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

Date of decision: 10th July, 2023

+ **CS(COMM) 94/2022 and I.A. 1212/2023, 3543/2023**

PFIZER INC & ORS.

..... Plaintiffs

Through: Mr. Pravin Anand, Tusha Malhotra,
and Aditya Kaushik, Advocates. (M:
8860276202)

versus

**WEST-COAST PHARMACEUTICAL WORKS
LIMITED**

..... Defendant

Through: Mr. Vikas Khera, Mr. Vishal Sharan
and Mr. Ved Prakash, Advocates.(M:
9456040966)

CORAM:

JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J.(Oral)

1. This hearing has been done through hybrid mode.
2. The present suit was filed for permanent injunction restraining infringement of patent numbers IN 218291, IN 249316, IN 243571 and IN 250050. The said patents as per the Plaintiff cover two products i.e., Palbociclib and Crizotinib in their different forms. The Plaintiffs are assignees to the said patents being asserted in the suit. The case of the Plaintiffs is that the patents are valid till 10th January, 2023 (Palbociclib) and 15th August, 2025 (Crizotinib) and are being infringed by the Defendant.
3. The details of the suit patents being asserted and the products they cover, as averred by the Plaintiffs are as follows:
 - (a) IN 218291 is assigned to Plaintiff No. 2- Warner Lambert Company LLC and the said patent covers and claims the product, which is commercially sold under the trade name 'Ibrance' and in India as 'Palbace'.



The bibliographic details of IN 218291 are as follows:

Indian Patent No.	218291
Indian Patent Application no.	1733/DELNP/2004
Patentee	Plaintiff No. 2 (Warner-Lambert Company LLC)
PCT Application No.	PCT/IB03/00059
Priority Date	January 22, 2002
International Filing Date	January 10, 2003
National Phase entry-filing date of Indian Application	June 18, 2004
Grant date	March 31, 2008
Patent valid up to	January 10, 2023

(b) IN 249316, IN 243571, and IN 250050 cover and claim the product of the Plaintiffs', 'Crizotinib', which is commercially sold under the trade name Xalkori and in India as Crizalk. Plaintiff No. 1- Pfizer Inc is the assignee of IN '571 and IN '050 and Plaintiff No. 3- Sugen LLC is the assignee of IN '316. The bibliographic details of the three patents covering 'Crizotinib' are as follows



India Patent No.	249316	243571	250050
Title	"an amino-pyridine compound of formula I"	"Aminopyridine compounds as protein kinase inhibitors for the treatment of cancer"	"enantiomerically pure aminopyridine compound of formula (1)"
Patentee	Plaintiff No. 3 (Sugen Inc.)	Plaintiff No. 1 (Pfizer Inc.)	Plaintiff No. 1 (Pfizer Inc.)
Indian Patent Application No.	3734/DELNP/2005	890/DELNP/2007	144/DELNP/2007
PCT Application No.	PCT/US2004/005495	PCT/IB 2005/002695	PCT/IB2005/002837
International Filing Date	February 26, 2004	August 15, 2005	August 15, 2005

4. The allegation in the present suit was that the Defendant had listed these products as being available for manufacture and sale, on its website. Thus, the Plaintiffs sought an injunction against launch of any products which would be infringing of its suit patents. This suit was first listed before this Court on 9th February 2022 and on the said date, an *ex-parte* injunction was granted against the Defendants vide order dated 9th February, 2022 in the followings terms:

"23. Till the next date of hearing, the defendant is restrained from releasing into the market or concluding or entering into any contracts with manufacturers for manufacture or marketing of Palbociclib, Crizotinib or pharmaceutically acceptable salts thereof, in which the plaintiff holds a valid suit patent. The defendant is also restrained from, directly or indirectly, marketing, manufacturing or releasing into the market Palbociclib, Crizotinib or its



pharmaceutically acceptable salts, in formulations of any strength whatsoever.”

5. Thereafter, pleadings have been completed in the matter. The Defendants have challenged the territorial jurisdiction of this Court by way of an application filed under Order VII Rule 11 CPC but did not choose to file written statement. On 22nd August, 2022, an affidavit of Mr. Kamlesh Patel was filed by the Defendant. The relevant portions of the said affidavit reads as under:

“6. At the outset, it is submitted that the Defendant applied to procure product permissions from the Drugs Authority for manufacturing medicines under the drugs Palbociclib Capsules and Crizotinib Capsules believing that the drugs Palbociclib and Crizotinib are not patented. It is pertinent to mention that the Drugs Department provided the product permissions to the Defendant after following the due procedure enshrined under the Drugs and Cosmetics Act, 1940 and therefore any claim regarding mala fide intention of the Defendant is misconceived and not called for. It is submitted that the Drugs Department should have not granted the product permissions to the Defendant. Drugs Department ought to know about the patents Palbociclib and Crizotinib in favour of the Plaintiffs.

7. That the defendant after getting the product permission from the Drugs Authority and believing that there were no patents contacted the third parties. It is pertinent to note that the defendant has not manufactured any drugs under the subject patents. It is submitted that if the Drugs Department had not given the product permissions to the Defendant, the Defendant would have not published the flyer or advertised about the alleged drugs. In any case, the Defendant has never manufactured the drugs and has no intention to use the same till the validity of alleged



patents. The Defendant has already filed request on 10/08/2022 before Food & Drugs Department for cancellation of product permissions.

9. Without prejudice to the statement on maintainability of suit and jurisdiction of the Hon'ble Court, I submit on instructions by Defendant company to state, as follows :

a. That the Defendant will not launch any product based on Palbociclib and Crizotinib either as API or any other form or in its pharmaceutically acceptable salts till the validity of IN 218291, IN 249316, IN 243571 & IN 250050;

6. Vide order dated 22nd August, 2022 after considering the affidavit filed by the Defendant, the following order was passed:

"1. An affidavit has been filed on behalf of the Defendant sworn by Mr. Kamlesh C. Patel, Director/Authorised Representative of the Defendant in which apart from objection to territorial jurisdiction of this Court, it is stated in Para 9 of the affidavit that the Defendant will not launch any product based on Palbociclib and Crizotinib either as API or any other form or in its pharmaceutically acceptable salts till the validity of IN 218291, IN 249316, IN 243571 and IN 250050. It is further stated that present suit can be disposed of by recording the above undertaking.

2. Affidavit is taken as undertaking on behalf of the Defendant."

7. Thus, the Defendant gave an undertaking not to launch any product which would be infringing of the suit patents. Subsequently, on 23rd September, 2023 a submission was made on behalf of the Defendant that the undertaking was subject to arguments before the Court on maintainability and jurisdiction. The same was not acceptable to the Plaintiff and hence a



stalemate ensued despite the Defendant having giving an undertaking that the suit could be disposed of by recording its stand.

8. An application ***I.A., 3543/2023*** was also filed under Order XXXIX Rule 2A in which notice was issued on 22nd February, 2023. On same date, the interim injunction was made absolute till the adjudication of the suit. Vide order dated 11th April, 2023, a Director of the Defendant was directed to appear before the Court as the explanation given by the Defendant for the continued listing of the impugned products was found to be unacceptable to the Court.

9. Today Mr. Dave Upendarkumar has appeared before the Court and has given a statement which has been recorded. As per the said statement, the Defendants' stand is that the state Food and Drugs Control Administration (FDCA), State of Gujarat, approval for both products, has been surrendered. A copy of the said letter dated 10th August, 2022 written by the Defendant to the FDCA has also been handed over to the Court. The Defendant is also agreeable to stand by the undertaking given by Mr. Kamlesh Patel. It is stated that the listings of the patented products have also been removed from the website. The statement is set out below for the sake of ready reference:

“Statement of Mr. Dave Upendarkumar S/o Mr. Vishnuprasad, Age: 56 years, R/o, A-10, Radheshyam Society, Kathavada Road Naroda Ahmadabad City, Gujarat-382330

On S.A.

I, Dave Upendarkumar, Technical Director, am in charge of quality control, production and quality assurance in West-Coast Pharmaceutical Works Ltd. I have been working in this company for the last 32 years.



I am a graduate by qualification, and have completed B.Sc. in Chemistry. I have also obtained the Food and Drugs Control Administration (FDCA) certification in tablet and liquid section.

I state and submit that the company has not manufactured or sold a single product of Palbociclib or Crizotinib. The Defendant in the present suit West-Coast Pharmaceutical Works Ltd. had obtained a drug approval from the said drug department without being aware of the status of patents of the products. For the said purposes, the Defendant had prepared a raw label and had submitted the same for the approval. Whenever any new product is approved by the State FDA for the Defendant, the same is put up on the website for marketing and promotion. In the present case, after the suit was filed and injunction was granted, we had instructed the concerned IT personnel to remove the listings of these two products. However, the same appears to have not happened due to an inadvertent error by the IT Department. The said listings have now been removed.

The Defendant has not even sourced or purchased the API for these two product formulations, from any procurement entity. I stand by the undertakings given by Mr. Kamlesh Patel who is one of the Directors of the Defendant.

The Defendant shall be bound by the submissions made in the affidavit of Mr. Kamlesh Patel.”

10. One of the products i.e., Palbociclib, covered by IN 218291 has also become off-patent as the patent has completed its full term in January, 2023. The undertaking of the Defendant to the effect that it does not intend to manufacture, sell, or offer for sale Crizotinib products is accepted and taken on record.
11. The statement made on behalf of the Defendant today clearly suggests that there have been no steps taken by the Defendant towards manufacture or sale of the products which were subject matter of the suit patents.



12. Under such circumstances, no useful purpose is served in continuing the suit inasmuch as Defendant having not manufactured or sold any product of Palbociclib or Crizotinib, no rendition of accounts would also be liable to be directed. However, insofar as the non-removal of the listing on the website is concerned, the explanation that the instructions were given to the IT department which did not remove the listing is clearly unconvincing. However, since the listing of the infringing products have now been removed and no manufacture or sale of any infringing products has been done by the Defendants, the application under Order 39 Rule 2A is disposed of by cautioning the Defendant to be careful in future and ensure that orders passed by the Court are duly complied with.

13. Accordingly, accepting the undertakings on behalf of the Defendant the suit itself is liable to be decreed. Since the product patent in respect of 'Palbociclib' has already expired, a decree of permanent injunction is issued against the Defendant from manufacturing or selling any 'Crizotinib' pharmaceutical preparations till the expiry of the patents IN 249316, IN 243571 and IN 250050 i.e., 15th August, 2025.

14. Since the suit itself has been decreed, the contempt application is also disposed of. However, the Defendant shall pay a sum of Rs.3,00,000/- to the Plaintiff within six weeks, as costs.

15. Insofar as the product Palbociclib is concerned, the interim injunction already granted shall no longer be operational.

16. The suit is decreed in the above terms. All pending applications are disposed of.

PRATHIBA M. SINGH
JUDGE

JULY 10, 2023
dj/am