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

\+ CS(COMM) 737/2018

PFIZER INC. & ORS ..... Plaintiffs

Through : Mr.Pravin Anand, Ms.Tusha Malhotra, Ms.Rashi Punia, Advocates.

versus

NAGESH PALEPU & ORS ..... Defendants

Through : Mr.J. Deepak, Mr.Nataraj Goswami, Mr.Avinesh K.Sharma, Advocates.

CORAM:
HON'BLE MR. JUSTICE YOGESH KHANNA

ORDER

% 15.03.2018

IA No.3622/2018

Exemption allowed, subject to all just exceptions.

The application stands disposed of.

IA No.3621/2018

In view of the reasons explained in the application, the original documents be filed by the plaintiff within four weeks from today.

The application stands disposed of.

CS(COMM) 737/2018 & IA No.3620/2018

The plaintiffs have filed the above suit for permanent injunction restraining infringement of Indian patent numbers ***i.*** IN 209251 (hereinafter referred to as "IN '251") which cover and claim the commercial product of the plaintiffs' *'Sunitinib'* sold under the trade name Sutent® (in India); and ***ii.*** IN 268331 (hereinafter referred to as "IN '331") which cover and claim the commercial product of the Plaintiffs', ***Tigecycline*** sold under the trade name Tigacil® (in India).

The plaintiff No.2 is the proprietor of the suit patent IN 209251 entitled "*Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors*". The said patent covers inter alia the molecule Sunitinib which has been granted approval by the US, FDA and CDSCO, India for the treatment of gastrointestinal stromal tumors (GIST) and advanced renal cell carcinoma (RCC). The plaintiff No.3 is the proprietor of the suit patent IN 268331 entitled "*tigecycline compositions and methods of preparation*". The said patent covers inter alia the molecule Tigecycline which has been approved by the US FDA and CDSCO, India for complicated intra-abdominal infections (cIAI), complicated skin and skin structure infections (cSSTI) and community acquired pneumonia caused by resistant pathogens. The grievance of the plaintiffs is that the generic versions of Sunitinib Malate and Tigecycline are being manufactured and sold/offered for sale by the defendants in complete disregard to the plaintiffs' right under Section 48 of the Patents Act, 1970 which gives the plaintiffs the exclusive right to make use, sell, import and distribute the subject matter thereof. The plaintiffs in the first week of February, 2018 were informed from their credible sources that the defendant No.2 is manufacturing the generic version of Plaintiffs' Sunitinib Malate and marketing them as Sunitinib Malate capsules under the brand name of the defendant No.2 "TherDose". The plaintiffs were reached out by oncologists inquiring regarding the authenticity of the generic drug. After online investigation into the website of the defendant No.2 i.e. www.therdose.com. revealed that the plaintiffs' Tigecycline has been advertised in the list of products of the defendant No.2 under the head

"Pipeline Products". The plaintiffs deputed an independent investigation, in second week of February, 2018 to ascertain the availability of the impugned generic products in the Indian market from TherDose Pharma (defendant No.2). The investigations brought the following facts into light:

a. The defendant No.2 maintains two websites namely www.therdose.com and

www.carmuther.com on which the following products are listed:

The product "Tigecycline" found a mention in the List of Products of the Defendant No.2 on its website www.therdose.com under the head "Pipeline products";

The product "Sunitinib Malate" found a mention in the List of Products of the defendant No.2 on its website www.carmuther.com under the head "Solid Oral".

b. The defendant No.3, on the website www.medicineexporter.com was found to be offering for sale and selling defendant No. 2's generic Sunitinib Malate capsules for 12.5mg/25mg/50mg;

c. The defendant No.3, when contacted through telephone, confirmed the availability of defendant No. 2's Sunitinib Malate and informed that the said product is available only through 'challan' without any bill since the manufacturing company TherDose Pharma does not have the permission to sell the product in India and therefore, the 'challan' will not be applicable for reimbursement in the government sector;

d. The defendant No.3 confirmed that the said product can be delivered to Delhi;

e. The defendant No.3 informed that the product Sunitinib Malate does not come with MRP since it is meant only for export;

f. The defendant No.2 was found to have exported generic Sunitinib Malate capsules in August 2014 and November 2017 and imported the same in December 2016;

g. The defendants have not commercially launched the impugned generic products in the market.

In view of above infringing activities of the defendants, the plaintiffs have approached this Court requesting a restraining order against the defendants from infringing its suit patents and for additional reliefs in light of such infringement.

The learned counsel for the plaintiff has taken me through various documents filed along with the plaint viz at page No.41 in respect of registration of patent No.251; page No.54 viz e-registration chart showing the annual renewals of the patent obtained every year; page No.57 viz complete specification of Sunitinib molecule; page No.265 viz claim No.7 showing - formulation structure of the molecule Sunitinib and claim No.8 viz salt used in said molecule viz L Malate Salt.

The learned counsel for the plaintiff has also taken me to the website of the defendant No.2 at page No.313 which shows finished dosages and then at page No.314 wherein item No.31 relates to

Sunitinib Maleate Capsules. Further at page No.319 the defendant has advertised the anti cancer drug i.e. Sunitinib Malate Capsule 50mg. At page No.340 is the website of an Iraqi company and it has listed defendant No.2 as its supplier of the said drug. The molecule Sunitinib is man made and is given its name by the World Health Organization (WHO) (see page No.414 viz WHO Drug Information, Vol. 20, No.1, 2006, Recommended INN List 55) and page No.427 where the formula, as is given at page No.265 of documents, is shown.

The learned counsel for the plaintiff also referred to various injunctions orders in its favour passed by different Courts annexed with the plaint at pages No.447,449, and 451 of the plaintiffs documents. It is alleged the defendants' production of the drug is in clear violation of the patent No.251 viz Sunitinib. Since patent No.331 is in production pipeline hence fairly conceded by the learned counsel for the plaintiff that that he would press for injunction qua this patent at a later stage.

The learned counsel for the plaintiff further argued the defendant No.1 is an ex-employee of the plaintiff No.1 as is shown in his bio data – the copy whereof is handed over across the board in the Court.

While refuting the claim of the plaintiff, the learned counsel for the defendants argued there are two post grant oppositions under Section 25(2) of the Patents Act, 1970 before the Controller and one revocation petition is filed before the Appellate Board under Section 64 of the Patents Act against patent IN 251 and also relied upon

Bishwanath Prasad Radhey Shyam vs Hindustan Metal Industries AIR 1982 SC 1444 which notes:-

> *"31. It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position, viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act, 1970. In the light of this principle, Mr. Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted."*

Further in *Ten XC Wireless Inc and Another vs Mobi Antenna Technologies (Schenzhen) Co. Ltd* 187 (2012) DLT 632 this Court inter alia, notes:-

> "***7.10.1*** *The registration of a patent per se does not entitle the plaintiffs to an injunction. The certificate does not establish a conclusive right.*
> ***7.10.2*** *There is no presumption of validity of a patent, which is evident from the reading of Section 13(4) as well as Sections 64 and 107 of the Patents Act.*
> ***7.10.3*** *The claimed invention has to be tested and tried in the laboratory of Courts.*
> ***7.10.4*** *The Courts lean against monopolies. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large.*

7.10.5 The plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. Credible challenge means a serious question to be tried. The defendant need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage whereas the validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.

7.10.6 At this stage, the Court is not expected to examine the challenge in detail and arrive at a definite finding on the question of validity of the patent. That will have to await at the time of trial. However, the Court has to be satisfied that a substantial, tenable and credible challenge has been made.

7.10.7 The plaintiff is not entitled to an injunction, if the patent is recent, its validity has not been established and there is a serious controversy about the validity of the patent."

The learned counsel for the defendants argued since the registration of the patent do not lead to the presumption for its validity and hence no stay be granted. However, I must say if the registration of the patent is not a proof of its validity, it is certainly not a proof of its invalidity either.

Undisputedly, the patent 'IN 251' has been renewed by the authorities for the last many years after being examined and hence, prima facie the plaintiff has a case against the defendants to restrain

them from using its patent No.251. The balance of convenience lies in favour of the plaintiffs and if injunction is not granted the plaintiffs would suffer an irreparable loss and injury. Of course, this would not debar the defendants to raise a substantial,. tenable and credible challenge in its pleading.

Hence, summons of the suit and notice of the injunction application is issued. The learned counsel for the defendants appearing on advance notice accepts summons and seeks time to file written statement and reply. Be filed within four weeks from today with an advance copy thereof to the learned counsel for the plaintiff. Replication/rejoinder thereto, if any, be also filed within two weeks thereafter.

List before the learned Joint Registrar on 05.07.2018 for completion of the pleadings and admission/denial of the documents. In the meanwhile, the defendants, their directors, employees, officers, servants, agents, associate and group companies and all others acting for and on their behalf are restrained from using, making, selling, distributing, advertising, exporting, importing and offering for sale, or in any other manner, directly or indirectly, dealing in any product that infringes the subject matter of Indian Patent No.251 (Sunitinib) till further orders. As far as prayer qua patent No.331 is concerned, same is not pressed *at this stage*.

Order *dasti*.

-Sd/-

YOGESH KHANNA, J

MARCH 15, 2018
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