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IMPLICATIONS OF COMPULSORY LICENSING ON INVESTMENT PATTERNS IN PHARMACEUTICAL SECTOR IN INDIA AND GERMANY

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ABSTRACT

Patent is one of the major Intellectual Property Rights. It is a set of exclusive rights given to the inventor for his innovations or for giving a new technical solution to a problem. The inventor is given monopoly rights for a limited period which helps him re- cover the costs of R&D and acts as an incentive for further research. These patent rights however may make the product unaffordable to many in need especially in case of life saving drugs produced by the pharmaceutical sector and on occasion can also be abused by the patent owner. Prevention of abuse of Patent protection in the form of Compulsory licensing therefore becomes a necessary safeguard to avert the same and also contributes in provision of welfare to those in need. This paper is a case study of compulsory licensing in India and Germany in the Pharmaceutical sector and infers how this tool helps to resolve and balance the conflict between public health and private rights by both developed and developing economies alike making this concept of compulsory licensing more acceptable in the years to come.

IPR REGIME IN INDIA AND GERMANY WITH SPECIAL REFERENCE TO COMPULSORY LICENSING

The concept of patents did not exist as we know it today till two centuries before. Inventors often protected their ideas and innovations through the means of trade secrets which passed on from generation to generation keeping the general public deprived of the benefits that the knowledge about that invention could provide.

Today, no product can be patented without the inventor sharing the knowledge about his invention. This patentee is then given exclusive monopoly rights in the market for approximately 20 years according to the TRIPS agreement after which his product is open for public use. The research based pharmaceutical industry is primarily dependant on patent protection as it is the profits gained from the exclusive monopoly provided to them in the later stages that helps them recover their R&D costs and also acts as an incentive to further research for new cures. Patent protection encourages researchers to take risks in developing new drugs and an exclusive market monopoly provides them with enough time to recover their investments educate and train medical professionals about the benefits and proper use of the new treatment options[1] Thus it can be said that patent protection strikes the right balance between public welfare as well as promotion of further R&D by keeping in mind the investors commercial interests.

It creates a secure environment for further research and investment by pharmaceutical companies which find a credible market to supply their drugs. Furthermore, patent protection also helps bridge the divide between developed and developing countries as licensees from developing countries can manufacture the same quality drugs and may also boost its exports in the long run.

Dr. Rapp and Dr. Rozek in their study ‘benefits and cost of Intellectual property protection in developing countries’ , prove that

economic growth fuelled by patent pro- tection is not an uncommon phenomenon and that most of the developed countries that went through economic development, export growth and diffusion of new technologies during the industrial revolution, have Intellectual property protection to credit it for.

Moreover, patent protection helps local inventors to commercialise their inven- tions and prevents them from going elsewhere to do their research or protect their inno- vation as a trade secret. This results in better access to the latest developments in the pharmaceutical sector leading to improved quality and access to healthcare.

Compulsory license is a license issued by the government of a country where in it allows someone to produce certain patented products/process without the consent of the patent owner. The patentee is compensated with a nominal amount but is not allowed to make profits on the same considering he still has rights over the product/process. This compensation however is in no way equal to the commercial benefits that the patent holder or company would have been getting otherwise. Compulsory license is therefore an interference in the exclusive rights of the patentee of the invention. It emerged as a concept keeping in view public welfare and the idea that the interest of the society is more important vis a vis the commercial benefits that the patent holder would get out of the invention.

Various treaties and agreements in the past have been signed with a view to en- force provisions of compulsory licensing, with a disclaimer that they may be used spar- ingly and only under conditions which demand public welfare be given due importance over commercial rights or where there are signs of abuse of patent rights.

The Paris Convention for the Protection of Industrial Property held in 1883 in Paris, France passed an internationally binding provision to “grant compulsory licenses to prevent abuses which might result from the exercise of exclusive rights conferred by the patent”. This can however only be done after 4 years of applying of the patent or

3 years form the date on which the patent was granted. [2] This time frame allows the in- vesting companies to reap enough commercial benefits providing them an exclusive monopoly, so it doesn't discourage them from investing in further R&D. The Paris Con- vention mentions only two conditions under which a CL might be issued namely abuse of patent rights and failure to work. Abuse of patents is a term all pervasive in nature.

Further in 1994, the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement for the first time amalgamated Intellectual Property Rights with the International trading system. Article 7 states that protection of intellectual property rights should be for the purpose of promoting innovation "in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[3] Keeping this in mind, Article 31 confers the right on all members of the World Trade Organisation to issue compulsory licenses. Interestingly, however, TRIPS does not mention the term Compul- sory license but instead refers to it as 'Other use of patents without authorisation of the rights holder. Article 31 as conferred by WTO is : [4]
Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

a) authorization of such use shall be considered on its individual merits;

b) b 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 rea- sonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-

commercial use. In situations of national emergency or other circum- stances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

c) the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

d) such use shall be non-exclusive;

e) such use shall be non-assignable, except with that part of the enterprise or good-
will which enjoys such use;

f) any such use shall be authorised predominantly for the supply of the domestic
market of the Member authorising such use;

g) authorization for such use shall be liable, subject to adequate protection of the
legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The compe- tent authority shall have the authority to review, upon motivated request, the con- tinued existence of these circumstances;

h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competi- tive practices may be taken into account in determining the amount of remunera- tion in such cases. Competent authorities shall have the authority to refuse termi-nation of authorization if and when the conditions which led to such authorization are likely to recur;

l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

. i) the invention claimed in the second patent shall involve an important tech- nical advance of considerable economic significance in relation to the in- vention claimed in the first patent;

. ii) the owner of the first patent shall be entitled to a cross-licence on reason- able terms to use the invention claimed in the second patent; and

. iii) the use authorized in respect of the first patent shall be non-assignable ex- cept with the assignment of the second patent.

This was followed by the Doha declaration on the TRIPS agreement and public health in 2001, On the issue of compulsory licensing, the declaration makes it clear that each member is free to determine the grounds upon which the licences are granted, this may include any public health crisis.

The only inviolable patent is that of life itself..

-Saraiva Felipe
Minister of health, Brazil[4a]

These provisions so distinctly mentioned in the above treaties were brought to use for the first time by Malaysia in 2004 where the government issued the world's first compulsory license allowing a local firm to import patented anti-HIV/AIDS drugs from an Indian generic company under fixed prices. This government use authorisation was given by the Ministry of Health, Malaysia for a period of two months where during which people benefitting from the price relaxation by using alternative generic drugs doubled. This step however caused an environment of insecurity and uncertainty with the pharmaceutical companies despite the Ministry of Health offering 4% share of royalties to the patent holders which was turned down by them.[4b]

Thirteen years later, Malaysia is again the latest country to have issued a compulsory license for generic Sofusbuvir which is a groundbreaking medicine for Hepatitis C Nearly 2.5% of the

Malaysian population are estimated to be living with Hepatitis C. Inspite of the patent holder being pharmaceutical giant Gilead which issued a voluntary license to 4 developing countries including Malaysia, not many benefits could be reaped by the Malaysian population as the cost cutting did not make the drug cheap and accessible enough to the affected populace. Malaysia therefore issued a compulsory license on the same which again doubled the number of people benefitting from the drug as compared to earlier.

OVERVIEW OF PHARMACEUTICAL SECTOR IN INDIA AND GERMANY

The global pharmaceutical industry is characterised by global market dominance and by an oligopolistic core of R&D based pharmaceutical companies. This being said there are still variations in terms of level of innovation, size as well as the orientation of the company. The industry started after the first world war with inventions of drugs such as insulin in the 1920's, penicillin in 1928 and sulphonamides in the 1930's which were produced mostly for treatment of those injured during war, the massive success of the same encouraged many scientists and investors to further the cause of access to medicines and healthcare and reap economic benefits in the course of it. **[6]** It was due to this initiative that the tetracycline group of antibiotics was developed which were among the first group of drugs to be patented and were in use until recently. Thus since 1950's the pharmaceutical sector has been flourishing with sup- port of a strong patent regime which further encourages R&D for cures of other dis- eases.Treaties such as the Uruguay round which took place as a part of GATT in order to protect patents and regulate trade in medicines in the developed and develop- ing countries. These agreements were clearly in favour of advanced economies as they held a clear monopoly of production rights which gave them stronger negotiating power over the issue. Closer home the statements of members of parliament and other prominent citizens on negotiations in the Uruguay round of GATT and Special

301 of the USA was reflective of the concerns of most developing countries who could foresee the pressure that they would potentially be facing for subjugation of their economic interests to those of the developed nations. The Uruguay round was dominated by the developed market economy nations because of which the indian leaders feared that the GATT framework will make fully legal the coercive bilateral method of economic domination. [7] The economy could be facing several setbacks at the hands of foreign monopolies and their powerful multinational corporations which would get entrenched in both production and trade of our country. They further resolved to not agree on dilution of the provisions of working of the patents in licensing of right and compulsory licensing and the extension of the period of patent to 12 to 15 years as against 5 to 7 years. The compulsory licenses issued however often prove to be against the interests of the pharmaceutical companies most of which be- long to advanced nations. This affects the R&D for those diseases that are specific to the developing world such as TB, Malaria, respiratory infections, diarrhoea etc which are also a major cause of concern in India. In addition to infectious diseases, people in developing countries contract many more familiar and equally untreated diseases, including diabetes, asthma, heart disease, cancer, and mental illness. For these dis- eases, there are a wider array of on-patent medicines, including anti-diabetics, beta-blockers, oncology drugs, and psychiatric drugs, all of which are critically important to the physical and mental health of poor people in developing countries and all of which are priced well beyond affordability.[8]

The exclusive market dominance granted to the patented drug makers has resulted in highly inflated prices even for life saving drugs.This has led to creation of strong generic drug industries in many countries manufacturing off patented versions. It is an alternative solution, pursued by developing countries and treatment activists internationally. The promotion of efficient generic production by a sufficient number of manufacturers will increase access to medicines at much lower costs. This has not only increased competition but also forced the pharmaceutical companies to improve the quality, price and access to their products.

India is one of the major developing economies to have taken advantage of the situation as a result of which it is one of the leading producers of generic medicines in the world. Indian pharmaceutical sector accounts for 2.4 per cent of the global pharmaceutical industry in terms of value and 10 per cent in volume terms. The cost of production of drugs in India is nearly 33% lower than USA and 26% lower than that of Germany. Labour costs are 50–55 per cent cheaper than in Western countries. The cost of setting up a production plant in India is 40 per cent lower than in Western countries. [9] All this enables India to have a strong presence in emerging markets like Africa where people cannot afford expensive drugs. This also boosts exports with the advanced nations where Indian generics give a tough competition to the patented drugs owned by domestic pharmaceutical companies. To add to the credibility that is often lacking in case of generics exported by developing countries, India has over 546 USFDA-approved manufacturing sites which is the highest number outside the US. Some Indian pharmaceutical companies namely Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs have also been backed by the UN's medicine patent pool where in six sub licenses have been signed allowing them to make generic anti-AIDS medicine TenofovirAlafenamide (TAF) for 112 developing countries. The strong institutional support in the form of government policies such as the Central Drugs Standards Control Organisation (CDSCO) which is working towards drafting a new Drugs & Cosmetics Act, 2016 and the Medical Devices Act, 2016 aims to match up with the current regulatory requirements related to safety, efficacy, quality of drugs and medical devices. The Union Cabinet has given its nod for the amendment of the current Foreign Direct Investment (FDI) policy in the pharmaceutical sector so as to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions. The Government of India also unveiled 'Pharma Vision 2020' with a view to make India a global leader in end- to-end drug manufacturing.

Germany on the other hand has a historical reputation as the 'world's pharmacy' with its domestic pharmaceutical industry consisting of companies such as Bayer, BASF and Hoechst. It is

home to Europe's largest and the world's fourth largest pharmaceuticals market, it has established itself through investing in extensive R&D and invention of rewarding innovations of new drugs. In 2015, the European Patent Office received 1,183 patent applications in the field of biotechnology and pharmaceuticals from Germany – only US companies had a higher application rate. At the same time Germany also successfully maintained a stable market for generics. The volume share of generic drugs in Germany is much higher as compared to other parts of Europe, having reached 77 percent in 2015 with a value of more than EUR 2 billion.[10] This however is no match to the generic industry of countries like India which is the today the world's largest provider of generic medicines; the country's generic drugs account for 20 per cent of global generic drug exports in volume terms. What such countries do lack is sufficient R&D for innovation of new medicines which is also the primary reason for the success of German pharmaceutical industries. In 2014, German pharmaceutical companies spent a record EUR 6 billion in R&D[10].Germany's regional initiatives for the advancement of modern life sciences in the form of "Bio-Regions," or 'Bio-parks' play an imperative role in maintaining a stable and innovation-friendly environment. Over the past three decades, these biotechnology clusters have developed into some of Europe's leading R&D hubs. Each region specialises in specific areas and facilitates collaboration between universities, R&D institutes and private sector companies.[10]

Countries like India need to follow suit to ensure a healthy growth rate in the sector. Recognising this challenge, Indian pharmaceutical giants have raised their expenditure on R&D which is likely to increase further due to the introduction of product patents as companies need to develop new drugs to boost sales. In 2017 the highest expenditure on research and development has been done by Sun Pharma, followed by Lupin. This investment in R&D is further being supported by the Government which has invited multi-billion dollar investment with 50 per cent public funding through its public private partnership program (PPP). All these initiatives are positive steps towards creating a larger space for innovative reform

in the Indian pharmaceutical sector along with a stronger patent regime.

COMPULSORY LICENSES ISSUED AND RELATED COURT RULINGS IN INDIA AND GERMANY

The Indian patents act, 1970 allows for grant of CL under sections 84 and 92 of

chapter XVI. As per section 84[1] :

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—
(a) that the reasonable requirements of the public with respect to the patented inven- tion have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably afford- able price, or
(c) that the patented invention is not worked in the territory of India.

The power of granting CL resides with the Controller of Patents (Section 88) and with the Central government (Section 92). An application under section 84(2) can be made by any person even if he is already a license holder. No person can be estopped from pointing out the short comings of the patented product as mentioned under section 84(1). The controller takes into account facts such as nature of invention, ability of the applicant to work the invention for public good, the risk taking capacity of the applicant for providing capital and working the invention and whether the applicant has made ef- forts in the past to get a voluntary license from the patentee on reasonable terms and conditions. This clause however shall not be applicable in cases of national emergency and

or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee. [11]

Section 92 of chapter XVI states that Compulsory licenses can be issued suo motto by the controller of patents following a notification issued by the Central Government incase of (i) a circumstance of national emergency; or (ii) a circumstance of extreme urgency; or (iii) a case of public non-commercial use.

Section 92A covers Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances such as exporting a patented pharmaceutical prod- uct including ingredients necessary for their manufacturing {section 92(A)(3)} to any country lacking or having insufficient manufacturing capacity in the pharmaceutical sec- tor for the concerned product to address public health problems provided compulsory licence has been granted by such country or such country has, by notification or other- wise, allowed importation of the patented pharmaceutical products from India. [11]

The mechanism under this provision is set in motion by the Central Government by a notification in the Official Gazette that extra-ordinary circumstances have dictated the grant of compulsory licences in relation to patents which help to address the exigency. [12]

India granted its first ever compulsory license to Natco, an indian generic company against Nexavar chemically known as ‘Sorafenib Tosylate’, patented by German pharma giant Bayer corporation. This drug is used for the treatment of advanced stage liver and renal cancer. In a judgment delivered on March 9, 2012, the Controller General of Patents granted the license to Natco, against which Bayer appealed to the IPAB. Mean- while, Bayer pleaded for a stay on the Controller’s decision but this was denied by the IPAB. [13] This was primarily because the principle of *audi alterem partem* would only come into play once the court has *prima facie* determined that a compulsory license would be issued.[14] The IPAB largely gave the same judgement but in addition to the

Controller General's observations, it viewed the case from a public health perspective under the context of the Right to Life, Article 21 of the constitution and further noted the major issues based on the three-pronged test laid out in section 84(1) of the Act.[15] Section 84(1)(a) which states that the reasonable requirements of the public shall be deemed not to have been satisfied was fulfilled as it was recorded that only 2% of the patients had access to the medicine[16]; While Bayer sold a month's dosage for for 2.8 lakh rupees, Natco offered to sell the same for around Rs. 9000 per month enabling ac- cess and affordability beyond just the rich class of the India [17] thus fulfilling 84(1)(b) i.e. the patented invention is not available to the public at a reasonably affordable price, 84(1)(c) i.e. the patented invention is not worked in the territory of India was also ful- filled on the pretext of the mere importation of drug into India as the Controller refused to accept Bayer's plea of non feasibility of manufacturing the drug in India.[16] The IPAB also considered Natco's request for voluntary license from Bayer under reasonable con- siderations making the scales tip even further in the favour of Natco. Thus the threat of a potential compulsory license can make pharma giants come to the talking table increas- ing the chances of the grant of a voluntary license in favour of the compulsory license applicants. However to meet the ends of justice IPAB increased the royalty rate payable by Natco to Bayer by 1% making it 7% of all sales on a quarterly basis in accordance with the guidelines set by the United Nations Development Programme (UNDP).

The successful grant of CL to Natco against Bayer's Nexavar gave a new hope to many others who wished to benefit from compulsory licensing and sell patented products in a cost effective manner making them more accessible to the general public. Lee pharma, a Hyderabad based Indian company filed for a CL application for selling and manufacturing the patented drug Sexagliptin registered under the name of AstraZeneca with title as a cyclopropyl fused pyrrolidine based compound which they branded as Onglyza [18]

This drug was used for treating type II diabetes mellitus. Lee filed the application on June 29, 2015 at the Patent office in Mumbai on a number of grounds. The main arguments put forth by them was

that the reasonable requirements of the public were not satisfied, the patented invention is not available to the public at a reasonably affordable price and that the patented invention is not worked in India {section 84(1)} In 2014, AstraZeneca had been approached by Lee Pharma for grant of voluntary license on the grounds of inadequate availability of drugs. The request was not approved by Astra- Zeneca and a clarification along with details of distribution of the drug were sent to Lee Pharma. Lee pharma accused AstraZeneca of catering only for a mere 0.23% of the market demand.However. they arrived at this figure on the basis of a series of estimates stating that there are virtually 60 million diabetes type II patients, and that 'even if' only 1 million out of the 60 million were to be prescribed Saxagliptin, 823,855 units falls far short of the required amount. It is important to note however their failure to describe the reasons as to why Saxagliptin is 'required' for this 1 million.[20] The controller also noted the availability of equally effective DPP- inhibiters as alternatives to sexagliptin such as linagliptin, sitagliptin and vildagliptin. This undermined the argument given by Lee Pharma regarding reasonable requirements of public not being met due to short comings in sexagliptin's demand supply ratio[21] and thus it was inferred that it was impossible for Lee to make assumptions about the demand for Saxagliptin without accounting for these substitutes. [22] Lee Pharma's second argument of the drug not being affordable by the public at large was not substantiated by them providing a cheaper alternative. Lee Pharma's version was only Rs. 9 per tablet (approx.) cheaper than what AstraZenca was selling at the time. Thus, the controller did not find the accusation to be a valid one as the difference was only marginal.[22] In the third argument given by Lee, The controller cited the Bayer case which stated that 'the local working does not entail local manufacturing in all cases'.[23] If the patentee possesses the necessary infrastructure for production in India, then it must justify its reasons for not manufacturing the product locally. Further more, Lee did not present any data concerning AstraZeneca's local manufacturing capability due to which the Controller refused to accept that a *prima facie* case under this provision has been made out. The final judgment was ruled in favour of AstraZeneca with the patent authority calling out the

assumptions made by Lee Pharmaceuticals pvt. ltd. in the absence of authentic data or statistics and that assumptions cannot form the basis to prove that the reasonable requirements of the public with respect to the patent- ed drugs.[24] Hence, to date, India has granted only one compulsory license against Bayer's Nexavar to Natco Pharma.

In Germany, the concept of compulsory license has been covered under section 24 of the German patent act: [25]

(1) The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where
1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and

2. the public interest calls for the grant of a compulsory licence.
(2) Where a licence seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if 1. the condition under subsection (1) no. 1 is fulfilled, and
2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date.
The proprietor of the patent can require the licence seeker to grant him a cross-licence on reasonable terms and conditions for the use of the patented invention with the later filing or priority date.
In Germany, a Compulsory license can only be granted if public interest calls for it. The term ‘public interest’ however hasn't been explained in the the German Patent Act and so any case involving the above contention has to be determined based on its individual facts, circumstances and as well as that of affected parties, primarily the public. Hence, issuing a CL is not an easy decision as

the grounds for determination of public interest being involved is based on subjectivity. Many attempts for the same have been made in the past however the only one which came close to completion was a provisional Compulsory license issued back in 1991 for Interferon-gamma/Polyferon by the Federal Patent Court (FPC, *Bundespatentgericht*) but its decision did not survive appeal to the Federal Court of Justice (FCJ, *Bundesgerichtshof* which is the equivalent of the Supreme Court of India).

Germany in its first issued a compulsory license in the recent case of a patented HIV drug called raltegravir marketed under the trade mark Isentress. According to the established German jurisprudence, the applicant for a CL must show public interest and prove that:[26]

(a) shortage of the respective drug exists in Germany, or

(b) ThedrugforwhichCLissoughthas:

(i) enhanced therapeutic efficiency,

(ii) lesser side effects as compared to the other drugs available in the market for the same disease,

(iii) no alternatives of the same quality.

In the case of Merc Sharpe and Dohme (MSD) V. Shionogi & co.limited, Shionogi, a Ja- panese Company brought a patent infringement lawsuit against MSD before the Re- gional Court of Düsseldorf (Docket No.: 4c O 48/15) in August 2015.[26] The case was filed for infringement by MSD's Raltegravir which is an anti-HIV therapy and is used to treat HIV-1 (the most common type). It is a 'first in class' drug, being the first antiretrovi- ral integrase inhibitor to be sold in Europe and has also been approved by the US FDA in 2007. Integrase is an enzyme found in retroviruses. It is essential for integration of the viral DNA into the host cell DNA. Integrase inhibitors target the viral integrase and interfere with integration of HIV DNA into the DNA of the infected cell. [27] Shionogi offered to settle the

dispute by granting MSD a license on the basis of a one time payment for the past sales along with a royalty for all future dealings. A counter offer was then made by MSD of a one-time payment of an amount of 10 million USD for obtaining a worldwide license, but this was not accepted by Shionogi. [28] It filed a suit for

patent infringement in Germany and the UK to which MSD brought an action for issuance of a Compulsory license before the Federal Patent Court in January 2016. An interim compulsory license was granted in Germany by the FPC and that too in the preliminary proceedings. This decision went in appeal by Shionogi to the Federal Court of Justice where it was upheld based on the presence of a public interest clause as there was a significant medical need among certain HIV-infected and/or AIDS patients for Isentress, and that these patients could not resort to other currently available integrase inhibitors without severe health risks. This was in particular true for pregnant women, infants and long-time HIV patients thus making this the first CL to be granted since the inception of the Federal Patent court of Ger- many. [29]

The topic of granting patent protection to pharmaceuticals, especially life saving drugs, has always been a debated one. The fundamental tussle between profit driven drug companies and the welfare oriented governments seeking to ensure greater affordability of essential medicines has frequently occupied the global centre stage[30] Inspite of the numerous agreements signed and rounds held, the concept of Compulsory licensing has still not become a word comfortably coined in the courtrooms of the legal world. The practice still continues to be denounced by Pharma companies all over the world as a tool for infringing upon patent rights. Article 7 of the TRIPS specifically provides that one of its objectives is to ensure that information sharing can help both manufacturers and consumers, this however is proving to be a slow process considering the ever increasing capitalisation of economies.[31] Thus, a balance needs to be struck between the two competing claims. The classic rationale for allowing compulsory licensing is that public welfare and particularly health in the immediate sense outweighs the long-term objective of encouraging innovation.[32] This does not mean completely slashing the prices of the profit making drugs but it does place innovation at a lower priority as compared to public health when the circumstances so warrant. This view however is strongly opposed by pharmaceutical companies backed by most developed nations.

Thus, path breaking decisions such as Natco V. Bayer and Merc. V. Shionogi give a new hope to arrive at a common ground as they prove that the developing and advanced na- tions alike may require the tool of compulsory licensing as and when the question of welfare arises. Such decisions can also have long term positive effects by creating a healthier market environment in which all stake holders will be put in advantageous positions. This will happen as a result of increase in grants of voluntary licenses on behalf of pharmaceutical companies in order to avoid government intervention thereby leading to increased efficiency and reduction of the gestation period for affordable access to essential medicines. At the same time, pharmaceutical companies will be able to dictate their own terms to a larger extent, thereby retaining some control over the process.[33]

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