

BDR Pharmaceuticals International Pvt. Ltd v. Bristol Myers Squibb Company

Controller of Patents, Patents Office, Mumbai

(BEFORE CHAITANYA PRASAD, CONTROLLER)

M/s. BDR Pharmaceuticals International Pvt. Ltd ... Applicant

VERSUS

M/s. Bristol Myers Squibb Company ... Patentee

C.L.A. No. 1 of 2013

Decided on October 29, 2013

ORDER

APPLICATION

1. An application under S. 84 of the Patents Act, 1970 (hereinafter referred to as the “Act”) was filed by the applicant on 4-3-2013, seeking the grant of a compulsory licence for Patent No. 203937 titled “A compound 2-amino-thiazole-5-carboxamide” granted to the patentee on 16-11-2006 on the Patent Application No. IN/PCT/2001, 01138/MUM. The active pharmaceutical ingredient DASATINIB (hereinafter referred to as the “drug”, unless the context suggests otherwise), used by patients with Chronic Myeloid Leukemia (hereinafter referred to as “CML”), was stated to be covered by this patent and was sold by the patentee under the brand name SPRYCEL. It was also submitted that DASATINIB had received Orphan Drug Status in USA, Europe and Switzerland.

DASATINIB

2. The applicant claims that DASATINIB is a suitable chemotherapeutic option for the treatment of CML and is prescribed when a patient is resistant or develops resistance to the drug IMATINIB, in view of the improved tolerance and efficacy of the drug. DASATINIB is administered as 50 mg tablets with a dosage of 100 mg per day. Thus, two tablets are to be consumed per day until disease progression or until the patient can no longer tolerate the medicine. It has also been submitted that the price of each tablet sold by the patentee is Rs. 2761 which works out to Rs. 1,65,680 for 60 tablets per month per patient and about Rs. 19,88,160 per year per patient.

TERMS AND CONDITIONS

3. The applicant voluntarily submitted the following terms and conditions:

- (a) The drug will be made available to the public at a proposed price of Rs. 135 per tablet working out to Rs. 8100 per month for the treatment of a CML patient. A breakup of the cost was also submitted.
- (b) Product under licence shall be manufactured with indication for CML.
- (c) Royalty will be paid to the patentee as per the rate fixed by the Controller.

(d) Special care will be taken to make the patented product available to patients who are economically weak and also to the patients residing in remote and rural areas.

(e) The drug will be offered free of cost to a certain percentage of patients suffering from CML as determined by the cancer specialists.

PENDING LITIGATION

4. The applicant submitted that an infringement suit CS(OS) No. 2303 of 2009 with respect to the subject patent was filed by the patentee against the applicant before the Hon'ble High Court of Delhi as the applicant had filed an application before the Drug Controller General of India for obtaining approval to market DASATINIB in India. The applicant submitted that the above suit was being adjourned over the last four years and that the patentee was indulging in delaying and blocking tactics. The applicant also informed that another suit CS(OS) No. 679 of 2013 was filed by the patentee against the applicant. No stay order so as to affect the present proceedings has been placed on record by the applicant. Also, no such order has been received from any court.

NOTABLE EVENTS

5. The chronological list of notable events is as follows:

2-2-2012	Applicant requested the patentee for a voluntary licence.
13-3-2012	Patentee raised certain queries.
4-3-2013	Applicant filed the application for grant of a compulsory licence under S. 84 of the Patents Act, 1970.
4-5-2013	Notice was issued by the undersigned to the applicant informing that upon consideration of the application under S. 84, a prima facie case has not been made out for the making of an order.
10-5-2013	Applicant replied to the letter of the patentee dated 13-3-2012.
13-5-2013	Applicant submitted a reply to the notice dated 4-5-2013 and requested to be heard.
23-5-2013	Applicant attended the hearing and defended his case. Applicant sought more time to file written arguments and one month time was given.
23-5-2013	Applicant filed a petition under R. 137 of the Patents Rules, 2003 (hereinafter referred to as the "rules") for condonation of delay in complying with procedural irregularities.
24-6-2013	Applicant filed the written arguments.
1-7-2013	Patentee replied to the letter of the applicant dated 10-5-2013.
9-7-2013	Applicant replied to the letter of the patentee dated 1-7-2013.
15-7-2013	Another petition under R. 137 of the Rules was filed by the applicant for condoning the delay in complying with procedural irregularities and requesting that the documents filed on 10-7-2013, namely, the applicant's letter dated 9-7-2013 and the patentee's letter dated 1-7-2013, be taken on record.
15-7-2013	Notice issued fixing a hearing on 31-7-2013.
17-7-2013	The applicant confirmed his presence in the hearing on 31-7-2013.
27-7-2013	The applicant requested for adjournment.

5-8-2013	Notice issued fixing a hearing on 9-8-2013.
7-8-2013	The hearing was adjourned, 9-8-2013 being a holiday.
14-8-2013	Hearing was fixed on 21-8-2013.
19-8-2013	Hearing was adjourned by the undersigned due to unforeseen circumstances.
2-9-2013	Applicant filed a petition under R. 137 of the Rules for condonation of delay and requested that the reply of the patentee submitted in the matter of CS(OS) No. 679 of 2013, where the applicant had filed an application for rejection of the suit/plaint under Or. 7 R. 11 read with S. 151 of the Civil Procedure Code, be taken on record.
2-9-2013	Notice issued fixing a hearing on 10-9-2013.
3-9-2013	Applicant requested for adjournment.
7-9-2013	Notice issued fixing a hearing on 16-9-2013.
16-9-2013	Hearing was held.

An effort was always made during the course of proceedings to fix a date that was convenient to the applicant to afford full opportunity to the applicant to present his case.

PROVISIONS

6. (I) S. 84(1) of the Patents Act, 1970 states as follows:

“84. *Compulsory licences.*— (1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, 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.”

In the application, it was claimed that all the aforementioned three grounds are applicable in the case of Patent No. 203937.

(II) S. 87 of the Act read with R. 97 of the Rules, lays down the procedure to be followed while dealing with applications under S. 84 of the Act.

(i) S. 87 of the Act states as follows:

“87. *Procedure for dealing with applications under Ss. 84 and 85.*— (1) Where the Controller is satisfied, upon consideration of an application under S. 84, or S. 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.”

(ii) R. 97 of the Rules states as follows:

“97. *When a prima facie case is not made out.*— (1) If, upon consideration of the evidence, the Controller is satisfied that a prima facie case has not been made out for the making of an order under any of the sections referred to in R. 96, he shall notify the applicant accordingly, and unless the applicant requests to be heard in the matter, within one month from the date of such notification, the Controller shall refuse the application.

(2) If the applicant requests for a hearing within the time allowed under sub-r. (1), the Controller shall, after giving the applicant an opportunity of being heard, determine whether the application may be proceeded with or whether it shall be refused.”

(III) In accordance with the scheme of the Act, the Controller, while considering an application under S. 84 of the Act is also required to take into account the factors mentioned in sub-s. (6) of S. 84 of the Act. The said provision is as follows:

“84. *Compulsory licences.*—

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

Explanation.— For the purpose of cl. (iv), ‘reasonable period’ shall be construed as a period not ordinarily exceeding a period of six months.”

PERSON INTERESTED AND CAPACITY

7. The applicant states that more than 6 years have lapsed since the patent was granted and that the patentee primarily imports the drug. The applicant is also a “person interested” and is into the field of pharmaceuticals, inter alia, manufacturing, distributing and exporting pharmaceutical active ingredients and dosage forms. It has been submitted that the applicant is extensively manufacturing anti-cancer products which are being marketed in India to a large extent and the manufacturing facilities of the applicant are approved under WHO's GMP (Good Manufacturing Practice). Prima facie, the applicant appears to have the capacity to undertake risk in providing capital to manufacture and make DASATINIB accessible in India as the applicant has his own manufacturing and marketing infrastructure. The applicant also claims to have access to a network of cancer hospitals and specialists.

COMMUNICATIONS PRIOR TO THE MAKING OF APPLICATION

8. In the present case, the applicant sent a letter dated 2-2-2012, to the patentee requesting for a voluntary licence for manufacturing Dasatinib. By letter dated 13-3-2012, the patentee raised certain queries such as “facts which demonstrate an ability to consistently supply high volume of the API, DASATINIB, to the market”, “facts showing your litigation history or any other factors which may jeopardise Bristol-Myers Squibb's market position”, “quality related facts and in particular compliance with local regulatory standards and basic GMP requirements”, “quality assurance systems due diligence”, “commercial supply teams”, “safety and environmental profile”, “risk of local corruption”. The applicant took this reply of the patentee as “*clearly indicative of the rejection of the application for voluntary licence*” and did not pursue the matter and made no further effort to arrive at a settlement with the patentee. The present application for compulsory licence was filed on 4-3-2013 i.e. after almost one year from *the date of receiving reply from the patentee*.

NOTICE

9. By notice dated 4-5-2013, the applicant was informed that a prima facie case has not been made out for the making of an order under S. 84 of the Act as “the applicant has not acquired the ability to work the invention to the public advantage”, in the absence of the requisite approval from the DCGI, and “the applicant has also not made efforts to obtain a licence from the patentee on reasonable terms and conditions” (hereinafter referred to as “efforts”). The applicant was informed that in accordance with the provisions of R. 97(1) of the Rules, a request for being heard is required to be filed within one month from the date of this order failing which the application shall be refused.

CLARIFICATIONS

10. The undersigned clarified to the applicant during the course of proceedings, that in the notice dated 4-5-2013:

- I. The undersigned had merely quoted the submissions forwarded by the applicant with respect to cl. (a), cl. (b) and cl. (c) of sub-s. (1) of S. 84 of the Act and that such mention does not by any stretch of imagination amount to a finding of any kind, whatsoever, on these clauses.
- II. The undersigned had not in any manner suggested that “a specific rejection of the offer made by the applicant to the patentee” was required in order to demonstrate that “efforts” have been made by the applicant. In fact, in the notice it was clearly mentioned that *“More than four-and-a-half months remained unutilised out of the ‘reasonable period’ prescribed by the legislature for the purpose of mutual confabulations but the applicant chose not to take any action during this precious time period that was available with the applicant.”*

EFFORTS

11. The applicant submitted that by not specifically replying to the request for voluntary licence, the patentee can continue to correspond asking for more and more information and keep the request for voluntary licence in abeyance. This clearly leads to unfair exploitation of the provisions of S. 84(6)(iv) of the Act. Moreover, the patentee can also use the information sought from the applicants against the applicants themselves in ongoing suits for patent infringement. If the patentee avoids to specifically reject the request for voluntary licence or does not address the terms for grant thereof, the application for compulsory licence could be indefinitely delayed for want of specific denial from the patentee, unless the learned Controller exercises his powers in appreciating the efforts made by the applicant towards fulfilling the requirements of S. 84(6)(iv). It was also submitted that this strategy is presently being adopted by all attorneys representing patentees in voluntary licence applications.

12. The contentions of the applicant that an application for compulsory licence can be indefinitely delayed for want of specific denial from the patentee are misplaced. The

“explanation” to S. 84(6) of the Patents Act, 1970, clarifies beyond doubt that a patentee cannot indefinitely prevent an applicant for voluntary licence from making an application for compulsory licence under S. 84 of the Act. At the most, if at all, the patentee can prevent a prospective applicant for six months from making an application for compulsory licence.

13. In the notice dated 4-5-2013 it was stated that some of the queries raised by the patentee appeared to be reasonable. In response to the notice, the applicant submitted that the applicant had approached the patentee for a voluntary licence with a clear conscience. The patentee however responded by their letter dated 13-3-2012 with a list of questions which were unreasonable and ambiguous. Under the guise of the questions, the patentee sought to extract information for use against the applicant themselves.

14. It is pertinent to mention that the applicant did not justify the contention that under the guise of the questions, the patentee sought to extract information for use against the applicant themselves. No query raised by the patentee has been specifically highlighted by the applicant that would jeopardise his position either before this forum or before the courts. In the absence of any kind of reasoning/justification, I am not inclined to accept the “mere” arguments put forth by the applicant. In fact, it is evident from the proceedings that the applicant realised his mistake and thereafter tried hard to somehow justify his inaction of not replying at all to the letter of the patentee dated 13-3-2012 due to which these submissions can only be termed as an afterthought.

15. It was submitted that to the utter surprise of the applicant, in the April 2012 issue of “*Indian Business Law Journal*”, the attorney for the patentee publicly declared that the strategy on behalf of the patentee was “to keep the potential licensee of a compulsory licence 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 said letter of the patentee seeking more information, because any response on the part of the applicant would have been treated by the patentee on these lines or in the same manner as publicly stated by their attorney. The applicant submitted that this is further exemplified by a subsequent reply received by the applicant from the same patentee in response to a request for voluntary licence for another drug, that demonstrates and fortifies their stand that simply raising queries without rejecting or accepting their application for grant of voluntary licence is a pre-meditated and well-planned strategy to frustrate the efforts of the applicant to obtain a compulsory licence.

16. The applicant ought to have appreciated that a statement/opinion given by the attorney of the patentee in a journal cannot be taken as evidence against the patentee in the present case. Even if the applicant sincerely believed that the statement/opinion was directly attributable to the present case, the applicant did not have, in light of the scheme of the law,

the freedom to bypass the procedure, namely, sincere mutual deliberations for a reasonable period that have been mandated by the law,

17. The applicant submitted that the timelines accompanied by the word “ordinarily” need to be distinguished from timelines that are not accompanied by the word “ordinarily”. It was submitted that the latter timelines are considered absolute and inflexible, without any exceptions or extensions, whereas the former ones are considered to be flexible. S. 84(6)(iv) of the Act states that “for the purpose of cl. (iv), ‘reasonable period’ shall be construed as a period not ordinarily exceeding a period of six months”. Applicant submitted that this limit is the upper limit and in this case it is unreasonable to assign the time-limit of six months as the “reasonable period” especially due to the ongoing litigations between the parties and the attempts by both sides to protect what they deem to be their rights. Precisely, the applicant sought to argue that in this case the reasonable time period should be construed as something less than six months.

18. If the applicant really believed that the “reasonable period” is something less than “six months” why did he not take action in accordance with his beliefs. That is, after making an offer on 2-2-2012 to the patentee and after receiving the patentee's reply dated 13-3-2012, why did the applicant wait till 4-3-2013 to file the present application. On the other hand, it is pertinent to mention that the term “efforts” is not accompanied by the qualifying term “reasonable” and the applicant ought to have appreciated that the duty cast upon the applicant to make “efforts” is absolute and inflexible and without exceptions. The conduct of the applicant in sending a letter (dated 4-2-2012) to the applicant and not at all responding to the reply of the patentee (dated 13-3-2012) cannot be termed as an “effort”. In fact, the applicant did not reply to the patentee's letter (13-3-2012) even till the date of filing of the application for compulsory licence (4-3-2013).

19. Looking at the scheme of the Act, it is clearly apparent that the legislature was fully aware that while a patentee may try to prolong the process of mutual deliberations by raising unnecessary queries, he was also entitled to satisfy himself regarding the credentials and capability of the applicant for a voluntary licence as well as the terms and conditions. The decision to grant a voluntary licence, particularly on a subject-matter covered by a patent, is an important decision for a patentee. While, it is possible that some of the queries raised by the patentee may not be strictly reasonable, it is natural that the patentee may seek additional information from the requesting party to satisfy himself about the credentials and capability of the said party.

20. The applicant ought to appreciate that there was intent behind insertion of the “explanation” to S. 84(6) of the Patents Act, 1970, which explained that the “reasonable period” available with the parties to engage in a dialogue for the purpose of exploring the

possibility of a voluntary licence on reasonable terms and conditions was to be construed as a period not ordinarily exceeding a period of six months. However, if an applicant desirous of getting a voluntary licence were to send a letter to the patentee seeking a licence and upon receipt of a reply were not to take any further step under a preconceived notion that the patentee was engaging in delay tactics, the very purpose of S. 84(6)(iv) of the Patents Act, 1970 would be defeated.

21. In the present case, the applicant made the request for a voluntary licence on 2-2-2012 to the patentee who, by letter dated 13-3-2012, raised some queries. More than four-and-a-half months remained unutilised out of the “reasonable period” prescribed by the legislature for the purpose of mutual confabulations but the applicant chose not to take any action during this precious time period that was available with the applicant. In fact, after receiving the reply from the patentee dated 13-3-2012, the applicant waited for 1 year to file the present application, which demonstrates that the applicant did not intend to engage in any kind of dialogue, whatsoever, after making the initial offer to the patentee.

22. On the face of the record, I am of the view that the applicant's contention that the said letter is “*clearly indicative of the rejection of the application for voluntary licence*” does not hold good, as the aforementioned queries raised by the patentee appear largely to be reasonable. Even if the applicant was under an impression that the patentee was engaging in delaying tactics, the omission of not replying at all to the patentee's said letter dated 2-2-2012 is unexplainable as it goes against the golden thread apparently visible in S. 84(6)(iv). Applicant ought to have appreciated that the provisions relating to compulsory licence are to be invoked as the last resort i.e. if the mutual deliberations do not lead to a result within six months, in accordance with the scheme of the law.

In my opinion, the applicant did not make efforts to obtain a licence from the patentee on reasonable terms and conditions.

MATTERS SUBSEQUENT TO THE MAKING OF APPLICATION

23. The applicant by letter dated 10-5-2013, i.e. after receiving the notice dated 4-5-2013, replied to the patentee's letter dated 13-3-2012. It is pertinent to mention that this reply was sent after a delay of about 14 months. It was submitted by way of petitions under R. 137 that the correspondence that took place between the applicant and the patentee subsequent to the filing of the application for compulsory licence, be taken on record.

24. The applicant raised a contention that in the matter of CLA No. 1 of 2011, the Controller had noted that S. 84(6), where it states that “*but shall not be required to take into account matters subsequent to the making of the application*” (hereinafter referred to as the “restrictive clause”), specifically bars the Controller from considering any measures taken by the patentee subsequent to the making of the application and that the intention of the

legislature appears to be that subsequent measures by the patentee to frustrate the proceedings shall not be considered. It was argued that in view of the above this restrictive clause is applicable only to the patentee.

25. S. 84(6) mandates certain aspects that are required to be taken into account by the Controller while considering an application under S. 84 of the Act. This provision also states what the Controller is not required to take into account as it states that “*but shall not be required to take into account matters subsequent to the making of the application*”. In my view, the restrictive clause is also applicable to the applicant in the present case due to the following reasons:

- I. In the matter of CLA No. 1 of 2011, the opinion expressed therein was limited to the facts of that case and was not exhaustive. That is, it was not suggested/decided in any manner that the efforts made by the applicant subsequent to the filing of the application for compulsory licence can be considered. In fact, the situation for making an observation on the applicability of the restrictive clause vis-à-vis the applicant did not arise in that case.
- II. It is clearly evident that mutual deliberations between the applicant and the patentee cannot succeed if they happen under the constant shadow of a pending application for compulsory licence. Even if they succeed, in most of the cases the success would be attributable to the shadow, which would amount to coercion of the patentee which is strictly not allowed under the scheme of the law.
- III. This is a case where the parties are engulfed in litigation. The restrictive clause will equally be applicable whether there is ongoing litigation or not between the parties. It cannot be said that in the present case, the litigation would have affected the mutual deliberations and hence the application of this clause should not be considered. The law has to apply with equal vigour, with the same intent and in the same manner to all situations falling within the purview of a provision.
- IV. I am convinced that considering such subsequent communication would amount to granting an undue advantage to an applicant seeking a compulsory licence, empowering him to file an application for compulsory licence and simultaneously enter into negotiations with the patentee. In such a case, the applicant would always have an undue advantage and the patentee will always be prejudiced, which is against the underlying intent behind the said restrictive clause.

ANTI-COMPETITIVE PRACTICES

26. It was submitted that the acts of the patentee, purportedly the filing of court cases and delay tactics, fall within purview of “anti-competitive practices”. The applicant contended that the infringement suits on products such as Dasatinib, Sunitinib, and Sorafenib have been

filed before the Hon'ble High Court of Delhi and Bombay against the applicant and that the protracted litigation in progress against the applicant clearly indicates anti-competitive acts adopted by the patentee,

27. In this regard, sub-s. (5) of S. 3 of the Competition Act, 2002, so far as relevant, is reproduced below:

“(5) Nothing contained in this section shall restrict—

(i) the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under—

(a) the Copyright Act, 1957 (14 of 1957);

(b) the Patents Act, 1970 (39 of 1970);

(c) the Trade and Merchandise Marks Act, 1958 (43 of 1958) or the Trade Marks Act, 1999 (47 of 1999);

(d) the Geographical Indications of Goods (Registration and Protection) Act, 1999 (48 of 1999);

(e) the Designs Act, 2000 (16 of 2000);

(f) the Semiconductor Integrated Circuits Layout-Design Act, 2000 (37 of 2000).”

S. 61 of the Competition Act, 2002 is reproduced below:

“61. *Exclusion of jurisdiction of civil courts.*— No civil court shall have jurisdiction to entertain any suit or proceeding in respect of any matter which the Commission or the Appellate Tribunal is empowered by or under this Act to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under this Act.”

28. Prima facie, in view of sub-s. (5) of S. 3 of the Competition Act, 2002, the acts of filing of infringement suits cannot be classified as “anti-competitive”. Even if the acts are, for the sake of argument, considered to be anti-competitive, by virtue of S. 61 of the Competition Act, 2002, the undersigned is not entitled to decide such an issue. I am of therefore of the view that these submissions are of no consequence so far as the present application is concerned.

PRIMA FACIE CASE

29. The applicant sought to argue that the three substantive requirements under cl. (a), cl. (b) and cl. (c) of sub-s. (1) of S. 84 of the Act have been met singularly and independently satisfied by the applicant due to which any irregularity in procedure/timeline may be either waived or condoned or declared to be not applicable.

30. The stage for making a ruling on the applicability of cl. (a), cl. (b) and cl. (c) of sub-s. (1) of S. 84 of the Act on merits has not yet arrived. I am of the considered opinion 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 a voluntary licence, and the exercise of a deliberate choice to only invoke the provisions relating to compulsory licences 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.

The applicant did not follow the scheme of the law as well as the procedure mandated by the law. I am therefore of the considered opinion that the applicant has failed to make out a prima facie case for the making of an order under S. 87 of the Act. The application for compulsory licence, along with all the petitions for condonation of delay/irregularity, is hereby rejected.

Given under my hand and seal on this 29th day of October 2013.
