

**ORDER SHEET
IN THE HIGH COURT OF SINDH AT KARACHI**

Suit No.2707 of 2021

M/s AGP Limited & another

Versus

M/s Galaxy Pharma (Private) Limited & others

Date	Order with signature of Judge
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For hearing of CMA 19999/21

Date of hearing: 08.09.2022

M/s. Abdul Sattar Pirzada and Mamoon N. Chaudhry for plaintiffs.

Mr. Haroon Dugal for defendant No.1.

Hafiz Bilal Bin Akbar, Deputy Director Legal DRAP.

Qazi Ayazuddin, Assistant Attorney General.

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Muhammad Shafi Siddiqui, J.- Plaintiffs have filed this suit for declaration, permanent and mandatory injunction with damages against defendants in respect of registration and/or transfer of certain drugs and through listed application seeks interim restraining orders in respect thereof.

Brief facts are that plaintiff No.2, per pleadings, is a pharmaceutical company and in course of its business inter alia manufacture, exports and markets its products. To carry on these business activities, plaintiff No.2 initially conferred rights upon defendant No.1 in respect of distribution of the products in Pakistan and some of the products were registered in the name of defendant No.1 by issuance of registration letters from the concerned Ministry of Health, Government of Pakistan (as it was at the relevant time under the law empowered to). To bring it in black and white an agreement was executed between plaintiff No.2 and defendant No.1 and defendant No.1 was granted non-transferable, non-assignable exclusive rights to commercialize the products of plaintiff No.2 in Pakistan. Clause 16.1 of the agreement provides mode for severance of relationship and in

consequence thereof it was notified by the plaintiff No.2 to defendant No.1 about expiry of the agreement w.e.f. 15.06.2021 in line with Clause 16.1 of the agreement. Followed by this termination, a regional distributor agreement was then executed between plaintiff No.1 and plaintiff No.2, effective from 15.06.2021 and such rights were then transferred by plaintiff No.2 to plaintiff No.1 which was non-transferable and non-assignable to commercialize the products within the territory defined in the agreement. Such facts were also communicated to defendant No.4 by plaintiff No.2 regarding termination of earlier agreement and execution of fresh one.

With these facts plaintiff No.1 then claimed for transfer of earlier registered product in its favour from the Secretary of Registration Board of defendant No.2 i.e. Drug Regulatory Authority of Pakistan and apart from other prerequisites, a No Objection Certificate was required from existing registration holder for the subject product which was objected though numerous letters were written by plaintiff No.2 to defendant No.1 in this regard, hence this suit.

Defendant No.1 has opposed grant of interim injunction, as claimed in the application under consideration. Primarily it is claimed that plaintiff No.2 is not an entity with whom they (defendant No.1) entered into agreement and hence the alleged cancellation or termination of the agreement is of no consequence. Learned counsel appearing for defendant No.1 has relied upon the agreement entered into between its principal and itself available as Annexure 'B' to the plaint at page 45 of the file and submits that it was Besins Healthcare (Hong Kong) Limited, which entered into an agreement with defendant No.1 and not plaintiff No.2 i.e. Besins Healthcare Distribution FZ-LLC.

Learned counsel further submitted that there is no provision as far as transferring of the registration of the said products is concerned.

Mr. Dugal, learned counsel, has relied upon Section 7 of the Drugs Act, 1976 which, per learned counsel, calls for cancellation or suspension of the registration and not for transferring its registration.

With the above facts, I have heard the learned counsel for the parties and perused material available on record.

The first letter that could be seen as initial correspondence meant for terminating agreement between plaintiff No.2 and defendant No.1 is a letter of 05.03.2021 wherein it was communicated to them that Besins Healthcare Distribution FZ-LLC was formerly called Besins Healthcare (Hong Kong) Limited. It sums up that Besins Healthcare (Hong Kong) is now recognized as a merged entity as Besins Healthcare Distribution FZ-LLC. The letter further reads that the defendant No.1 was appointed as distributor for the territory of Pakistan within the frame of the agreement dated 16.06.2016. For the reasons assigned therein foreign principal notified about the expiry of agreement w.e.f. 15.06.2021 in line with Clause 16.1 of the agreement. The principal operator i.e. Besins Healthcare Bruxelles (Belgium) further informed the Drug Regulator Authority that their affiliated Besins Healthcare has terminated the distribution agreement with M/s Galaxy Pharma (Pvt.) Ltd./defendant No.1, for the distribution of the products. It was further clarified that Besins Healthcare Benelux S.A. and Besins Healthcare Distribution FZ-LLC have a new agreement with AGP Limited i.e. plaintiff No.1 to distribute the products within the territory of Pakistan and four specific drugs were highlighted. Plaintiff No.1 was again authorized by the foreign principal vide letter dated 25.05.2021, which facts were communicated to Drug Regulatory Authority of Pakistan. Defendant No.1 who insists that their principal at Hong Kong has not notified them anything in this regard is not substantiated by any correspondence, nor

it could as it is now recognized as merged entity as Besins Healthcare Distribution FZ-LLC.

About the transfer of the activities from Besins Healthcare (Hong Kong) Limited to Besins Healthcare Distribution FZ-LLC, the facts were communicated via email of 10.12.2019 to defendant No.1 that with a view to focus their resources on yet underdeveloped regions, Besins Healthcare (Hong Cong) Limited are moving globally with a new subsidiary such as Besins Healthcare Distribution FZ-LLC. It was then came out as a lawfully merged entity and the severance of a contract cannot be disputed by defendant No.1 on this count.

Four applications for transfer of the registration of four products were then submitted to the concerned authority which was responded on 08.09.2021 by the Drug Regulatory Authority of Pakistan wherein they demanded following three documents:-

- a) Copy of registration letter, renewal trail and post-registration variation for the products Oestrodose Gel (Reg. No.066122) and Oestrogel (Reg. No.066123).
- b) Copies of complete renewals for the products Utrogestan 100mg Capsule (Reg. No.062214) & Utrogestan Vaginal 200mg soft Capsule (Reg. No.059079).
- c) NOC (original and notarized) not later than 06 months from existing registration holder for all applied products (i.e. M/s Galaxy Pharma (Pvt.) Ltd. Karachi).

The documents at Sr. No.(c) is a question of concern as far as current issue is concerned. I do not see it as a lawful claim of NOC as the foreign principal has severed the relationship which existed through agreement of 16.06.2016 between plaintiff No.2 and defendant No.1.

I now deal with the question of transferring the registration of the drug in favour of plaintiff No.1. Under Drugs Act, 1976 registration of the drug is being dealt with by its Section 7. Subsection (11) of Section 7 then deals with the issue of cancellation or suspension of registration.

Subsection (11) of Section 7 provides that if Registration Board, on the basis of “information received” or an inquiry conducted by it, is of opinion that:-

- (a) “...
- (b) The circumstances in which a drug was registered no longer exist;
or
- (c) ...
- (d) ...

the Registration Board may, after affording to the person on whose application the drug was registered an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject, and inform such person and the provincial government accordingly.

Undoubtedly and undisputedly the circumstances governed by an agreement no longer exists to enable defendant No.1 to continue using the registration. This drug was registered on the application of foreign principal in favor of defendant No.1 enabling it to manufacture, market and sell the products of the foreign principal. In view of severance of relationship between plaintiff No.2 and defendant No.1, as disclosed above the agreement came to an end. Mr. Pirzada and Mr. Dugal have not taken me to any of the provisions which could enable the drug authority to process the “transfer” of the registration of the product/drug. However, once the drug authority reached to such conclusion that the circumstances no longer exist on the face of which these drugs were registered in favour of defendant No.1, on an application of the foreign principal, they must act within the frame of Section 7(11) of the Drugs Act, 1976. However, the NOC from the existing registration holder is unlawfully demanded by the drug authority. Why would an agent/ distributor whose contract was severed by the principal would come forward to give no objection for the benefit

of his rival; normally it does not happen unless it is all by some amicable settlement. At the most the drug authority at the time of registering the drug in favour of plaintiff No.1, if the circumstances so demand, could asked for a No Objection Certificate (NOC) from foreign principal and that is it.

In the absence of any contract between foreign principal and defendant No.1 it would be a matter of serious concern if defendant No.1 would continue to manufacture, market and sell product of foreign principal without its permission and authorization. Plaintiffs thus have disclosed a prima facie case with balance of inconvenience and irreparable loss in their favour. I, therefore, in view of above facts and circumstances, allow the application under consideration as under:-

- I) That the defendant No.1, its officers, employees, agents and every person working through or under it, or on his behalf from representing or claiming themselves as partners, distributors, affiliates or representatives of plaintiff No.2 and is restrained from claiming any rights in the products, i.e.,
 - a) Utrogestan 100 mg soft capsule
(Micronized Progesterone 100mg)
(For Oral or Vaginal use)
 - b) Utrogestan 200 mg soft capsule
(Micronized Progesterone 200mg)
(For Oral or Vaginal use)
 - c) Oestrogel Gel (in Tube)
(Estradiol 0.6 mg/g)
 - d) Oestrodose Gel
(in Canister with metering pump)
(Estradiol 0.6 mg/g)

or utilizing the registration certificate of these products in any manner whatsoever.

- II) As far as the importing of subject goods are concerned since it is an independent issue not arising out of the arguments, as

raised, if otherwise prohibited, I am not inclined to pass any such order in this regard unless argued independently.

- III) That the Drug Regulatory Authority within 15 days from the date of this order shall decide about the fate of registration of the above drugs in favour of defendant No.1 under the above facts and circumstances without asking for any NOC from defendant No.1 and submit report in this regard before this Court.
- IV) In case they (Drugs Regulatory Authority) reaches to a conclusion that on account of severance of the contract, defendant No.1 is no more entitled to retain the registration of the aforesaid drugs and consequently cancel all such registrations, the application of the Besins Healthcare Distribution FZ-LLC and that of its principal be taken into consideration with immediate effect and an order be passed in this regard at the earliest with report to this Court.

Application stands allowed in the above terms.

Dated: 15.09.2022

J U D G E