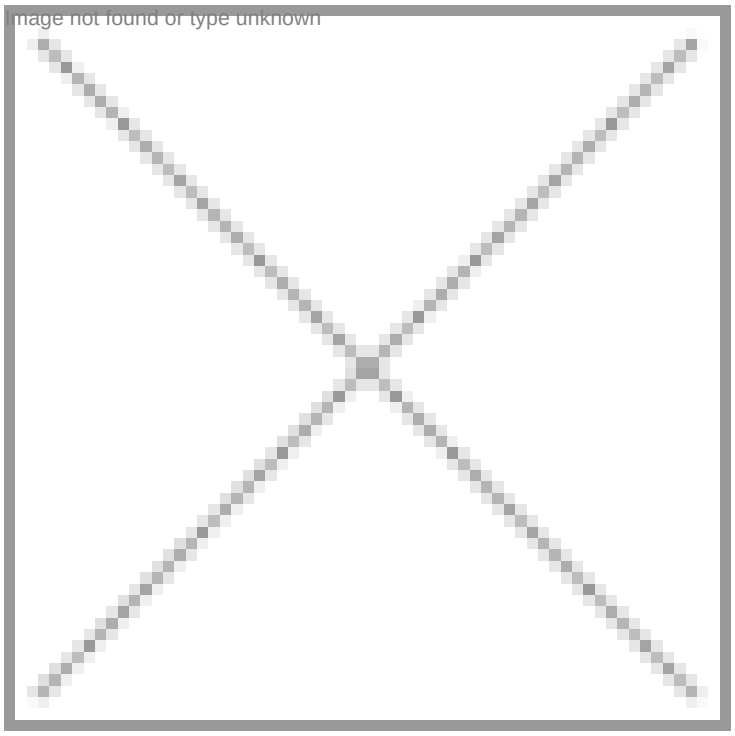

Though WTO has flexibilities in TRIPS agreement to increase access to medicines, a debate on issuing compulsory licensing continues in India, with stakeholders pointing out that the governing agency should prudently decide as to how and when to use this provision

When the Indian patent office granted compulsory license to Hyderabad-based Natco Pharma to market the generic version of a patented cancer treatment drug, Nexavar in March this year, it was not the first nation to do so. In last 10 years, governments of the developing nations such as Zimbabwe (2003), Malaysia (2003), Zambia (2004), Indonesia (2004 and 2007), Thailand (2006 and 2007) and Brazil (2007) have already evoked compulsory licensing to increase their access to medicines. Even after six months of issuing compulsory licensing by the Indian government, it still remains as a subject of debate in many forums and conferences in India.

India never felt the need to issue compulsory licensing since 2005, as it didn't face a situation that has demanded the use of this provision until 2012. However, Mr YH Gharpure, Gharpure Consulting Engineers, Pune, opined, â€œThere is a provision in the patent act for government to evoke compulsory licensing under clause 100 as has been done by Brazil government, thereby forcing the multinationals (MNCs) either to reduce the exorbitant prices of the patented drugs or the government take recourse to compulsory licensing and give the same to several companies so that essential drugs are available at reasonable prices.â€?

Elaborating on compulsory licensing, Mr Kirit S Javali, Partner, Jafa & Javali, Advocates, New Delhi pointed

out that, â€œThe grant of a patent confers limited monopoly on the patentee to the exclusion of others. Though the law permits this, it also takes into account the fact that the monopoly granted through a patent may be abused and hence, provides for certain restrictions to its enjoyment. The grant of compulsory licence is one such restriction imposed on the absolute exploitation of a patent.â€?

Use of compulsory licensing and government use by developing countries

Apr 2003	Zimbabwe	all HIV/AIDS - related Medicines	not indicated	not indicated
Oct 2003	Malaysia	didanosine, zidovudine, FDC didanosine + zidovudine	two years	not indicated
Sep 2004	Zambia	FDC lamivudine + stavudine + nevirapine	until notification of expiry of the compulsory license	2.50%
Oct 2004	Indonesia	lamivudine, nevirapine	7-8 years (end patent term)	0.50%
Nov 2006	Thailand	efavirenz	until 31 December, 2011	0.50%
Jan 2007	Thailand	lopinavir/ritonavir	until 31 January, 2012	0.50%
Jan 2007	Thailand	clopidogrel	patent expiry or no longer needed	0.50%
Mar 2007	Indonesia	efavirenz	until 07 August, 2013	0.50%
May 2007	Brazil	efavirenz	five years	1.50%

Source: www.moph.go.th

Sharing his thoughts on the topic, Mr KV Balasubramanian, managing director, Indian Immunologicals, Hyderabad said, â€œIndia amended its patent act in 2005. Even before, compulsory licensing was there in place, but was not evoked. For any society, where people are unable to meet up with their daily requirements, compulsory licensing would bring in cheer on their faces as the healthcare costs are beyond their reach. India granted its first ever compulsory licensing to Natco Pharma only this year. Thailand and many developing nations have already granted compulsory licensing to overcome the monopoly in the market. If I am not wrong, even developed nation such as Canada has used compulsory licensing earlier.â€?

The spokesperson from Sun Pharmaceutical remarked, â€œMost countries have some form of compulsory licensing or similar provision to protect the interest of the patient, which itself seems like a reasonable thing. Having said that, it may be too early as yet to see how this has impacted the society-there have not been too many instances of compulsory licensing being granted.â€?

In India, the provisions on compulsory licensing were introduced into the Patents Act pursuant to the recommendations by the Ayyangar Committee. The predominant purpose behind the grant of a compulsory license is to ensure the supply of the patented invention in the Indian market. Patents are not granted to enable the patentee to enjoy a monopoly by importing the patented articles into India.

â€œThe Patents Act makes the working of the invention in India an important requirement. At the same time, the effort expended by the patentee in inventing the patented article, the expenditure incurred in research and development, and in obtaining and keeping the patent in force cannot be disregarded. The provisions on compulsory licensing endeavors to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights,â€? states Mr Kirit S Javali, partner, Jafa & Javali, Advocates, New

Delhi.

â€œAs the patent regime came in full force under World Trade Organization (WTO) from 2005, the MNCs started registering patents for a large number of new drugs, importing the products and marketing them in India without working the patent,â€? says Mr Y H Gharpure of Gharpure Consulting Engineers, who has been studying the compulsory licensing issue.

â€œIf the patent is not working for three years, the compulsory licensing provision can be evoked as was done by Natco Pharma. There is a case for evoking such provisions for many other patented products for treatment of cancer, HIV/AIDs, etc. This, however, will become apparent if the information patentee files to the patent authorities under form 27 is made public. This will clearly reveal whether the patent is being worked in India or otherwise. Currently, although the information is available on request, it is not available in public domain,â€? he adds.

â€œCompulsory licensing works as a double edged sword,â€? said Dr Ajay Kumar Sharma, associate director, pharma and biotech, healthcare practice, Frost & Sullivan, South Asia & Middle East and added, â€œIt helps the patent products to become more affordable and accessible in order to save lives. Thus helping the society at large. But if one has to analyze, in the long run, it deprives the innovator companies from making money, which they would have invested in discovering this successful drug and many unsuccessful trials. Also this money helps them to generate a surplus amount for funding future research which can be of immense use to mankind to fight newer disease challenges. By awarding compulsory licenses (on impulse) we are destroying this natural market equilibrium. Hence, the best way in such case would be that, the government chips in its share in providing these essential medicines at subsidized rates to the population at large rather than destroying the market equilibrium under the guise of compulsory licensing.â€?

Ms Sunita K Sreedharan, partner, SKS Law Associates, New Delhi, said, â€œIn areas like healthcare, patented inventions appear to evoke high emotional content. In case of epidemics, the Patent Act provides for government intervention. In a routine system, the Drug Price Control Order can be used to control price without resorting to grant of compulsory licensing. Similarly, companies holding the patents can be encouraged to make the patented drugs available to the afflicted patients belonging to the poorer sections of the society through CSR (Corporate Social Responsibility) programs that can be implemented for a certain time period, failing which the compulsory licensing can be granted.â€?

WHO SUPPORTS MEASURES TO IMPROVE ACCESS TO ESSENTIAL MEDICINES

A report titled â€œImproving access to medicines in Thailand: The use of TRIPS flexibilitiesâ€? prepared by a team of seven experts from World Health Organization (WHO), United Nations Development Program, United Nations Conference on Trade and Development, WHO South East Asia Regional Office led by Dr German Velasquez, made the following four remarks after visiting Bangkok in 2008 and holding discussions with stakeholders aimed at facilitating an understanding of the context and circumstances related to the granting of compulsory licences in Thailand, and identifying the appropriate technical and policy support required on the use of TRIPS flexibilities.

- In seeking greater access to essential medicines, national authorities may consider the full range of mechanisms available to contain costs of essential medicines and examine how the various tools may complement one another.
- A sustainable system for the funding of medicines could be based on three main components:
  1) the creation or enhancement of a national or social health insurance or of medicine prepayment mechanisms.
  2) the introduction and use of all possible cost-containment mechanisms.
  3) the use of TRIPS-compliant flexibilities. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies.
- The use of compulsory license and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes.

- WHO supports measures which improve access to essential medicines, including application of TRIPS flexibilities.

Source: www.moph.go.th

â€œWe believe that while some developing countries may use compulsory licensing provisions in certain limited circumstances, compulsory licensing cannot address the underlying issues of access to medicines and healthcare. Systematic issuance of compulsory licenses sets a negative precedent and can reduce the incentive to invest in the research and development of new medicines. Pfizer is committed to applying science and our global resources to improve health and well-being at every stage of life,â€? commented spokesperson from Pfizer.

Echoing similar sentiments, Mr KV Balasubramanian of Indian Immunologicals pointed out, â€œThe governing agency could issue compulsory licensing after proper examination and considering many aspects such as need, urgency and affordability. Otherwise, decision based on only technical aspects will open up the matter for a debate. A core committee comprising ministry of health, scientists with different back grounds should take the decision based upon situations and need instead of patent office judging the case purely on technical matters. Then only it will serve the purpose of granting the compulsory licensing to improve the access of essential medicines.â€?

'ISSUING OF CL WILL NOT EXPAND ACCESS EVEN AT REDUCED PRICES'

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icensing (CL) provisions in the Indian Patents Act are basically in consonance with nent. However, provisions in the Indian CL law regarding pricing, local working, in eyond what is provided in the TRIPS Agreement and the Doha Declaration, and are lia's obligations as a WTO member.

overnment can achieve its objectives for patients through collaboration without the ises from unilateral actions taken on compulsory licensing. In those instances where not prove to be a fruitful approach, developing countries like India may make use of compulsory licensing as a last resort. However, the issuance of compulsory licenses to address pricing or budget constraints could come at a long-term cost, limiting important incentives for research and development that are necessary to positively impact the lives of millions of patients worldwide.

Issuing of compulsory licenses will not significantly expand access as even at reduced prices generics are out of reach for the poor in India. Once we have the right ecosystem in place, that fosters innovation, then the balancing acts with compulsory licensing on a case-by -case basis such as in times of a national health emergency could be justified. Compulsory licenses are powerful rights granted to governments to deal with the extraordinary situations. And with great power comes great responsibility. It is therefore incumbent upon those who deal with such power to ensure that these rights are exercised judiciously.

- Mr Ranjit Shahani, president of the Organisation of Pharmaceutical Producers of India (OPPI), a premier association of research based international and large pharmaceutical companies in India and also the vice chairman and managing director, Novartis India, which is fighting for a patent based on increased safety of the Glivec drug due to modification of the naked chemical molecule.

In all this situation, Ms Sunita K Sreedharan, concludes that the society must not lose sight of the fact that the patent system is a mere tool which can be used effectively to benefit society by bringing in technological progress or to its detriment by blocking development of technology. And in the latter context it is important to identify and block entities that use the compulsory licensing as a tool for a low-cost piggy-back ride on a research and development (R&D) company to attain bigger profits with least scientific or business efforts.

An industry veteran on condition of anonymity said, â€œThe â€œlow-hanging fruitsâ€? are of the past and the diseases that affect people have become more complex. Compulsory licensing would hinder the innovation and creativity that are an integral part of drug discovery. There should be an appreciation for the years of research and billions of dollars that go into developing medicines. Pharma companies are always

willing to work with the government to ensure that drugs are made affordable for the common man.â€?

Narayan Kulkarni (with inputs from Manasi Vaidya)