Compulsory licences: Is India protecting its own?

India's policy of issuing compulsory licences for life-saving drugs has been welcomed by its thriving generics industry, but has drawn the ire of big pharma, Remfry & Sagar's **Swarup Kumar** describes some of the issues involved

India issued its first ever compulsory licence to Natco Pharma, an Indian generic company, for Bayer's blockbuster anti-cancer drug Nexavar (Sorafenib) in March 2012. Almost 20 months have passed since the granting of such a licence and yet no other compulsory licence has as yet been issued by the Indian Patent Office. This, to some extent, appears to belie the perception that India – irrespective of its international obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), World Trade Organization (WTO) and so on – is on a spree to issue as many compulsory licences as possible. In this respect, it is also crucial to note that contrary to public opinion, not many applications for compulsory licences have been filed by Indian generics in the interim. With this in mind, let us look at what has recently transpired in India's compulsory licence regime.

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Nexavar Case

The granting of a compulsory licence on Nexavar (Sorefinib) attracted strong criticism from multinational pharma giants, patent attorneys and other interested parties and, on certain issues, understandably so. The most dreaded implication of this decision was the Indian Patent Office's take that non-compliance with the requirement of domestic production of Nexavar by Bayer was indeed grounds for granting of a compulsory licence. In other words, mere importation of a patented drug into India was considered not to amount to commercial working of the invention. This stance was believed to have stretched the working requirement a little too far. More so since the Indian Patent Act, 1970 envisages mentioning in the working statement (to be submitted to the patent office) the amount of the patented drug that has been imported. The other two grounds for the granting of a compulsory licence, ie, reasonable requirements of public not being met (in terms of quantity of drug), and the price of the drug not being reasonably affordable to the

public were also held to have been met in the case of Nexavar. Natco was, thus, granted a compulsory licence and was mandated to pay to Bayer a royalty of 6% (per quarter) on the net sales of the drug.

The Controller General's decision to grant a compulsory licence was appealed by Bayer before the specialised tribunal – the Intellectual Property Appellate Board (IPAB) which, after considering the matter in detail in turn upheld the decision. The board, in its order, categorically observed, "we must bear in mind that these proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee." The silver lining in the appellate board's decision was that the thrust of the requirement for local commercial working of the patented invention as a standalone criterion for granting of a compulsory licence was substantially diluted. The board held that in the absence of a definition for "working" of a patent locally in the TRIPS or Paris Convention, its meaning must be determined on a case-by-case basis. There was a sigh of relief from all the patentees irrespective of the disparate fields of technologies their inventions related to. The IPAB also increased the royalty rate to be paid to Bayer from 6% to 7%.

Bayer, again not convinced by the appellate board's decision, has moved its case to the Bombay High Court challenging the IPAB's order. Hearings on this matter are underway and only time will tell what the outcome will be.

Roche's Herceptin

Following the Nexavar case, a compulsory licence application was filed for Roche's breast cancer drug Herceptin by none other than the Ministry of Health, Government of India. Interestingly, this application was eventually rejected by the Department of Industrial Policy and Promotion. One school of thought is that following the granting of a compulsory licence for Nexavar, there was intense international scrutiny of India's IP policies, and that India did not want to encourage further licence applications.

Dasatinib

In the Dasatinib case, BDR Pharma, an Indian generics company, sent an initial request for a voluntary licence to Bristol Myers Squibb. Bristol Myers Squibb asked whether BDR has (i) the ability to continuously supply high volumes of Dasatinib, (ii) the capacity to maintain the high quality of the drug as well as the ability to comply with local regulatory standards, and (iii) the capability to maintain a safety and environmental profile. Bristol Myers Squibb also asked BDR to provide its litigation history. Interestingly, BDR Pharma took these queries as "clearly indicative of rejection of the application for voluntary licensing" and did not pursue the matter and made no further effort to arrive at a settlement with the patentee. In fact, BDR preferred filing a compulsory licence application almost a year after the queries were raised by Bristol Myers Squibb.

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In support of its compulsory licence application, BDR argued that in an article published in *India Business Journal*, a reputed publication, the attorneys of the patentee voiced their strategy to "keep the potential licensee of compulsory licence engaged without a clear outright rejection". This, according to BDR, led it to believe that there was no point in responding to the queries raised by Bristol Myers Squibb since it will in any case stick to its delaying tactics.

After considering the matter at hand in detail, the Controller General held along the following lines: The term "effort" (in Section 84(6) of the Patents Act, 1970) is not accompanied by the term "reasonable" and the compulsory licence applicant ought to have appreciated that the duty cast upon them to make an effort (to negotiate a voluntary licence) is absolute, inflexible and without any exception. The conduct of the applicant in not replying to the patentees queries till the date of filing the compulsory licence application cannot be said to have qualified as having made "effort" as required by our law.

The licence applicant ought to have appreciated that a statement/opinion by the attorney of the patentee in a journal cannot be taken as evidence against the patentee in the present case. Even if the applicants sincerely believed that the statement/opinion was directly attributable to the present case, the applicant did not have, in the scheme of the law, freedom to bypass the procedure, namely sincere mutual deliberation for a reasonable period as mandated by law.

Accordingly, the Controller General quite rationally rejected BDR's application since no *prima facie* case for grant of a compulsory licence could be made. This decision is in consonance with the tenets of Article 31 of TRIPS which, *inter alia*, mandates initial voluntary negotiation by the applicant of a compulsory licence, and only on failure of such negotiation with the patentee, permits the prospective licensee to file a compulsory licence application.

In view of the patent office's rejection of the compulsory licence application, BDR Pharma now has an option either to file an appeal against the Controller General's order before the appellate board or renegotiate with Bristol Myers Squibb the possibility of a applying for a voluntary licence complying with the requirements of the aforementioned Section 84(6). Only when such efforts to negotiate a voluntary licence fail, can BMR apply (again) for issuance of a compulsory licence before the Indian Patent Office.

Notwithstanding BDR's future strategy, the Indian Controller General's decision to reject the compulsory licence application filed by BDR – though only on formal grounds - tells a story somewhat different from what one would have perceived just after the issue of the Nexavar compulsory licence.

Some practical tips

As long as the provisions of compulsory licences are present in Indian legislation – and they will remain for a long time – just like the laws of many other countries including US, Canada, Germany and so on, it cannot be denied that such provisions will be relied upon by third parties for securing a grant of such a licence. Therefore, it will be prudent to follow the maxim "prevention is better than cure" and take proactive action to reduce the chances of compulsory licences being applied for and granted against one's patent(s). On the other hand, the prospective licensees will do well in exhausting the avenues for securing a voluntary licence before applying for a compulsory licence.

A few pointers for pharma companies and in-house attorneys regarding compulsory licences in India

- Patentees must file the so called statement of working for every invention(s) patented in India each year, irrespective of whether they have been worked or not. If not worked yet, state what is being done to work it in near future.
- If actual working in terms of local manufacture and so on, is not feasible, at least work the invention by way of importation of the patented drug (in sufficient amounts) and mention such importation amount in the working statement.
- Search for the possibility of licensing, technology transfer arrangements, joint ventures etc, if *de facto* direct working by the patentee is not feasible.
- Given the sociopolitical and economic situation in India, one must think and strategise about differential pricing of at least the life-saving drugs.
- If faced with a request for voluntary licensing from companies, always reply to such requests within a reasonable period.
- Ask the prospective licensee to establish their manufacturing capacity, quality control capacity, safety and/or environmental compliance profile through, for example, a questionnaire.
- The terms and conditions of voluntary licences are to be decided upon by mutual consent of the patentee and licensee and therefore, negotiations for terms and condition of licence and rate of royalty need to be carefully considered and bargained for.
- For a licensee, it is crucial to have exhausted the opportunity to seek a voluntary licence from the patentee before applying for a compulsory licence. In other words, the prospective licensee must have made "efforts" to seek a voluntary licence by following the requirements of law lest their request for a compulsory licence may be dismissed at a preliminary stage.
- A prospective licensee will do well in doing enough ground work in terms of its manufacturing capacity, quality control and environmental compliance strategy and so on, before going ahead with negotiations for issue of a licence.

The pointers in the left box are, of course, indicative in nature and a specific strategy needs to be devised on a case-by-case basis. Nevertheless, a few lessons learnt from past experiences should be helpful in the long run.

Summary

One thing that is apparent from the compulsory licence cases in India is that due process of law was followed in each instance. Parties on both sides were provided with enough opportunity to present their case, counter other sides' stance and substantiate their arguments. Moreover, the decisions by the patent office are subject to judicial review/scrutiny. This strengthens the belief that we may agree or disagree with the outcome of the decisions, but faith in the fairness of the overall judicial process will remain undeterred.

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While the Nexavar decision has been criticised by many as being anti-patent, the other point of view maintained by non-governmental organisations (NGOs), pro bono activists, academics, and so on is that since all the prerequisites for granting of a compulsory licence were fulfilled in this case, the decision in favour of Natco was inevitable. Since the Nexavar matter is again *sub-judice* and final outcome is awaited this, along with other issues, can be debated *ad infinitum*.

However, the bigger question perhaps is whether the granting of a compulsory licence is the most rational means of making available the patented drugs in sufficient quantity, at the right time and at a reasonable price to needy patients. A study suggests that even though Nexavar was being produced at a much cheaper price by Natco, substantial numbers of the Indian population still cannot afford the medicine. Therefore, is it not prudent that the Indian government take on more responsibility and work towards making quality healthcare available to the masses rather than merely relying on a compulsory licence regime? Also, should not the generic industry as well make sacrifices to their profit margin on compulsory licence drugs – so as to make the drugs available to an even larger section of the populace – if the idea is to propagate public good through a compulsory licence regime?

Furthermore, should not the multinational companies give serious thought to a differential pricing model in less developed countries and go ahead with implementation thereof? Lastly, is not the introduction of new strategic policies such as the new drug pricing policy, which enables the Indian government to regulate prices of at least 348 essential drugs, an alternative to compulsory licences for bringing down prices of life-saving drugs? It is a different matter that this policy is drawing flak from many corners including the Supreme Court of India and the policy needs to be thought over and substantially fine-tuned.

In a nutshell, striking a balance between promoting access to existing drugs and promoting research and development into new drugs is a tough job and all the interested parties as well as parties not so interested will have to come together to devise novel, inventive and industrially applicable ways of doing so

Author

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