COMPULSORY LICENSING

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INTRODUCTION

In India, the legislation on Compulsory Licensing is limited due to a lack of precedent. While parallels to TRIPS and the Paris agreement can draw inferences about the law's implications, this essay only analyses the impact of the judicial opinion of the Indian courts, analysing the factual scenario and the standards for consideration, which indicate a propensity toward public welfare, but sufficient safeguards to prevent abuse of the law.

WHAT IS COMPULSORY LICENSING?

An agreement between a willing applicant and an unwilling patent holder for the licence to produce and sell the patented product, if the following conditions are met: I the reasonable needs of the product for the public are not being fulfilled; (ii) the patented product is not fairly priced by the public; and (iii) the product is not being worked in India[1]. This is akin to an exemption to the protection granted by intellectual property rights, in which a patentee's rights may be disclosed to a third party without their approval.

Bayer Corporation (Bayer) v. Natco Pharmaceuticals Ltd. (Natco)[2] is the first case in India to issue a compulsory licence. Natco, an Indian generic pharmaceutical business, has asked for a compulsory licence for Sorafenib, also known as Nexavar, a cancer medicine invented, owned, and manufactured by Bayer. Natco was awarded a forced licence to manufacture the medicine due to Bayer's alleged incapacity to make the drug accessible and inexpensive to the public. In addition to procedural concerns, the ruling addressed the following reasonings.

Accessibility for the public - Without mentioning pricing, the tribunal analysed the number of Bayer's deliveries. While it was estimated that over 23,000 people need the treatment, Bayer argued that only 8,800 individuals in stage IV of cancer required the medication. In either event, the supplies served a relatively tiny percentage of the population, since just 200 bottles were imported in 2008 and 593 bottles were imported in 2011, with no explanation as to why there

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[1] Section 84, The Patents Act, 1970.
[2] Judgement by Intellectual Property Appellate Board, Chennai [MIPR 2013 (2) 97]

was no supply between 2008 and 2011. This indicates that Bayer made no attempt to make the medication fairly available to the public, even if consumers could afford or want to purchase the drug. Bayer countered that CIPLA's manufacturing of the allegedly infringing medicine was a means of compensating for shortages and making the drug accessible.

Importance of Cipla's presence - Bayer argued that the availability of the drug to the public cannot be judged solely by the statistics of its insignificant imports, because a significant portion of the public was being served by the allegedly infringed drug of CIPLA. This argument was based on the fact that a large part of the public was being served by the drug. An uncertain supply by an accused infringer has the possibility of being injuncted at any moment, which is why the decision said that it should not be regarded since Bayer cannot benefit from the sales that are being conducted by CIPLA. Also, between 2008 and 2010, Bayer's supply was very low, almost non-existent—even before CIPLA began manufacturing in 2010. This was the case even before CIPLA began its operations in 2010. In the Lee Pharma Case, the position on how the availability of a different drug on the market can affect the consideration for reasonable accessibility is viewed differently. In this case, the existence of alternatives of any kind is inferred as the availability of options to the general public. This is despite the fact that the factor of an alleged infringement is not taken into account.

Unreasonable pricing - Nexavar was priced exorbitantly at INR 2,80,000 a week, allegedly in violation of monopoly rights. It cannot be deemed inexpensive for any reasonable patient, even when viewed objectively and ignoring the small number of patients who use the medicine. Bayer stated that "fair pricing" should involve both the customer and the manufacturer, as it must include a reward for innovation and R&D expenditures. However, the Controller noted that Bayer might have utilised differential pricing to make the medicine cheaper for various segments of society, and rejected all of Bayer's arguments despite utter silence on how to decide a suitable price or what an acceptable price would be in this instance. However, Natco's weekly price for the medicine was just INR 10,000, which was fairly accessible for the majority of patients. Though the court did not make a direct connection between the reasonable pricing of the product and its accessibility to the public, the demand-supply principle in economic terms has a correlation between these two factors for determining what any reasonable and accessible price could be, and any judicial determination should consider the interrelationship between these economic considerations.

To be worked in India - A lack of clarity exists on the need that the patent not be "worked in India." Contrary to Bayer's reasoning, importation was not deemed adequate for use in India. In order to avoid being required to get a licence, the current case establishes a stringent and restricted threshold requiring production to occur in India. For corporations that outsource manufacture, or for items that need just assembly in India, or are only accessible on a territorial basis, this criteria is ambiguous and subject to future court interpretations.

THE IMPORTANCE OF PRE-REQUISITES BEFORE APPLYING FOR CL

Before applying for a compulsory licence under the Act, the following requirements must be met:

- three years must have passed after the award of the patent;
- the applicant must endeavour to acquire a voluntary licence from the patentee on acceptable conditions.

However, the nature of the patent and its existence is taken into account; similarly, from a socialist viewpoint, such a time period is deemed long enough to allow for the exploitation of the public, after which the advantages must be distributed. Such a finding demonstrates the socialist objective of this clause, as well as the public interest orientation of this law.

If not judicially investigated, the necessity to seek to get a voluntary licence may be nothing more than a disguised formality. As they have in the past, the courts should be wary of the reasonableness of proposed conditions for the voluntary licence. As a business decision, any applicant seeking a compulsory licence would never settle for a proposal that is acceptable to the patentee, or would use the possibility of a compulsory licence as leverage to obtain a better deal; as in the Natco case, where the request for a voluntary licence appeared to be a veiled threat, based on the tone of the letter. The limited jurisprudence leads us to think that the request for a voluntary licence, prior to filing for a mandatory licence, is not only a formality but rather has a threshold for reasonableness that must be reached, in order to prevent the exploitation of this provision.

PRECEDENCE IN THE MAKING

After the IPAB's decision to award Natco a compulsory licence, the floodgates were expected to open, much to the pleasure of generic medicine makers eager to capitalise on the efforts and

costs of patent breakthroughs and much to the chagrin of market leaders. However, unexpectedly, no more mandatory licences have been issued in recent years.

In Roche v. Emcure Pharmaceuticals, the Department of Industrial Policy and Promotion (DIPP) refused the Ministry of Health permission to apply for a licence for the medicine 'Herceptin' in the event of a national emergency, dismissing the presence of an emergency-like circumstance.

Similarly, in BDR Pharma v. Bristol-Myers Squibb, the authorities dismissed the existence of a prima facie case for the issuance of a compulsory licence since the need to make reasonable attempts to secure a voluntary licence was not reached. Recently, in Lee Pharma v. Astra Zeneca, the patented medication had already been licenced to BMS operations in India when Lee Pharma complained that the drug was overpriced and inaccessible to the general people. In addition, the medications were imported, and Astra Zeneca was accused of not making the necessary steps to produce the drug in India. However, the Controller declined the award of obligatory licence on the grounds that Lee Pharma lacked empirical proof of the number of patients in need of this medication and those who were unable to acquire it due to its high cost.

Similar to the Natco instance, an objective appraisal of the availability based on a statistical survey has been deemed crucial. The applicant failed to demonstrate the relative demand for this medication and the absolute need for it in the absence of alternatives. The applicant's claim of the excessive cost was insufficient to demonstrate that the medicine was inaccessible to the general population.

In addition, unlike in the Natco case, the medicine was packed and labelled in India, which was deemed sufficient to meet the definition of "being worked" in India. Therefore, a stringent standard for the requirements for obligatory licencing, supported by the most objective analysis, implies that the law is not easily manipulated, and there is no danger to market leaders from tiny companies living parasitically off their invention.

CONCLUSION

Initially, Bayer's patented product should not be manufactured by a third party. However, this protection is compromised due to concerns of public interest, accessibility, and cost. While there may be arguments regarding the inhibition of innovation or the disincentivising of FDI as a result of compulsory licencing, the cost-benefit analysis of making essential drugs

available, subject to safeguards against the abuse of this law, indicates that such legally infused social responsibility is always advantageous in a welfare state like India. In a capitalist market, where the preservation of profit-making abilities and the recovery of expenses and earnings for inventors are crucial factors, compulsory licencing produces an anomaly where 'public interest' is prioritised. This clause of the legislation implicitly endorses a socialist approach to protecting the health and safety of the people against exploitation.