

Policy Shift On Compulsory Licensing?

It seems preposterous to suggest that government can undo a set mechanism and policy on Compulsory Licensing that is part of Patent legislation through a statement to the business delegation

Compulsory licensing provisions under the Indian Patent Act have made research companies uncomfortable. They are now being viewed with suspicion by Indian generics, after the alleged news of Indian Government offering private assurance to US Trade Representative that it will not invoke compulsory licenses anymore (save for public non-commercial use). As the news started to be covered in legal and mainstream media with indication that there is a shift in government policy on grant of compulsory license, the government, in a dramatic development, decided to issue a clarification. The government, through Department of Industrial Policy and Promotion (DIPP), clarified in its statement, "There have been recent media

reports that the Government of India has privately assured that it will not issue any more compulsory license. It is hereby clarified that such reports are factually incorrect. In this regard, it may be noted that India has a well-established TRIPS compliant legislative, administrative and judicial framework to safeguard IPRs. Under the Doha Declaration on the TRIPS Agreement Public Health, each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

Even as the Government of India is conscious of the need to spur innovation and protect individual rights, it retains the sovereign right to utilize the flexibilities provided in





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the international IPR regime. It may be noted that till date, there has been only one case of compulsory license in India and that too after a well-thought out and laid down process, which was subsequently upheld right up to the highest Court of the land.”

Why Compulsory License

The Compulsory licensing provisions are part of most of the countries' Patent law. It is widely accepted as an intervention mechanism, through which, the Government balances the rights of the patent holder with its obligations to ensure proper and reasonable working of patents along with imparting protection of public health and nutrition (through section 92 and 92A of the Indian Patent Act). In the context of access to medicines, compulsory licensing is stated to act as effective safeguard after the grant of patent particularly the compulsory licensing provisions arguably attempts to prevent monopolies and assure access to new medicines that are important to public health.

Compulsory License Cases

So far, there have been three applications filed for grant of compulsory license and all in the pharmaceutical sector. Looking at the background of the three applications for grant of Compulsory License, there has been only one case where the license was granted to the applicant, while the other 2 applications were rejected.

1. The first was brought by Natco against Bayer seeking permission to produce Nexavar (“SorafenibTosylate”). Bayer's admission that only 2% of kidney and liver cancer patients were able to access the drug and that the drug was imported and not manufactured within India went against it and the controller looking up the facts concluded that the Patentee did not meet public requirements and accordingly, the application for seeking Compulsory license was allowed. Bayer approached IPAB and High Court

against the decision of the Controller General of Patents, but didn't get a favorable order. IPAB stated “It is only because of public interest, we are not interfering in this appeal on this ground”. The high court said it saw no reason to interfere with the findings of the authorities under the Act. The appeals were dismissed up to the Supreme Court. The Supreme Court also upheld the decision of Controller and upheld the grounds for which Compulsory license was issued.

This decision was thought to be a precedent for further compulsory licensing application, however, to the contrary, the other 2 applications were rejected.

2. In the second case, the application for compulsory license was rejected when BDR Pharmaceuticals filed an application to make a generic version of Dasatinib, an anti-cancer drug, on which Bristol-Myers Squibb owned a patent. Here, the Controller ruled in the favor of patentee stating that the applicant has not made efforts to obtain a license from the patentee on reasonable terms & conditions as evident by the applicant's conduct by not taking any action on the queries by the patentee.
3. The latest decision is relating to application filed by Lee Pharma for AstraZeneca's drug Saxagliptin, the Controller rejected Lee Pharma's application majorly on the grounds that applicant was unable to substantiate that the public requirement was not being met and the drug was unaffordable to the public.

Thus, the sum and substance from the decided cases is that Patent Office is strictly evaluating the primary grounds of reasonable requirement of public being met, reasonable affordable price and working of Invention based on data/evidence submitted by the applicant in his application for grant of Compulsory License. Therefore, the fate of the case lies in the accompanying data provided by the applicant for substantiating these grounds.

In summary what worked and what did not work in the three decided cases on the subject:

- (a) Nexavar's Decision (Natco vs Bayer) that Controller gave high consideration to the affordability factor- the main reason on which Natco's compulsory license application was granted. As Natco Pharma proposed to manufacture an affordable generic version of Sorafenib Tosylate at 8,800 rupees (approximately USD 160) for a month's dose – which was a fraction of Bayer's price of 280,000 rupees (approximately 5,098 USD)
- (b) Dasatinib case (BDR vs Bristol-Myers) - the Controller was not convinced that sufficient efforts have been made by the applicant to obtain a license from the patentee on reasonable terms & conditions. This being crucial requirement, it does seem all conditions for grant of compulsory license must be complied.
- (c) Saxagliptin Case (Lee Pharma vs Astrazeneca) – The Controller was not convinced that there was sufficient supportive data to justify/establish the facts stated for grounds to grant Compulsory License such as requirement of the public being met/unmet, affordability factor, working requirement were provided. In other words, mere hypothetical statements in the application were not considered sufficient.

To Sum up

With the news of “private assurance”, the questions that had started to be raised was possibility of any change at the policy level for grant of compulsory license and subsequently an unending series of questions and doubts further piled up after the clarification statement of government was released. This has been fueled by a recent press statement published by NDTV website (on 12th April) where both BDR Pharma and Lee Pharma blamed lack of government support for cheap generics and pressure from Big Pharma for not pursuing Compulsory License application anymore.

The first compulsory license was granted in the year 2012, and at that time, it was feared by many Patent holders that this process will spread to different technology areas and will not stay limited to medicines. This has clearly not happened. At the same time, we have not experienced a flood of applications for grant of compulsory license as was feared and written about at that time. In fact, the three applications that have been decided show complete independent view expressed by the adjudicating authority linked to facts and circumstances of the case. Thus, it seems preposterous to suggest that government can undo a set mechanism and policy on Compulsory Licensing that is part of Patent legislation through a statement to the business delegation.

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