# IP Hotline

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## IPAB UPHOLDS THE FIRST COMPULSORY LICENSE GRANTED TO GENERIC DRUG COMPANY

In March last year, the Controller General of Patents ("**Controller**") created history with a landmark judgment granting the first ever Compulsory License to an Indian generic company Natco Pharma to manufacture and sell a generic version of Bayer Corporation's patent protected anti-cancer drug 'Sorafenib Tosyalte' marketed as NEXAVAR by Bayer. We had analyzed the Controller's order in our IP Lab available here. Bayer appealed against this order to the Intellectual Property Appellate Board ("**IPAB**"), which by an order dated March 4, 2013 upheld the Controller's order. The IPAB however, seems to have diluted the requirement of "local working" as interpreted by the Controller.

### WHAT IS A "COMPULSORY LICENSE"?

To recapitulate, CL is an involuntary contract between a willing licensee and an unwilling patentee imposed and enforced by the State. Chapter XVI of the Indian Patent Act, 1970 ("**Act**") provides for detailed provisions for CL, when the application for the same is made by an intended licensee (person interested) and also in cases where government may suo moto issue a CL. Under Section 84 of Act the Controller of Patents ("**Controller**") may grant a CL at any time after three years of the grant of a patent on any one or all of the following grounds:-

- The reasonable requirements of the public with respect to the patented inventions have not been satisfied, or
- The patented invention is not available to the public at reasonably affordable prices, or
- The invention is not exploited commercially to the fullest extent within the territory of India.

Once an application has been filed, the Controller, needs to take into account the steps already taken by the patentee towards making full use of the patent and importantly, the capacity and ability of the applicant to work the invention to the advantage of the public and whether the applicant has made efforts to obtain a voluntary license from the patentee on reasonable terms and conditions. Upon grant of the CL, the grantee can manufacture and sell generic versions of a patented product for the remaining term of the patent, unless the CL is revoked earlier. The Controller determines the royalty payable by the grantee of the CL to the patentee.

### FACTS OF THE CASE

'Sorafenib Tosyalte' ("**the Drug**") is a compound patented by Bayer Corporation, a Pittsburgh, USA ("**Bayer**"). It is marketed as NEXAVAR and is used in the treatment of advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular carcinoma). Bayer was granted a patent as well as regulatory approval for importing and marketing the Drug in India in the year 2008. The drug is life-extending drug and not a life-saving drug. It can increase the life of a kidney cancer patient by 4-5 years and that of a liver cancer patient by 6-8 months. Natco Pharma ("**Natco**") filed an application in July 2011 for grant of Compulsory License in respect of Sorafenib Tosylate covered under Indian patent No. 215758. Both parties filed evidence and after extensive hearings, the Controller granted a compulsory license to Natco. Bayer appealed against this order to the Intellectual Property Appellate Board ("**IPAB**").

### IPAB'S ORDER

Bayer raised the following preliminary issues:-

1. When the Controller came to the prima facie view that a case has been made out, it ought to have given notice to Bayer.

   As per Section 87(1) of the Act, on receiving an application for CL, if the Controller is satisfied that a prima facie case is made out, he will direct the serving of the application on the patentee. Bayer's argument was that prior to coming to this conclusion, the Controller ought to have given notice to Bayer. The IPAB held that when an application is made for grant of a CL, the Controller has two options -one is to decide that on the face of it, there is no merit in the CL application, if for instance the application has been filed pre-mature. The second option is to come to a view that this is a matter where both parties have to be heard. It is not required for the Controller to hear any party before examining this prima facie to issue notice to the parties.

2. Natco did not file any evidence

   Bayer argued that Natco had not provided evidence along with its CL application. The IPAB held that while Natco could have filed documentary evidence along with the CL application, all the evidence that was required to be filed was present before the Controller before the Controller came to his decision to issue CL. The IPAB held this

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to be a 'mere procedural lapse' based on which the order granting CL could not be set aside.

**Substantive Issues**

1. While deciding whether the 'reasonable requirement of the public has been met' should the Controller have considered the sales being made by CIPLA?

   CIPLA is allegedly an infringer against whom BAYER has filed a suit in the Delhi High Court. The Hon'ble Delhi High Court had not granted an injunction against CIPLA, but had ordered CIPLA to maintain accounts. Bayer contended that if CIPLA had effectively met the requirement of the public, then there would not be a grant of CL to another entity. Bayer contended that in such a situation, infringers like CIPLA would take away the patentee's market leading to grant of CL on the ground that the patentee is not meeting the requirement of the public. According to Bayer, should this to be allowed, generic companies would be able to get CLs for all patented products.

   The IPAB referred to Section 83(1) of the Act, which lays down the philosophy of why patents are granted as well as the fact that the section clearly refers to "patentees" and persons deriving title or interest from patentees. The IPAB held that when the law refers to 'patentees' it means patentees or persons deriving title or license from patentees and no one else.

   Therefore when Section 83 (1) (g) states that patents are granted to make the benefit of the patented invention available at reasonable affordable prices to the public, it clearly indicates that the quid pro quo for the grant of the patent is the duty of the person to whom the patent was granted.

   The IPAB held that were it to be otherwise, it would mean that a monopoly is granted to a person who does not make any effort to make his invention available to the public and would rest on the labour of a third party. Hence for the grant of a CL, only the sales made by the patentee or its legal licensees are to be considered.

2. How to construe "reasonably requirement of public"?

   The IPAB held that the failure to meet the demand of the public on reasonable terms has to include both "quantity" and "price" i.e. the patentee has to work the invention in India on a commercial scale and the invention has to be available at a reasonably affordable price.

   Bayer argued that the term "reasonably affordable price" should be construed on the basis of differential classes/sections of public and the price of any product must be reasonable to the public as well as the manufacturer. Bayer filed several affidavits showing that the price being charges by Bayer is comparable to what is charged in other developing countries as well as oncology products of other originator companies. The affidavits also stated that originator products are more expensive than generic ones since they also involve R & D cost as against persons who merely copy the drug.

   - Price -The IPAB referred to the affidavits filed by Bayer and noted that none of the affidavits considered the perspective of the public or the patients' views. The IPAB held that "reasonably affordable price" has to be necessarily fixed from the view point of the public and the word 'afford' indicates whether the public can afford to buy the drug. The IPAB held that subsidized schemes run by the patentee, insurance schemes are not relevant in determining "reasonably affordable price". Also, the IPAB did not consider the R & D costs submitted by Bayer, since the R & D costs were not particular to the drug in question nor to India. The IPAB held that the Controller was right in holding that the sales of the drug by Bayer at INR 2,80,000 was alone relevant for the determination of public requirement and that the Controller was right in considering the purchasing power of the public and the available evidence to conclude that the invention was not reasonably affordable by the public.
   - Quantity - The Act requires the patentee to work the invention on a commercial scale in India. The IPAB referred to the Form 27 filed by Bayer which clearly stated that while packs for patient assistance were imported, no sale packs were imported. Bayer argued that working in India did not mean local manufacturing. Bayer relied on the fact that Section 90 of the erstwhile Patent Act (which is now Section 84 (7) ) deleted the phrase "manufacture in India". The IPAB held that this issue is to be judged on a case to case basis. The IPAB did not rule either way that "working in India" necessarily means "local manufacturing" or not. The IPAB held that "In a given case there may be an invention which cannot be manufactured in India and it is also possible that there is an invention where the reasonable requirement of the public itself is small in number and setting up a factory for the said purpose is not practicable." In the same breath, the IPAB also held that the patentee needs to show why its invention could not be manufactured locally and that a mere statement to the effect that working can be done only by way of import is not enough. The patentee needs to adduce evidence to support this statement.

## CONCLUSION

The IPAB has not differed from the Controller to a large extent. The only significant divergence is in increasing the royalty rate to be paid by Natco to Bayer from 6% to 7 %. Also, the IPAB has not settled the position as to whether it is mandatory for a patentee to locally manufacture the invented product in India or not. By leaving this analysis to be on a "case to case" basis without providing any guideposts as to what factors such an analysis should consider, the IPAB may have made the issue even more vague. The IPAB has in its order at several places noted that a CL proceeding is for public interest and not an adversarial proceeding favouring one party against the other. This conclusion will be useful in determining the rights of parties in subsequent proceedings before the Controller. The Controller will need to have a macro-level view of the issues in front of him, while always bearing in mind that public interest needs to be served. By choosing to completely ignore the costs incurred by patentee in the analysis of what is "reasonably affordable price" as well as the fact that even if the market price is high, the drugs may be available to patients through subsidies, schemes and insurance, the IPAB has taken a view which is at one extreme end of the spectrum. It remains to be seen how the High Courts and the Supreme Court will interpret these issues.

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After the Controller granted the first Compulsory License in March last year, there was tremendous speculation if the watershed event would open the floodgates and several CL applications would be filed by generic companies. However, much against public expectation, there has in fact not been too much activity in this area. Recently, BDR Pharma has filed an application for compulsory license of anti- cancer drug Dasatinib patented by US based innovator company BMS (Bristol-Myers Squibb). There have also been media reports that the Government of India (through DIPP) has been mulling issuing compulsory licenses for Sprycel, Ixempra and Herceptin. Once the Bayer-Natco saga is settled by the Supreme Court, and there is more certainty as to the interpretation of various CL provisions of the Act, there may be heightened activity in this area, necessitating innovator companies to revisit and reevaluate their India strategy and India operations.

- Aditi Jha and Gowree Gokhale
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