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Compulsory Licensing of Patented Drugs

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Recent developments at the US International Trade Commission have triggered renewed interest in the Indian Patent Regime. Most patent cases (in the Court or at the Patent Offices) that have so far dealt with the much-debated Section 3(d) of the Indian Patent Act (2005), in terms of patents not awarded or revoked, if analyzed in detail, are based purely on the merits of patentability and substantiated by well-grounded arguments. While refusal of a patent or revoking of it has never gone too well with leading pharmaceutical companies, the more recent entrant to the debate is "Compulsory License" (CL). Simply put, CL is a legal mechanism wherein a patented invention is used without a license or permission from the patentee and the permission is granted by the Government. It is pertinent to note that CL is not a section unique to India alone. Secondly, India is not the sole practitioner of this provision. Interestingly, according to Knowledge Ecology International (KEI), "US leads the world in use of Compulsory licenses" than any other country in the last 4-5 decades. And thirdly CL is well within the framework of Trade Related Intellectual Property (TRIPS) and particularly dealt with in Article 31.

While TRIPS allows some level of tweaking to suit a country's policies and practices, in case of CL, the provision is largely untouched by the Indian Patent Act (Sections 84-94). While the law is established as per the sections, the actual practice throws in complex layers and ambiguities worth discussing especially in view of Natco's CL for Nexavar (an anticancer drug marketed by Bayer) granted in March 2012 (India's first since the new patent regime of 2005).

A brief understanding of TRIPS' stance on CL may be a useful exercise. Firstly, TRIPS offers that CL can be invoked in situations of national or extreme emergency or for public non-commercial use; for the latter, with a caveat that, the negotiations with the patent holder have yielded no positive results. TRIPS, however, is silent on the conditions under which an application for CL can be triggered. This probably is an intentional freedom bestowed on the country to device a regional framework to encompass the domestic requirements. The Doha Declaration has in fact suggested that the member countries have 'the freedom to determine the grounds upon which such (compulsory) licenses are granted'.

Availability and affordability have been primary reasons for importation of HIV drugs to Africa by Cipla in 2001. Similarly, HIV drug TriAvir was imported to Rwanda in 2007 by Apotex under CL. While availability and affordability are common concerns in developing countries, afore mentioned cases however were routed through WTO safeguards that are slightly different mechanisms as against Nexavar case and thus cannot be directly compared with the Indian case. These, however, are glaring examples that a country can decide to issue CL based on lack of public availability or affordability.

In India, lack of reach to essential medicines for common man due to affordability is correlated with lack of public availability; CL for Nexavar was largely issued on this basis (Sec. 84 of Indian Patent Act) where NATCO was to make the drug available to public for about Rs 8,800 per month as against a pricing of Rs 2, 80, 000 per month offered by the patentee. Price control has always been a concern all over the world, irrespective of developed or developing nations. Not too long ago, in 2001, Bayer was forced to bring down the price of Cipro in the US by about 50 percent to avert issuance of CL. Thus, contrary to widespread speculation, it is not a scenario unique to India alone and thus should be viewed as an important aspect that may

trigger issuance of CL. Moreover, the drug not being manufactured in India by the patentee clearly limited its availability as per Sec. 84 which states, "...the reasonable requirements of the public with respect to the patented invention have not been satisfied...", thus rendering strong support for grant of CL.

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Another point of interest is whether a patentee gets a chance to present his view point in response to CL applications. A thorough analysis of Natco's CL for Nexavar reveals that the controller had presented an opportunity for the patentee to be heard despite the Act (Indian Patent Act, 2005) not explicitly having such provisions. It can, however be contended that common law always accommodates the doctrine of "audi alteram partem" (in legal language meaning "hear the other side too") and by giving an opportunity for the defendant (the patentee in this case) to be heard during the course of review of the application, the Controller had wisely followed the rule of law.
Yet another keenly contested argument is whether CL hampers innovation as the commercial incentive for the pharmaceutical company (developing the drug) is believed to be threatened. A well-researched paper from Chien (Berkeley Technology Law Journal, 1-56, 2003)
where in the rate of innovation in a therapeutic area versus patent counts before and after issuance of CL has busted any such myth. Herein, the author observes no measurable decline in R&D efforts of the companies (patent holders) as a result of CL. The study cohort comprises US pharmaceutical companies, which one would believe, are profoundly affected in terms of commercials. In sharp contrast, India may not even be the primary market for the drugs where CL have been issued or deliberated so far, thus again questioning whether the commercial benefits are in reality marred to the extent that the patentee will terminate the R&D activity.

CL has been a controversial subject matter in almost every country since its passage as a law. Granting CL for Nexavar raised serious concerns around the world that India may just use it as a tool to foster homegrown generic companies. All eyes were on India with regard to the second CL application for Dasatinib, an anticancer drug from Bristol Myers Squibb (BMS). In a neatly deliberated case (Oct 2013), the Controller has rejected the application by BDR pharmaceuticals on the ground that the applicant failed to sufficiently negotiate with the patentee prior to filing for a CL. As referred above, it is essential that there is prima facie evidence that the applicant has negotiated with the patentee before approaching the Government for grant of CL. It is observed that BDR initiated the process of dialogue but left it incomplete by failing to answer the queries raised by BMS, the patentee. Thus, the very premise of CL application was challenged. In the wake of this rejection, there certainly must be a sense of relief among many who believed that Nexavar (CL) would open a floodgate thwarting many patented drugs.

Every country with a mature patent law has evolved through years of practice and changing policies and above all the number of cases that have been deliberated have facilitated the understanding of the various interpretations of the law. India is still nascent when it comes to IP policies and practices and has as yet experienced minimal litigations. With passage of time, there will be learnings and CL is not an exception.

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