

MANU/IC/0020/2013

Equivalent Citation: 2013(55)PTC562(IPAB)

**BEFORE THE INTELLECTUAL PROPERTY APPELLATE BOARD
CHENNAI**

M.P. No. 13 of 2013 in OA/5/2013/PT/DEL

Decided On: 05.04.2013

Appellants: **Sugen Inc. and Pharmacia & Upjohn Company LLC**
Vs.

Respondent: **Controller General of Patents, Design, Trademark and
Geographical Indications, Patent Office and Cipla Ltd.**

Hon'ble Judges/Coram:

Prabha Sridevan, J. (Chairman) and D.P.S. Parmar, Member (T)

Counsels:

*For Appellant/Petitioner/Plaintiff: Mr. Andhyarujina, Mr. S.C. Agarwal, Senior Counsels,
Mr. Praveen Anand and Ms. Archana Sankar, Advocates for Anand & Anand*

*For Respondents/Defendant: Mr. P.S. Raman, Senior Counsel for S. Majumdar, Counsel
for R2*

ORDER

Prabha Sridevan, J. (Chairman)

1. In the post grant opposition to Patent No. 209251 which related to a compound which modulates the activity of protein kinases, the Assistant Controller was pleased to revoke the patent. The patent covers the product Sunitinib which is marketed under the name, Sutent. This is the second round of litigation. Earlier, the post grant opposition was allowed and the patent was revoked on 24.9.2012. Aggrieved by that, the appellants filed a writ petition challenging the order on the ground of violation of the principles of natural justice. An interim order was passed by the Writ Court directing the respondent No. 2 not to take any steps towards marketing its drug. Against this, the respondent No. 2 filed an appeal and thereafter, moved the Hon'ble Supreme Court. The order dated 24.9.2012 was set aside for violation of the principles of natural justice and the matter was sent back to the Assistant Controller for disposal after hearing afresh. After rehearing, the Controller again revoked the patent on February 11, 2013. Thus, the matter is before us and now, the appellant presses for stay.

2. Before we heard the counsel for both the parties, we indicated to the counsel that it was in the interest of all parties that the main matter is heard at the earliest, whatever be the outcome of the stay petition. And as agreed by both the counsel, 13th May, 2013 has been fixed for hearing of the main matter.

3. Few days after the matter was argued and orders were reserved, the appellants made a mention for filing written submissions. No permission had been asked for at the end of arguments. So, we informed the counsel who represented the counsel for the appellants that if they should be permitted to file written submissions, the same permission should be given to the respondent No. 2 as well and this would only result in postponement of the pronouncement of the orders and we left it to the counsel to make a decision. Thereafter, the counsel for the appellants submitted that they would

not be filing written submissions.

4. Pursuant to the revocation of the patent, it is alleged that other pharmaceutical companies which make generic drugs are attempting to introduce into the market the generic version of the invention. Mr. Praveen Anand, learned counsel appearing for the appellants submitted that a temporary arrangement could be arrived at between the parties herein by which stay could be granted on the understanding, the appellants would not proceed against the second respondent herein. Learned senior counsel appearing for the second respondent submitted that they were not willing to make any concession which would secure to them an advantage over other generic manufacturers.

5. Three counsel appeared on behalf of the appellants. Learned senior counsel Mr. Andhyarujina, submitted that Section 25(2) of the Patents Act, 1970 ('Act' in short) makes it clear that the opposition can be filed only on the grounds specified in the said section and no other, whereas the grounds raised show that Section 25(2)(b) was given up. It was also submitted that though in the opposition, in paragraph 6.1, the ground of prior public use/public knowledge has been referred to, in Form-7 only four grounds had been raised and they are, Section 25(2)(d), 25(2)(e), 25(2)(f) and 25(2)(h) of the Act. It was submitted that since Section 25(2)(b) was given up, the Controller cannot mix up the grounds under Section 25(2)(d) with prior publication. He referred to page 5 of the impugned order. He relied on *Bachhaj Nahar v. Nilima Mandal* [MANU/SC/8199/2008 : (2008) 17 SCC 491]. He submitted that the reply evidence was filed beyond the statutorily provided time. He submitted that the petition under Rule 137 was filed stating that since no petition could be filed under Rule 138, the irregularity in the procedure may be condoned. According to the learned senior counsel, there is nothing on record to show that an order was passed thereon. He submitted that when the reply evidence was filed beyond time, that ought not to have been considered by the Controller. He submitted that entertaining the reply evidence was wrong since there was no speaking order. The next error pointed out by the learned senior counsel was regarding the second affidavit of Dr. Cui. Learned counsel submitted that this evidence ought to have been sent to the Opposition Board whose recommendations are taken into account by the Controller for arriving at the decision. Without this evidence, the Opposition Board's recommendations are vitiated. He referred to the letter dated 8.9.2009 filed by the respondent which shows that the affidavit of Dr. Cui was received by them and that they were requesting for a chance to file a counter affidavit. Learned senior counsel submitted that both Sections 25(3)(b) and Rule 56(4) must be borne in mind by the Controller. He submitted that it is not clear why the Controller held that the documents cannot be sent to the Opposition Board because it did not form part of the pleadings. Learned counsel referred to *Union of India v. Col. J.N. Sinha* [MANU/SC/0500/1970 : (1970) 2 SCC 458].

6. Learned senior counsel Mr. S.C. Agarwal submitted that Sections 25(3)(b) & 25(3)(c) read with Rule 58 and 59 make it abundantly clear that the rules are mandatory and the Opposition Board must consider all the documents and if any evidence is not considered by it, then, the order is vitiated. He submitted that the words, 'such procedure' in Section 25(3)(c) refer to the Rules and if it is not so, the edifice of the Opposition Board is not in accordance with law. He submitted that the crucial evidence was not considered. He pointed out two grievous errors which vitiate the order; (i) reception of time barred reply evidence and (ii) rejection of the valid evidence. Learned counsel submitted that the ground taken in paragraph 5.1 of the Opposition regarding D-3 is insufficient and the Board has not made any recommendation on D-3.

7. Learned counsel Mr. Praveen Anand made his submissions on merits, after the learned senior counsel made their submissions on the technical flaws. He submitted

that the patent has been on the Register for five years and anticipation is not a ground for attack since novelty is admitted. Learned counsel referred to prior publication D-1, D-2 and D-3 and submitted that the opposition fails for not describing who is the person skilled in the art. He submitted that in D-1, there was a teaching on Pyrrole substituted indolinone compound and the alleged obviousness is only a hindsight obviousness. Learned counsel submitted that all the teachings are towards necessity of having a bridge and the teachings are completely against the invention. Learned counsel submitted that if one sees the reply, it is clear that there are shifting stands with regard to the closest prior art and the opponent is confused. He submitted that there is no pleading of combinatorial library. He submitted that comparative data has been given to ISR and that is available. He submitted that selection of lead compounds may give unexpected results. There was commercial success and the invention addressed a long felt need. The Controller had grievously erred in allowing the opposition without considering any of these aspects.

8. In response, Mr. P.S. Raman, learned senior counsel appearing for the second respondent submitted that it was not open to the appellant to raise all these grounds since they were all available to the appellant in the first round of litigation, but they restricted their challenge only to non-furnishing of Opposition Board's recommendations. It is not open to them to now raise these grounds regarding Section 25(2)(b), reception of reply evidence, non-forwarding of affidavit of Dr. Cui, etc. He submitted that the reply evidence consisted of two affidavits and the second affidavit of Dr. Cui was filed only in response to the reply affidavit. He submitted that 2nd Dr. Cui affidavit was filed with covering letter and not with a petition. He submitted that though the Controller felt that Dr. Cui affidavit was not filed in accordance with law, he has considered it because public interest required that all evidence be received. Therefore, there is no fault on the part of the Controller. Learned counsel submitted that if the ground regarding non-forwarding of the 2nd Dr. Cui affidavit has to be accepted, then a fresh Opposition Board ought to be constituted. This was not the order of the Hon'ble Supreme Court. Therefore, the Controller had totally complied with the directions of the Supreme Court. He submitted that the appellant cannot restrict the issue to four grounds raised in the statement of case. The requirement of pleadings is only to put the opponent on notice of the grounds the appellant should meet and the ground regarding prior publication has been categorically raised by the opponent. Learned counsel submitted paragraphs 5.1.3 and 5.1.4 clearly describe who is the person skilled in the art and no one can be taken by surprise regarding prior publication. It is there in the pleadings and Dr. Cui affidavit also relates to D1 to D3. Learned counsel submitted that while R-58 dealing with reply contains a clause which provides that if no evidence is filed within a period of two months from the date of receipt of the opponent's pleadings and evidence, the patent shall be deemed to be revoked, there is no such in terrorem clause in R. 59. Taking any additional evidence will not vitiate the order, unless it violates the principles of natural justice.

9. In reply, Mr. Praveen Anand, learned counsel for the appellant gave an undertaking on behalf of the appellant that the appellant will not press this patent against CIPLA till the appeal is disposed of.

10. At this stage, Mr. P.S. Raman, learned senior counsel appearing for the second respondent submitted that the interim order passed by this Board on the earlier date of hearing was that 'the impugned order shall be kept in abeyance only as regards the removal of the patents from the Register', whereas on that date, the Registrar had recorded revocation and therefore, in strict sense, there was nothing to be stayed.

11. In view of the last submission made by Mr. P.S. Raman, we sought a clarification from the Deputy Controller of Patents and Designs, Delhi who replied that "it is further

clarified if any patent is revoked by the Controller, IPAB or by any Court the entries are made in the electronic register about the same as per the order and status of the case is corrected as Revoked or ceased without removing the details of the patent from the register". Therefore, it is clear that the patent with its number will remain on the Register and along side an endorsement is made to the effect that it has been revoked or ceased as the case may be.

12. In deciding the prayer of stay, the conditions that normally prevail upon the authority while deciding an Order XXXIX CPC petition will be more or less applicable to us and we should be prima facie convinced that the party seeking stay has made out a case and we should also see whether irreparable injury or hardship will occur.

13. Union of India v. Col. J.N. Sinha [MANU/SC/0500/1970 : (1970) 2 SCC 458] was cited to support the appellant's case that the rules of natural justice can operate only in areas not covered by any law and they do not supplant law but supplement it. Bachhaj Nahar v. Nilima Mandal [MANU/SC/8199/2008 : (2008) 17 SCC 491] was cited in support of their case that no amount of evidence can be looked into upon a plea which was never put forward in the pleadings and that the Court cannot make up a case not pleaded. But in the same case, the Hon'ble Supreme Court has stated that the case not specifically pleaded can be considered where the pleadings in substance, though not in specific terms, contain the necessary averments and the parties were conscious of the plea put forward. Therefore, the fact that in the statement of case certain grounds were taken and certain grounds were not taken will not clinch the issue, if in the body of opposition, the opponent had in clear and categorical terms raised the objection against the grant of patent. Therefore, this issue relating to Section 25(2)(b) will not prevail with us at this stage of grant of stay.

14. The opponent can file reply evidence and it was filed and it was accompanied by a petition under Rules 137 and 138 of the Patents Rules. The reply evidence contains the affidavit of Dr. Rao and affidavit of Mr. Manjinder Singh. The second Dr. Cui affidavit relates totally to the affidavit of Mr. Manjinder Singh and that of Dr. Rao. The appellant who is aggrieved by the non-forwarding of the second Dr. Cui affidavit has lost sight of the fact that the relevance of the second Dr. Cui affidavit arises only if the reply evidence is taken on file and not otherwise. Further, Rule 59 relating to reply evidence does not contain any in terrorem clause and at this stage, we are not inclined to grant stay on this ground alone.

15. Now, we come to the orders passed by the Hon'ble Delhi High Court and the Hon'ble Supreme Court which have great relevance for establishing prima facie case. First is W.P. No. 6361 of 2012, where order was passed on 8.10.2012. The counsel for the appellant herein had urged before the Delhi High Court in this case that the order dated 24.9.2012 must be set aside 'on the short ground that it takes into account the recommendations of the Opposition Board (in short, the Board), a copy of which is not supplied to the petitioner'. It was further submitted before the Delhi High Court that the entire challenge qua the impugned order 'is pivoted on this ground, i.e., the breach of natural justice'. Learned Single Judge of the Delhi High Court was not convinced by the respondent's argument that the Opposition Board's recommendations need not be furnished. Therefore, on a prima facie view of section 25(4), an order was passed that the respondent shall not take any steps towards marketing any drug till 15.12.2012. Then, the matter went to the Division Bench at the instance of the respondent herein who was aggrieved by the direction not to market the drug. This was dismissed by the Hon'ble Division Bench of Delhi High Court. The respondent approached the Supreme Court. The order of the Hon'ble Supreme Court again reiterated the fact that the controversy is on the non-furnishing of a copy of recommendations of the statutory Board, since it was noticed that the Controller had

placed reliance on the recommendations of the Opposition Board without giving a copy of the report, the principles of natural justice were violated. The Hon'ble Supreme Court set aside the order of revocation passed by the Controller and directed the recommendations to be made available to the parties and directed the Controller to decide the matter afresh after allowing the parties to raise their contentions for and against the recommendations of the Opposition Board. It would appear on the face of it that at least the ground relating to Section 25(2)(b) and the reception of reply evidence were grounds that ought to have been raised at the earliest point of time, but the appellant chose to concentrate only on one ground. It is the appellant's contention that the ground relating to non-furnishing of the second Dr. Cui affidavit to the Opposition Board was known to them only after the report was filed and therefore, they could not have raised this ground earlier. Assuming without accepting this plea, we definitely feel that the other two grounds could have been raised in the earlier writ petition, but they had not chosen to do so. Therefore, they cannot be grounds which can be raised now for the purpose of grant of stay.

16. Now, we come to the last order of the Hon'ble Delhi High Court which throws a lot of light. After the impugned order was passed, the appellant again moved the Delhi High Court with a writ petition where the following grounds were raised viz., (a) the Controller had taken into account inadmissible documents D1, D2 and D3 which could have been relied upon only if the second respondent had challenged the grant inter alia on the ground of Section 25(2)(b), (b) even though the second respondent had given up, the ground of challenge that it was publicly known or publicly used, and the same ground was brought into play by the Controller, (c) the condonation of delay in filing the reply statement, and (d) the failure to refer to the 2nd Dr. Cui affidavit to the Board. On behalf of the second respondent, a preliminary objection to the maintainability of the writ petition was raised before the Hon'ble Delhi High Court. It was contended that the matter was in effect remanded to the Controller for a limited aspect and the aspects which were now raised in the writ petition were not available. Learned Single Judge appears to have indicated in the order that he was "persuaded to accept the submissions advanced by the counsel on behalf of the second respondent" who is also the second respondent herein, Learned Judge also stated that the directions contained in the judgment of the Supreme Court are explanatory.

17. It was brought to our notice that the appellant had filed a civil suit against Natco, a third party for injunction.

18. The grounds that were raised on merits by the appellant are grounds that are to be examined in detail while we hear the appeal. According to the appellant, they have a strong case for patentability of the invention and the prior arts are actually teaching away from the invention. The jurisdiction of this Board is restricted and limited by the statute. We have no powers to restrain the second respondent from marketing the drug or to direct them to keep accounts if they so market the drug. However, we cannot brush aside the apprehension of the appellant that if stay is not granted, third parties will rush in with their generic drugs and that it will be impossible to set the clock back thereafter. We are also informed by the letter from the Controller's Office that the patent will not be removed and the details of the patent remain on the Register with the endorsement as to the orders passed by the Controller or IPAB or the High Court. Considering the injury that may be caused to the appellant, if the order of revocation is not stayed, we grant stay till 13th May, 2013, subject to the undertaking given by the appellant that they will not use the revoked patent against the second respondent herein in other proceedings. The petition is ordered accordingly. List the main appeal along with the connected appeal on 13th May, 2013.