Eisai Co. Ltd. & Anr vs Satish Reddy & Anr on 14 January, 2019

Author: J.R. Midha

Bench: J.R. Midha

$~O-11
* IN THE HIGH COURT OF DELHI AT NEW DELHI
+ CS(COMM) 1169/2018 & I.A.13934/2018, 15885/2018

EISAI CO. LTD. & ANR. ..... Plaintiffs
Through Mr.Sudhir Chandra, Senior Advocate with Mr.Pravin Anand, Mr.Dhruv Anand, Ms.Udita Patro, Mr.Nischay Mall, Advocates.

versus

SATISH REDDY & ANR. ..... Defendants
Through Mr.Saikrishna Rajagopal, Ms.Sneha Jain, Ms.Sauni Dutt, Mr.mitavo Mitra, Mr.Devvrat Joshi, Advocates along with Mr.Girish Parahate, Director, Regulatory Affairs, Mr.M.V. Ramana, CEO Branded Markets and Dr. Poonam Raghuvanshi, Vice President and Head, Intellectual Property

CORAM:
HON'BLE MR. JUSTICE J.R. MIDHA

ORDER

% 14.01.2019 Mr.Girish Parhate, Director, Regulatory Affairs of the defendant is present in Court and he has been examined on oath separately in exercise of the power under Section 165 of the Evidence Act.

Further arguments heard.

List for continuation of the arguments on 15th January, 2019. Copy of this order along with statement be given dasti to the parties under the signature of Court Master.

J.R. MIDHA, J.

JANUARY 14, 2019/dk/savita
Item O-11 CS(COMM) 1169/2018

Statement of Girish Parhate, S/o Sh. Sadashiv Parhate, aged about 40 years, R/o D0601, Sunway Opus Grand Neville, 3A, Sy. No. 162 P, 164,, Ameenpur, Hyderabad-502032 on S.A.:

I am the Director of the defendant for Indian Drug Regulations Affairs of the defendant company since December, 2015. I am not aware who took the decision to develop the medicine named Lorcaserin Hydrochloride Hemihydrate (herein after referred as 'LHH').

In June 2016, I was instructed by Business Strategic Unit of the defendant to apply for grant of permission for manufacture and marketing of LHH where upon I prepared and submitted an application dated 29th June, 2016 before the Drugs Controller General of India, Directorate General of Health Services. I produce the copy of the application dated 29th June, 2016 which is marked as Ex.C1.

Q.1 In para 3 of the application (Ex.C1) you have stated that the defendant has developed the drugs substance LHH. Please tell who developed this drug substance and when was it developed?

Ans. The drug substance LHH was developed by the Research Development Unit of the defendant during the period 2013 to 2016. Q.2 Did you disclose to the Drug Controller that the plaintiff already has a patent on this salt?

Ans. I did not disclose in the application that the plaintiff is holding the patent in respect of the drug substance because there is no provision for such disclosure in the application form. Earlier, there was a column in the application form to disclose the patent but the same was removed in the format of the application and therefore such disclosure was not made.

The drug substance LHH is different from the drug substance in respect of which the plaintiff is having patent. I can produce the earlier form showing the requirement of the patent disclosure as well as the amended format in which the said requirement was omitted. However, I am not technical qualified to tell the difference. I can produce the documents relating to the drug substance namely LHH by the defendant.

The 31st Subject Experts Committee (SEC)-Endocrinology and Metabolisim in its meeting dated 08th November, 2016 permitted the defendant to carry on phase III Clinical Trial. The copy of the approval of the SEC is marked as Ex.C2.

On 06th January, 2017, the defendant received the NOC from the DGHS for conducting Clinical Trial of LHH. The copy of the NOC dated 06th January, 2017 is marked as Ex.C3.

On 24th May, 2017, we informed to Drugs Controller General of India having completed Bio equivalence study of LHH. The copy of the reported dated 24th May,

2017 is marked as Ex.C4.

Q.3 Did you ever inform the Drug Controller of the plaintiff's patent? Ans. I need to check upto the answer this question.

(Deferred for lunch break) Examination of Mr.Girish Parhate continued after lunch break.

I have verified from the records with respect to the disclosure of the plaintiff's patent. I say that the defendant disclosed in their application dated 29th June, 2016 that the drug in question is covered by the plaintiff's patent No.IN 215528. I produce the copy of the application dated 29th June, 2016 in which the relevant disclosure is made in item 8 of Form 44. The copy of the complete application dated 29th June, 2016 is marked as Ex.C-4 on which item 8 of Form 44 is marked as Mark-A (Copy of the application dated 29th June, 2016 handed over earlier and marked as Ex.C-1 was without the Form 44 which has now been furnished).

I produce the notification dated 03rd April, 2017 whereby item 8 of Form 44 of the Drug and Cosmetic Rules, 1945 was omitted and therefore, no information relating to the patent of any drug is required to be disclosed by a pharmaceutical company. The notification dated 03rd April, 2017 is marked as Ex.C-5.

RO&AC J.R. MIDHA, J.

14.01.2019