Bayer Corporation Vs. Union of India and Others
(Bayer v. Natco)
Before the Indian Intellectual Property Appellate Board (IPAB)
Decision Date: 04.03.2013

Prepared by UNCTAD's Intellectual Property Unit

Summary

The Intellectual Property Appellate Board upheld the decision of the Controller of Patents to grant India's first compulsory license and elaborated when the grounds and conditions for compulsory licenses are satisfied.

The Facts

- "Sorafenib", an active pharmaceutical compound used for the treatment of liver and kidney cancer was patented by Bayer Corporation, Germany, in India (Patent No. IN 215758). Sorefenib is marketed worldwide under the brand name Nexavar.
- The Indian generic manufacturer CIPLA started producing and marketing the generic version of Sorafenib in 2008 under a brand name 'Soranib' and the description of 'Sorafenib Tablets 200mg'. Bayer filed a suit for infringement against CIPLA before the Indian courts (not the subject of this case summary).
- At the time of the suit, Bayer charged 280,438 INR (~ US $ 5280) per month compared to CIPLA's generic version marketed at 27,960 INR (~ US $ 525) for the same amount of tablets.
- During the ongoing dispute between CIPLA and Bayer, another generic manufacturer, Natco Pharma Limited, filed a request for compulsory license against Bayer's patent on Sorafenib before the Controller of Patents. Natco requested the compulsory license based on Section 84 (1) of the Indian Patent Act of 1970, as amended in 2005.
- Section 84 (1) of the Indian Patent Act as amended provides for compulsory license after the expiration of three years from the date of the grant of a patent on any of the following grounds:
  a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
  b) the patented invention is not available to the public at a reasonably affordable price, or
  c) the patented invention is not worked in the territory of India.
- The Controller found that Natco Pharma was deserving of a compulsory license as Bayer had failed to meet the requirements of S. 84 of the Patents Act, 1970. The Controller drafted the terms and conditions of the compulsory license and awarded a 6% royalty from profits to Bayer.
- Bayer appealed the Controller's decision before the Indian Intellectual Property Appellate Board (IPAB).

The Legal Issues

- The appeal raised procedural as well as substantive grounds, and particularly raised several questions of pure law.
- The IPAB affirmed the order of the Controller, modifying only the royalty set by the Controller. The law regarding compulsory licenses was clarified further by the IPAB.

- At the outset the IPAB clearly stated that the grant of compulsory licenses would be made on a case by case basis. The IPAB stated that the TRIPS Agreement did not give a *carte blanche* in the matter of compulsory licenses but rather tempered its grant with the condition that such licenses ought to be granted on a 'case to case basis of individualness'. The focus of the IPAB's decision was founded on the benefit granted to the public rather than any benefit that could be gained by either the patentee or the applicant.
- The IPAB *inter alia* held that the following markers could not be ignored when deciding the appeal:
    - The grant of patents shall not impede protection of public health;
    - The grant of patents must balance the patentees' rights and obligations;
    - The patentee must make the benefits of a patented invention available at a reasonably affordable price to the public.

- One of the contentions before the IPAB was that the respondent (Natco) had not made a proper request in compliance with Section 84 (6) (iv). Section 84 (6) (iv) requires the applicant for a compulsory license to first seek out a voluntary license from the patentee. The respondent's letter to the appellant (Bayer) detailed how the appellant had failed to meet the requirements set out by Section 84 and that it wanted to sell the drug for a fraction of the price that the appellant charged. Further, the letter stated that the request for voluntary license was made without prejudice to the respondent's right to challenge the patent, causing the appellants to label the request a veiled threat.
- The Board noted that if there was a veiled threat, there was an equally veiled answer. The Board found that an offer had been made by the respondent and was rejected by the appellant. The Board saw no reason why the respondent should make another effort when the first one had failed and held that the law does not require subsequent efforts either. It found that the law's requirement had been met and rejected this objection.
- The IPAB considered the three conditions laid down in S 84 (1) for the grant of compulsory licenses, namely:
    - (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
    - (b) that the patented invention is not available to the public at a reasonably affordable price, or
    - (c) that the patented invention is not worked in the territory of India.

  The IPAB held that it is enough if one condition is satisfied as the three conditions are separated by the disjunctive 'or'.

Points of Significance

Reasonable Requirements of the Public

- The IPAB, like the Controller, found that the reasonable requirement of the public had not been met by the patentee. The IPAB then postulated that the reasonable requirements had not been met for the following reasons:
    - if there is no working of the patented invention the reasonable requirement is not satisfied,
    - if the price is not reasonably affordable the reasonable requirement is not satisfied,
    - if the working of the patented invention is not on a commercial scale then the reasonable requirement is not satisfied.

- In essence the IPAB's ruling states that the reasonable requirement condition laid down in S. 84 (1) (a) is not met if the conditions in S. 84 (1) (b)-(c) are also not met. The IPAB found that the public could neither access nor afford the drug. The IPAB held that the failure to meet the demand on reasonable terms must logically mean that the quantity of the drug supplied was minimal and the price was too prohibitive for the general public.

Affordability

- The issue of reasonable affordability as a sole factor was also addressed by this decision. The IPAB unequivocally stated that the issue of reasonable affordability would necessarily be adjudged on the basis of whether the general public is able to afford the drug.
- The IPAB agreed with the Controller that the price of the drug made it unavailable to the public at large and therefore the drug was not found to be reasonably affordable.

Working of the Patent

- While the IPAB did not make it clear whether the term 'working of the patent' meant manufactured in India or imported into India, it found that the patent was not being worked in India.
- The IPAB agreed that there could be certain situations in which a drug could only be imported and not manufactured in India and such import could completely satisfy the requirement of the drug being worked in India. However, IPAB held that such import must be on a commercial scale to an adequate extent and at a reasonably affordable price.
- Therefore the IPAB held that the drug could not be said to be worked in India.
- Further, the IPAB rejected the argument advanced by the appellant that its Patient Assistance Program contributed to the working of the invention. This argument was rejected on the ground that philanthropic efforts did not contribute to working on a commercial scale.

Public Interest

- The IPAB held that the public interest was paramount and efforts made by the appellant to make the drug available to the public subsequent to the filing of the application seeking a compulsory license are not disallowed.
- The IPAB found that the words of S. 84 (6)[1] are not a taboo to prevent the inventor to step down from his position and make the invention available to the public. The provisions of

[1] Section 84 (6) provides: In considering the application filed under this section, the Controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices

the Patents Act dictate that the patentee must provide the necessary technical information about the patented invention. The provisions favour public interest and not the interests of either the patentee of the compulsory license applicant.

- The IPAB held that patents are granted for the benefit of the public and therefore must be easily attainable and affordable by the public.
- Further, the IPAB noted that the patentee was allowed a gestation period of three years from the date of grant of the patent to work the patent in India.

Sale by CIPLA

- The IPAB then considered the relevance of the sale of Nexavar made by an infringer.
- CIPLA had been engaged in the manufacture and sale of Nexavar without obtaining a license from the patentee. The patentee had filed a suit for infringement against CIPLA (see above). Although the Delhi High Court refused to grant an injunction, it directed CIPLA to maintain accounts of the sales from the infringing product. The appellant argued that both the appellant and its infringer together meet the reasonable requirements of the Indian public (S 84 (1)) and therefore the compulsory license cannot be granted upon this ground.
- The IPAB opined that the term 'patented invention' used in S 84 (1) of the Patents Act, 1970 must refer to:
  - the invention that must be made available to the public by the patentee;
  - the invention in respect of which reasonable requirements of the public must be satisfied by the patentee; and
  - the invention which the patentee must work in the territory of India.

- The IPAB held that 'patented invention' can only mean that which is made available to the public by the patentee or the patentee's licensee. If it were otherwise it would mean a monopoly is granted to a person who does not make an effort to ensure the invention reaches the public but instead shifts this obligation on a third party.
- The IPAB held that while CIPLA's presence in the market is relevant, the law is clear that the requirements and conditions to be satisfied for the grant of the compulsory license is something to be decided with respect to the patentee alone and not a party whose presence itself is litigious.
- The IPAB further stated that the patentee is expected to furnish technical knowledge and render assistance to licensees since the invention is the patentee's property. It was undisputed that Bayer had not shared any technical knowledge with CIPLA.
- The IPAB found that it is the patentee who should make sure that the invention is worked adequately and commercially.

Final Holding

The IPAB refused to interfere with almost all of the findings of the Controller's order on both substantive and procedural grounds. The IPAB allowed the appeal of Bayer to the limited extent that the royalty to be received by Bayer under the compulsory license was increased from 6% to 7% of the profits made by Natco.

Aftermath of *Bayer v. Natco Pharma*

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adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

- On 15 July 2014, the Bombay High Court confirmed the findings of the IPAB. Bayer filed a special leave petition against the Bombay High Court's decision with the Supreme Court of India, which however dismissed the petition and upheld the compulsory license.[2]
- Although other applications for compulsory licenses have been filed since the grant of the first compulsory license, no new compulsory licenses have been granted by the Controller.
- On 29.10.2013, the Controller of Patents rejected a compulsory license application filed by BDR Pharma against Dasatinb, an anticancer drug patented by Bristol-Myers Squibb. This application was rejected by the Controller on the ground that BDR Pharma had not made out a *prima facie* case for the grant of a compulsory license. Further, it was found that BDR Pharma had not engaged in the prerequisite of obtaining a voluntary license before filing an application for obtaining a compulsory license.

Keywords: Compulsory licensing · working of patented invention · public interest.

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[2] See at http://infojustice.org/archives/33690#:~:text=Supreme%20Court%20Says%20No%20to%20Bayer%2C%20Upholds%20Compulsory%20License%20on%20Nexavar,-Posted%20by%20REPOST&text=The%20grant%20of%20Compulsory%20license,of%20its%20kind%20in%20India.