Controller Refuses Compulsory License against Bristol Mayer's Dasatinib

> *"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent…[1]"*

When the Intellectual Property Appellate Board of India (an appellate forum for appealing the decisions of Controller of Patents, Designs and Trademarks in India) upheld the grant of first ever Compulsory License (CL) to an Indian generic manufacturer- Natco, for the manufacture and sale of Sorafenib tosylate, (sold under the trade name Nexavar by Bayer, an effective and approved medication for chronic myeloid leukaemia) last year, it elicited strong reactions from the pharmaceutical industry and from the public health groups with some calling it a 'warning for price gouging drug companies[2]', and hailing as 'the ray of hope for public to access innovative health products at affordable prices' while others terming it as 'an attempt to weaken the international patent system which endangers pharmaceutical research[3]'.

One year later, and arguably under similar circumstances, the decision of the [new] Controller at the Indian Patent Office of rejecting the compulsory license application by BDR Pharmaceutical for the manufacture and sale of drug Dasatinib- on finding that the applicant failed to establish its sincere efforts in getting a voluntary license from the patentee- Bristol Mayer Squibb (BMS) before approaching the office of Controller of patents for grant of compulsory license has ignited the debate

[1] Text of Article 5A (2) of the 1883 Paris Convention which envisaged provision for each contracting state to take legislative measures for the grant of compulsory licenses. While the term "compulsory licensing" did not appear in the later TRIPS agreement, it allowed 'compulsory licensing' as part of the agreement's overall attempt to strike a balance between granting access to newer medicines and promoting research for new drugs by allowing "other use without authorization of the right holder" (Article 31).

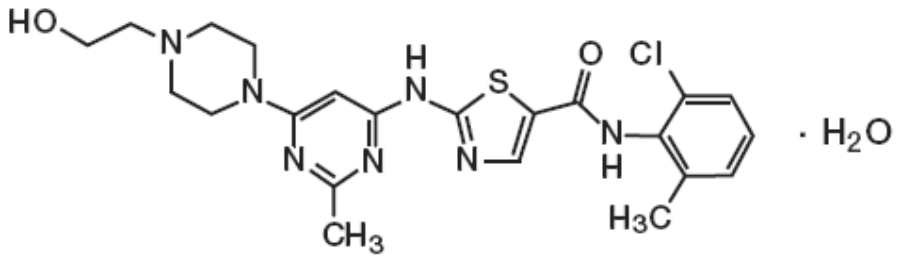
[2] http://www.doctorswithoutborders.org/press/release.cfm?id=5816&cat=press-release (last visited on November 02, 2013)

[3] http://www.ip-watch.org/2013/03/05/bayer-will-appeal-india-compulsory-licence-on-its-cancer-drug/ (last visited on November 02, 2013)

on affordable and accessible healthcare in India and challenges in undertaking high risk research for bringing newer medicines to market.

Background: The drug in question-Dasatinib, marketed and sold as Sprycil by BMS is a kinase inhibitor. The chemical name for dasatinib is N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide, monohydrate.

Dasatinib has the following chemical structure:



Dasatinib was approved by USFDA in 2006 and is presently indicated for treating chronic myeloid leukemia (CML; a type of cancer of the white blood cells), including treatment in people who have developed resistance to or can no longer benefit from other medications for leukemia. Dasatinib is covered by six orange book listed patents in the USA, with patents expiring as late as March 28, 2026 (US Patents listed in OB for Dasatinib: 6596746, expiring on June 28, 2020; 6596746 expiring June 28, 2020; 7125875 expiring April 13, 2020; 7125875 expiring April 13, 2020; 7153856 expiring April 28, 2020 and 7491725 expiring March 28, 2026).

Compulsory License (CL): The two provisions of the Indian Patents Act that allow for compulsory licenses are Sections 84 and 92. Section 84, which was the invoked in the present case, allows the Controller of Patents to issue a compulsory license, three (3) years after the issuance of a patent if one of the following conditions is met:

1. *The reasonable requirements of the public with respect to the patented invention have not been satisfied; or*
2. *The patented invention is not available to the public at a reasonable price; or*
3. *The patented invention is not worked in India.*

CL Application: BDR Pharmaceutical (applicant) approached the patentee (Indian patent no. 203937) for a voluntary license on 2nd February 2012, offering a cost of INR 97,200 (approx US $ 1594) per patient per year as against the cost of INR 1, 98, 816/- (approx US $ 3260) per year per patient by the patentee. In response to applicants' offer, patentee raised certain queries on 13th March 2012- mostly directed towards establishing the competency of the applicant, necessary quality assurances and authorizations to manufacture and sell the patented drug in question. In its response of 10th May 2013, applicant replied to the queries after having filed the request for compulsory license before the Controller on 4th March 2013.

Submissions by Applicant: Applicant submitted that they did not reply to patentee's queries as the delay in eliciting a response from the patentee and unnecessary queries by patentee were an indication of the rejection of the application for voluntary license. The patentee, thus, chose not to pursue the matter or make further efforts in arriving at a settlement with the patentee.

The applicant also submitted that the attorney for the patentee had publicly declared that the strategy on behalf of the patentee was *'to keep the potential licensee of a compulsory license engaged,* ***without a clear outright rejection and continue with fresh queries'***. According to the applicant, this led them to conclude that there would be no purpose in responding to the letter of the patentee.

Findings of Patent Office: In its well reasoned decision, the Controller pointed out that the applicant has not sought approval from DCGI (Drug Controller General of India, head of 'Central Drugs Standard Control Organization'- a central authority established under Drug and Cosmetics Act, for the regulation of manufacture, sale and distribution of Drugs. DCGI is responsible for approval of licenses of specified categories of Drugs in India) to work the invention for public good. Controller also noted that the applicant has not made efforts to obtain a license from the patentee on reasonable terms & condition as evident by the applicants' conduct by not taking any action on the queries by the patentee.

While acknowledging the applicants' apprehension on the delays caused by the patentee, Controller pointed out that the legislature was fully aware that while a patentee may try to prolong the process of mutual deliberation by raising unnecessary queries, **the patentee is also entitled to satisfy itself on the credentials and capabilities of the applicant before deciding on granting a voluntary license**. On applicant's contention that the said 'query' letter by the patentee is clearly indicative of the rejection of the application for voluntary license does not hold good as the queries raised by the patentee appear to be reasonable.

Decision: The Controller opined that the deliberate intent on part of the applicant to refrain from entering into any kind of dialogue with the patentee for the purpose of securing the grant of voluntary license and the exercise of a deliberate choice to only invoke the provision relating to compulsory licenses without taking the requisite steps laid down by the law, cannot be classified as an irregularity in procedure/ timeline, which can be waived or condoned or declared to be not applicable, therefore **the applicant has failed to make out a *prima facie* case for the compulsory license**. Since this very threshold for a compulsory license application was not satisfied, the application did not merit further consideration.

Our comments: The decision lays down important guidelines and preparatory work to be done before making an application for a compulsory license under section 84 of the Indian Patents Act. One could draw following conclusions from the decision;

- Mere attempt in seeking a license from the patentee will not be enough to satisfy the requirement of 'reasonable efforts by the applicant' in negotiating a deal for a voluntary license with the patentee;
- It is advisable to have documentary evidence for establishing consistent efforts by the applicant in having approached the patentee for grant of voluntary license; and
- the fact that the patentee may delay the process by seeking certain clarifications on the application may not be enough to show the unwillingness of the patentee to grant a voluntary license and hence a fit case for the grant of CL.

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