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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **FAO(OS) (COMM) 158/2019 and CM APPL. 30589/2019 (Stay)**

NATCO PHARMA LIMITED

..... Appellant

Through: Mr.C.S. Vaidyanathan, Senior Advocate with Ms.Rajeshwari, Mr.Sai Deepak, Mr.Natraj and Mr. Tahir A.J, Advocates.

versus

BAYER HEALTHCARE LLC

.... Respondent

Through: Dr.A.M.Singhvi, Senior Advocate, Mr.P.V. Kapur, Senior Advocate with Ms. Archana Shankar, Mr. Dhruv Anand, Ms.Udita Patro, Ms.Tusha Malhotra, Ms. Prachi Agrawal, Ms.Kavya Mammen, Mr.Avishkar Singhvi, Mr.Sindhant Kapur, Ms.Kaveri Gupta, Advocates.

CORAM:

JUSTICE S.MURALIDHAR

JUSTICE TALWANT SINGH

ORDER

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11.07.2019

Dr. S. Muralidhar, J.:

1. Notice. Ms. Archana Shankar, learned counsel accepts notice on behalf the Respondent/Plaintiff. With the consent of learned counsel for the parties, the appeal has been heard finally.

2. This appeal by the Defendant in C.S. (COMM) No.343/2019 is directed

against the order dated 5th July, 2019 passed by the learned Single Judge in I.A. No.8878/2019 in the said suit whereby, *inter alia*, the Appellant was restrained from infringing Indian patent IN No. 240207 held by the Respondent/Plaintiff.

3. The Respondent, which is part of the Bayer Groups of Companies, filed the aforementioned suit against the Appellant/Defendant for permanent injunction to restrain it from making, using, selling, distributing, advertising, exporting, offering for sale and in any other manner directly or indirectly dealing with any product that infringes the subject matter of the Plaintiff's Indian Patent No. 240207 or any claims thereof, including Regorafenib and any forms thereof.

4. The Plaintiff averred in the plaint that it was granted the above patent on 29th April 2010 and the drug covered i.e. Regorafenib is used for treatment of metastatic colorectal cancer and advanced gastrointestinal stromal tumors. It was averred that this was a valid and subsisting patent having a term of 20 years from 22nd July, 2004. It was disclosed in the plaint that Appellant/Defendant had filed a revocation petition against the said patent before the Intellectual Property Appellate Board (IPAB) and that the said application is pending. The plaint also disclosed that another patent registered in favour of the Respondent/Plaintiff is IN 215758 which related to "Carboxyaryl Substituted Diphenyl Ureas" and that "the said patent does not cover Regorafenib".

5. It was stated in the plaint that in the last week of June 2019, the Plaintiff

became aware of the infringing activities of the Defendant when it found out from various sources that the Defendant was planning to commercialize the Regorafenib product in Indian market. It was further averred that the Defendant was planning to introduce in the market the said product under the brand name 'Regonat' and that the said product had not yet been commercially launched.

6. The Plaintiff referred to a photograph of the Defendant's product obtained by its personnel which showed that the tablet strength was identical to the strength in which the Plaintiff markets its commercial Regorafenib products viz., Stivarga, Nublexa and Resihance. It was alleged therefore that the Defendant had merely copied the patented product of the Plaintiff. In Para 34 of the plaint, it was averred that the Plaintiff had recently learnt that the Defendant had filed in the City Civil Court in Hyderabad, a suit for declaration of non-infringement against the Plaintiff pertaining to the product having international non-proprietary name Regorafenib and that the said suit was listed on 28th June, 2019. It was further stated that notice appeared to have been made returnable on 8th July, 2019.

7. In para 35 (iv) of the plaint it was averred that without waiting for an injunction sought in the suit to be granted, the Defendant appeared to have "sent its infringing products to their distributors, although the infringing product has not entered the commercial and retail market as believed by the by the Plaintiff."

8. The suit C.S.(COMM) No.343/2019 was listed first for hearing before the
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learned Single Judge on 5th July, 2019 along with the aforementioned I.A. 8878/2019 filed by the Plaintiff under Order XXXIX Rules 1 and 2 CPC seeking an interim injunction.

9. A perusal of the impugned order shows that the Defendant appeared on caveat and was represented by a senior counsel. Para 11 of the impugned order indicates that the learned Single Judge “straightaway asked the senior counsel for the Defendant as to why the interim order in terms of the order dated 31st May, 2019 in CS(COMM) No. 314/2019 titled as ***Sterlite Technologies Ltd. V. ZTT India Pvt. Ltd.*** should not be passed till the completion of pleadings and hearing of the application for interim relief”. A copy of the aforementioned order in ***Sterlite Technologies Ltd.*** (*supra*) was also “handed over to the senior counsel for the Defendant.”

10. At this stage it requires to be noticed that the suit, in which the said interim order in ***Sterlite Technologies Ltd. v. ZTT India Pvt. Ltd.*** was passed (incidentally by the same learned Single Judge who passed the impugned interim order), was for a permanent injunction restraining the Defendant in that case from infringing two Indian patents. The subject patents there were ‘method patents’. The case of the Plaintiff in that case was that “the optical fibre being marketed by the Defendant had the same technical parameters as of the optical fibres of the Plaintiff produced with the patented technology.” The said interim order in ***Sterlite Technologies Ltd.*** granting ad interim injunction was passed *ex-parte*. Interestingly in Para 9 of the said order, the learned Single Judge observed that “at this stage, it is not possible to form an opinion, even *prima facie*.” In the said order the

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learned Single Judge was of the view that there should invariably be an interim injunction granted in the first place in favour of a patent holder for the reasons set out in paras 16-17, which read as under:

“16. I say so because, a patentee, even after succeeding in the suit, in the absence of any interim order, is entitled only to profits earned by the defendant and which do not reflect the profits which the plaintiff would have earned if there had been no infringement. As aforesaid, the infringer is able to market at a much lower price, resulting in earning far less profits than which the patentee would have earned if there had been no infringement. The patentee would then also be entitled to punitive action against defendant for violation of the interim order.

17. Such arrangement, in my view, will also ensure that suits for infringement are not contested, only to take advantage of and to reap the fruits of delays in Court process, in spite of defendant in its heart knowing the truth. Each defendant, in its heart knows the truth and if in spite of knowing that it is in infringement, violates the interim order, will, besides taking the risk of financial liability, also run the risk of penal consequences. This will also ensure purity of the Court process.”

11. According to the learned Single Judge “this experimentation, with interim orders in patent infringement suits, is the need of the hour.”

12. On the above reasoning there was in the instant case by the impugned order granted, on the lines of the order granted in *Sterlite Technologies Ltd. (supra)* till the next date i.e. 20th September 2019, an interim injunction restraining the Appellant/Defendant herein from infringing the IN Patent No. 240207. A copy of the order in *Sterlite Technologies Ltd. (supra)* was

annexed to the impugned interim order “for convenience”.

13. Mr. C.S. Vaidyanathan, learned Senior counsel appearing for the Defendant/Appellant submitted as under:

(i) The impugned interim order is contrary to the settled law explained in several decisions of the Supreme Court and this Court in the matter of granting an ad interim injunction. In particular there is no satisfaction recorded of the Plaintiff having made out a *prima facie* case or that the balance of convenience is in his favour or that it would suffer irreparable hardship if the injunction is not granted.

(ii) On essentially the same issue regarding the validity of the patent IN240207 in respect of Regorafenib, the earlier suit filed by the Defendant in the Civil Court in Hyderabad against the Plaintiff is pending and, therefore, in terms of Section 10 of the Code of Civil Procedure, 1908 (CPC), the suit before this Court could not have proceeded.

(iii) There was no presumptive validity in the grant of a patent; there was already a revocation application filed against the suit patent pending before the IPAB; inasmuch as the compound patented in IN240207 stood already disclosed in IN 215758 and was in the public domain there could not have been a valid patent granted in respect thereof again in favour of the Plaintiff, particularly since the Plaintiff had after making such disclosure deleted the claim made in respect thereof in IN 215758.

(iv) The impugned order overlooked the fact that the defendant's product is

already in the market. In support of this assertion, Mr. Vaidyanathan tendered in this Court an affidavit on behalf of the Defendant stating *inter alia* that it had released its product Regonat in the market on 27th June 2019.

(v) Although the Plaintiff's product was in market since 2013, the price of a bottle containing 28 tablets was either Rs.36,000/- or Rs. 40,000/- (for 2 varieties of the tablets), whereas the Appellant/Defendant's product price is Rs,9,000/- per bottle. He added that the Defendant is prepared to provide medicines to 2000 patients free for life.

(vi) The impugned order does not account for the balance of convenience and the prejudice that would be caused to the Defendant if the interim injunction was to be granted. According to Mr. Vaidyanathan assuming without admitting the Plaintiff's case that its annual sales of Regorafenib is around Rs. 25 Crores, the Defendant was prepared to deposit in the Court Rs. 5 Crores without prejudice to its rights and contentions towards the plausible losses that might be suffered by the Plaintiff.

(vii) Mr. Vaidyanathan also made reference to the decision of the Division Bench of this court in ***Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals 2015 (63) PTC 257 [Del][DB]*** where *inter alia* it was held that the safe approach for a Single Judge to adopt in the matter of grant of interim injunction in a patent infringement suit was to deny relief in the first hearing and "if there is slightest doubt, set down the application for hearing at the earliest opportunity, even while requiring some semblance of formal disclosure of the defendant". He accordingly prayed that the matter

regarding grant of interim injunction, after setting aside the impugned order, should be remanded to the learned Single Judge for fresh disposal on merits.

14. Dr. A.M. Singhvi and Mr. P.V. Kapur, learned Senior counsel appearing for the Respondent/Plaintiff made the following submissions:

(i) The elements of *prima facie* case, balance of convenience and irreparable hardship to the Plaintiff in support of the grant of interim injunction in its favour, even if not so stated in express terms, were discernable from the impugned order.

(ii) It was plain that the only defence of the Defendant was regarding invalidity of the patent whereas there was sufficient admission even in the plaint in the suit filed by the Defendant in the City Civil Court at Hyderabad that the suit patent covered the product Regorafenib.

(iii) Without pursuing its revocation application pending before the IPAB to its logical conclusion, the Defendant had risked introducing its product in the market. This was dishonest and done knowing fully well that the product sought to be introduced by it was already covered by a valid patent held by the Plaintiff.

(iv) The Defendant had in the suit filed in the City Civil Court at Hyderabad only spoken of its proposal to 'explore' the market. It was inconceivable that between first hearing of the said suit on 28th June, 2019 and the date of hearing of the Plaintiff's suit by the learned Single Judge of this Court on

5th July, 2019, the Defendant could have commercially launched its product in the market. In the list of dates filed in the present appeal it is disclosed that the product was launched by the Defendant on 20th June 2019 whereas in the affidavit now filed with the present appeal, it is stated that the product was released in the market on 27th June 2019. These inconsistent statements give rise to grave doubts whether the product of the Defendant was actually in the market.

(v) The mere fact that the ‘genus’ of the formula for Regorafenib was disclosed in IN 215758 would not preclude the Plaintiff from being granted a patent in respect of a specific species thereof i.e. for the drug Regorafenib. Mr. Kapur placed reliance on a decision dated 8th February 2017 of the US Patent & Trademark Office in support of such proposition.

(vi) Serious prejudice would be caused to the Plaintiff if the interim injunction granted would not continue. Reliance is placed on the decision in ***Merck Sharp & Dohme Corporation*** (*supra*) to urge that irreparable hardship and loss which cannot be compensated monetarily would be caused to the Plaintiff, as a holder of a valid pharmaceutical patent, if the interim injunction granted by the learned Single Judge was not continued.

15. By way of rejoinder, Mr. Vaidyanathan pointed out that the Defendant’s revocation application filed in the IPAB in October, 2014 itself could not be taken up for hearing for various reasons beyond the Defendant’s control. In particular, the IPAB itself was not functional due to the absence of a Technical Member for over two years. It is further pointed out that the

Defendant's suit in the City Civil Court, Hyderabad was filed first as a commercial suit on 21st June, 2019 but after removal of objections and refiling, it could be heard as a regular suit only on 28th June, 2019. The facts averred in the said plaint pertained to the date of initial filing i.e. 21st June, 2019.

16. The above submissions have been considered. At the outset, the Court would like to observe that the impugned order was clearly not an 'ex parte' order in an application for interim injunction, in a suit alleging infringement of a patent. The Defendant appeared on caveat on the very first date and made the submissions. On the other hand, the order which has been adopted by the learned Single Judge as the order in the application for interim injunction in the suit filed by the present Respondent/ Plaintiff i.e. the order in *Sterlite Technologies Ltd. (Supra)* was an *ex parte* order.

17. This Court would like to preface the discussion by reference to the settled law in relation to the passing of orders of interim injunction. Illustratively, reference may be made to the decision in *Wander v. Antox (1990) (Supp) SCC 727* where the legal principles were enunciated as under:

“9. Usually, the prayer for grant of an interlocutory injunction is at a stage when the existence of the legal right asserted by the plaintiff and its alleged violation are both contested and uncertain and remain uncertain till they are established at the trial on evidence. The court, at this stage, acts on certain well settled principles of administration of this form of interlocutory remedy which is both temporary and discretionary. The object of the interlocutory injunction, it is stated

“...is to protect the plaintiff against injury by violation of his rights for which he could not

adequately be compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial. The need for such protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated. The court must weigh one need against another and determine where the "balance of convenience lies."

The interlocutory remedy is intended to preserve in status quo, the rights of parties which may appear on a prima facie. The court also, in restraining a defendant from exercising what he considers his legal right but what the plaintiff would like to be prevented, puts into the scales, as a relevant consideration whether the defendant has yet to commence his enterprise or whether he has already been doing so in which latter case considerations somewhat different from those that apply to a case where the defendant is yet to commence his enterprise, are attracted."

18. In *Dorab Cawasji Warden v. Coomi Sorab Warden (1990) 2 SCC 117*, the Supreme Court explained:

"16. The relief of interlocutory mandatory injunctions are thus granted generally to preserve or restore the status quo of the last non-contested status which preceded the pending controversy until the final hearing when full relief may be granted or to compel the undoing of those acts that have been illegally done or the restoration of that which was wrongfully taken from the party complaining. But since the granting of such an injunction to a party who fails or would fail to establish his right at the trial may cause great injustice or irreparable harm to the party against whom it was granted or alternatively not granting of it to a party who succeeds or would succeed may equally cause

great injustice or irreparable harm, courts have evolved certain guidelines. Generally stated these guidelines are:

(1) The plaintiff has a strong case for trail. That is, it shall be of a higher standard than a *prima facie* case that is normally required for a prohibitory injunction.

(2) It is necessary to prevent irreparable or serious injury which normally cannot be compensated in terms of money

(3) The balance of convenience is in favour of the one seeking such relief.

Being essentially an equitable relief the grant or refusal of an interlocutory mandatory injunction shall ultimately rest in the sound judicial discretion of the Court to be exercised in the light of the facts and circumstances in each case. Though the above guidelines are neither exhaustive or complete or absolute rules, and there may be exceptional circumstances needing action, applying them as prerequisite for the grant or refusal of such injunctions would be a sound exercise of a judicial discretion.”

19. The decision in *Dorab Cawasji (supra)* has been followed by the Supreme Court in its recent judgment in *Tek Singh v. Shashi Verma 2019 (3) SCALE 86*, in which it clarified that “when a mandatory injunction is granted at the interim stage much more than a mere *prima facie* case has to be made out.”

20. In *Shiv Kumar Chadda v. Municipal Corporation of Delhi (1993) 3 SCC 161*, reiterating the above principles, the Supreme Court held:

"30....It has been pointed out repeatedly that a party is not entitled to an order of injunction as a matter of right or course. Grant of injunction is within the discretion of the court and such discretion is to be exercised in favour of the plaintiff only if it is proved to the satisfaction of the court that unless the

defendant is restrained by an order of injunction, an irreparable loss or damage will be caused to the plaintiff during the pendency of the suit. The purpose of temporary injunction is, thus, to maintain the status quo. The court grants such relief according to the legal principles - *ex debito justitiae*. Before any such order is passed the court must be satisfied that a strong *prima facie* case has been made out by the plaintiff including on the question of maintainability of the suit and the balance of convenience is in his favour and refusal of injunction would cause irreparable injury to him."

21. Matters involving alleged infringement of patents constitute a separate species of litigation. A further sub-species would be those concerning pharmaceutical patents. This is because the law concerning them under the Patents Act 1970 and other related legislation has peculiar elements that would have to be kept in view by the Court. Unsurprisingly, therefore, there is a growing volume of Indian case law dealing with the parameters that should weigh with the Court while examining the case of alleged infringement of pharmaceutical patents. While the parameters that have to generally be kept in view in all suits where interim injunctions are sought would apply in such cases as well, they would indubitably involve other parameters which have been discussed in a large number of decisions including the decision that both parties have relied upon, *Merck Sharp & Dohme Corporation (supra)*. A further example, illustratively, is the decisions in *Cipla Ltd. v. F.Hoffmann-La Roche Ltd. (2009) 40 PTC 125 (DB)*. The question of challenge to the validity of pharmaceutical patents has also engaged the attention of the Indian Courts at all levels. The need for the principles that would have to be kept in mind while dealing with those contentions, even at the interim injunction stage, hardly need be emphasised.

Illustratively, reference may be made to *Novartis Ag v. Union of India* (2013) 6 SCC 1.

22. Dr. Singhvi sought to defend the impugned order in so far as the forming of a view of the existence of a *prima facie* case in favour of the Plaintiff. According to him the appellate Court as ‘a Court of substance’ has to go by an overall reading of the order under appeal and not by the particular wording of it. He referred to paras 12 and 13 of the impugned order and submitted that they reflected that the learned Single Judge had in effect held that the Plaintiff had a *prima facie* case in its favour. The said paras read as under:

“12. The senior counsel for the defendant draws attention to para no.9 of the plaint, where the plaintiff has disclosed Indian Patent No.IN 215758 also held by it and has contended that the plaintiff, while applying for Indian Patent No.IN 215758 has disclosed what is the subject matter of suit patent being Indian Patent No.IN 240207, and made a claim with respect “REGORAFENIB” but subsequently deleted the same. It is argued that Indian Patent No.IN 240207 is invalid for this reason only, because the plaintiff, after making a disclosure of Indian Patent No.IN 240207 could not have subsequently sought separate patent therefor and was not entitled thereto on account of waiver and acquiescence. It is also contended that there is no inventive step.

13. In my view same would be a ground for invalidity of the patent. The same would also be a ground for defeating the suit and if the suit is defeated, the consequences as provided in the order dated 31st May, 2019 in *Sterlite Technologies Ltd. supra* would not apply.”

23. The observation of the learned Single in para 14 of the impugned order

on the above submission simply reads thus: “The argument of the Defendant is thus not a ground at least till the next date of hearing, for not passing interim orders in terms of *Sterlite Technologies Ltd. (supra)*” Far from rejecting the submission, the learned Single Judge acknowledges that it would be ‘a ground for invalidity of the patent’ and would also be ‘a ground for defeating the suit’. However, there is no formation of an opinion of the Plaintiff having made out a *prima facie* case in its favour for grant of an interim injunction. Even the order in *Sterile Technologies Ltd. (supra)* incorporated as it were ‘by reference’ by the learned Single Judge in the impugned order does not set out any *prima facie* view. On the contrary, it records in para 9 that ‘at this stage, it is not possible to form an opinion, even *prima facie*’. As regards the other two elements viz., balance of convenience and irreparable hardship, there is no mention of these, even impliedly in the impugned order.

24. Although, there are special features in litigation involving infringement of patents, that still would not obviate the Court dealing with the question of grant of interim injunction to record the three important elements as have been stressed in a large number of decisions of the Supreme Court. While the Court agrees with Dr. Singhvi that it is not necessary that the order granting or refusing interim injunction should expressly state about the above elements but a reading of the order should indicate the forming of an opinion by the Court on the said aspects. A reading of the impugned order does not reflect that the Court has formed such an opinion on the three elements.

25. Again, each case of alleged infringement of patent, particularly a pharmaceutical patent, would turn on its own facts. It is not possible to conceive an ‘across-the-board’ blanket approach that would apply to all such cases, where as a matter of routine at the first hearing there would be a grant of injunction in favour of the Plaintiff. The decision in the application of interim injunction has to necessarily indicate the view of the Court on the three elements mentioned herein before and the additional features when it involves a case of alleged infringement of a patent, and in particular, a pharmaceutical patent. It is not the length of the order or its precise wording that matters. It is necessary, however, that the factors mentioned hereinbefore must be discernible from the order which comes to a conclusion one way or the other regarding grant of an interim injunction.

26. The Court would also like to add here that the impugned order which restrains the Defendant from infringing the suit patent does not lend itself to sufficient clarity. Although the Appellant/Defendant has understood it to mean that the Defendant is restrained from manufacturing, selling its product in the market, it would have helped if the order specified what the Defendant can or cannot do. There is a possibility, given the wording of the impugned order that it might lead to further litigation on whether in fact there has been compliance or not with the said order.

27. This Court hastens to clarify that it should not be understood as having expressed any opinion one way or the other on the respective contentions of the parties noted hereinbefore. These have been set out only to highlight what their respective cases at this stage for grant of interim injunction are.

These necessarily have to be considered. A reading of the impugned order does not reflect a consideration of the above issues placed before the Court by the parties. It must be added that the broad aspects of the submissions are indeed contained in the plaint, pleadings and documents which were available to the learned Single Judge when the impugned interim order was passed.

28. For the aforementioned reasons, the Court is of the view that the impugned interim order requires to be set aside and the application for interim injunction i.e. IA 8878/2019 be heard once again by the learned Single Judge on merits.

29. It was urged before this Court on behalf of the Respondent/Plaintiff that till the next date before the learned Single Judge, this Court should continue the interim injunction granted by the impugned order. The Court is not inclined to accept this prayer. It is however clarified that the status quo as on 5th July, 2019 prior to the passing of the impugned interim order will be maintained by the Appellant.

30. The Court directs IA 8878/2019 to be placed for hearing before the learned Single Judge on 17th July, 2019. The Appellant will, on or before 16th July, 2019 file its reply to the said application with an advance copy to the Plaintiff. It will be open for the Plaintiff to present its rejoinder thereto, if any, in the Court on 17th July 2019.

31. The learned Single Judge, will after hearing the parties, pass a fresh

order uninfluenced by the order in *Sterlite Technologies Ltd. (Supra)* or the order dated 5th July 2019, which has been set aside by this Court or by the present order.

32. The appeal and application are disposed of in the above terms.

33. Copy of this order be given *dasti* under the signatures of the Court Master.

S. MURALIDHAR, J.

TALWANT SINGH, J.

JULY 11, 2019

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