Order Sheet

IN THE HIGH COURT OF SINDH KARACHI

Suit No. 368 of 2023

Date	Order with Signature of Judge

For order on CMA No. 9885/23 (Rule 94 r/w O39 R1&2 CPC)

07.07.2023

Mr Raashid Mureed, Advocate for Plaintiff
Mr Haroon Dugal, Advocate for Defendant No.1

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1. The Plaintiff is a distributor of a Singapore company, Defendant No.1 and imports and sells different types of blood bags ("medical devices") of Defendant No.1 in Pakistan. The medical devices imported by Plaintiff into Pakistan are registered with the Directorate of Medical Devices Board of the Drug Regulatory Authority of Pakistan ("DRAP")(Defendant Nos.2&3).

2. Plaintiff filed this suit against the Defendants on 14.03.2023. During the pendency of the suit, on 19.06.2023, the Medical Device Board of DRAP ("MDB")("Defendant Nos.2") informed Plaintiff that they had cancelled Plaintiff's import registration of medical devices (the "impugned decision"). Plaintiff filed CMA No.9885/2023 seeking Orders from this Court for:

> "withdrawal of the impugned decision [of 19.06.2023] and to further restrain [Defendant Nos.2&3] . . .from taking any adverse, coercive or punitive action taken against the Plaintiff till disposal of the instant suit."

3. Plaintiff's Counsel submits that Defendant No.2 never heard Plaintiff and unilaterally cancelled his import registration before taking the impugned decision. To illustrate this point, he relies on Plaintiff's letter dated 24.03.2023 addressed to Defendant No.2. He contends that Plaintiff wrote to Defendant Nos.2&3 requesting them to provide another opportunity of being heard as the notice to Plaintiff to appear for a personal hearing in the 58th Meeting of the Medical Device Board in Islamabad on 25.03.2023 was too short. Counsel contends that no opportunity of being heard was provided to Plaintiff and his license was cancelled vide the impugned decision of 19.06.2023. He claims a personal hearing and relies on Rule 18 of the Medical Devices Rules ("MDR"), 2017.[1] He has also relies on reported judgments on the right of

[1] "Rule 18. Certificate of enlistment or registration of medical device,—(1) A certificate of enlistment or registration of a

hearing as reported in 2022 SCMR 1387, 2021 CLC 1160, 2022 MLD 1081 and 2019 CLC 1141. Finally, Plaintiff claims that he has not (apparently) received any direct notice from Defendant No.1 that the latter has cancelled the Distribution Agreement, so how could Defendant Nos.2&3 cancel his import registration?

4. Counsel for Defendant No.1 submits that he appears on a without-prejudice basis out of respect for this Court's Order of 06.07.2023. He still awaits further and better particulars from Defendant No.1 in Singapore. He does not have notice of this application and does not wish to take any steps in the proceedings.

5. By way of background, Plaintiff and Defendant No.1 entered into a Distribution Agreement dated 01.04.2020 (Annexure "B" on page 25 of the suit file) (hereinafter referred to as "the DA"). The duration of the DA was two years, from 1st April 2020 to 31st March 2022. According to the documents filed with the Plaint and Plaintiff's Statement dated 07.07.2023 (which is taken on record and the office is directed to flag the same), Defendant No.2 commenced proceedings to cancel Plaintiff's import license on **10th May 2022** (Annexure "F" to the Plaint on page 159 of the suit file). On **6th December 2022**, Defendant No.2 asked Plaintiff if they wished to avail an opportunity for a personal hearing by Defendant No.2 (page 161 of the suit file). In response, on **12th January 2023**, Plaintiff submitted a detailed response to Defendant No.2 and conceded in paragraph 8 of the said Reply :

> ". . .That it is further submitted that we are in talks with M/s Terumo [Defendant No.1] for the ongoing dispute and would take the matter to the competent forum for resolution."
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> (Annexure "G" on page 163 of the Suit file)

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medical device shall not be assigned or transferred to any other person or classes of persons except with prior written approval of the MDB.

(2) If an enlistment or registration holder assigns or transfers his enlistment or registration of the medical device to any other person or classes of persons without the prior written approval of the MDB, the MDB may cancel or suspend the enlistment or registration of medical device as it may deem fit, after giving to the enlistment or registration holder the opportunity of being heard.

(3) A certificate of enlistment or registration issued for a medical device shall without demand be surrendered to the MDB within fourteen days after the enlistment or registration of the medical device is cancelled by the MDB under sub-rule (2)."

6. It is an admitted position that the distribution of medical devices relates to public health. According to Form-8A dated 05.12.2019 and another Form-8A dated 07.04.2021, the shelf life of the medical devices of Defendant No.1 imported into Pakistan as authorised by Defendant Nos.2&3 to be distributed in Pakistan is 36 months (Annexures "B" of the Statement dated 07.07.2023). Yet Plaintiff has not filed any information with the Plaint regarding the stocks and inventory currently lying with Plaintiff, the remaining shelf life of the medical devices, or if such medical devices are in good, sellable condition. Based on the pleadings, Plaintiff apparently also has not provided information regarding his inventory/stocks to Defendant Nos.2&3. Further, when this Court asked Plaintiff's Counsel if Plaintiff had imported any medical devices of Defendant No.1 after 01.04.2022 till present, he responded in the negative. This implies that the inventory of the medical devices of Defendant No.1, presumably available with Plaintiff (lying in his stocks for distribution in Pakistan), was manufactured at least 15 months ago and are still in circulation since 01.04.2022 till the impugned decision of 19.06.2023. However, the quantity remains undisclosed by Plaintiff. Thus, from a public health perspective, Defendant No.2's impugned decision of 19.06.2023 ended Plaintiff's continuing 15 months of distribution of medical devices in Pakistan based on an expired DA as of 31.03.2022.

7. During the period of the Show-Cause Notice from May 2022 to the impugned decision of 19.06.2023, Plaintiff's Counsel has pleaded that Plaintiff allegedly secured several tenders, and Plaintiff will suffer losses if the cancellation is not set aside. However, at the same time, Plaintiff has filed with his Plaint an email from Defendant No.1 representative dated 22.02.2022 (before the expiration of the DA on 31.03.2022) wherein Defendant No.1 instructed Plaintiff not to participate in future medical device tenders (available on page 61 of the suit file). It appears that Plaintiff did not take this advice as Plaintiff has attached two Purchase Orders of Indus Hospital dated 17.08.2022 in relation to an LC favouring Defendant No.1 marked as Annexure "E" on page 153. No copies of any other secured tenders are available with the Plaint to suggest that several tenders are currently in play. It is a trite principle of law that the Court should avoid any interim relief if it creates a new situation during the pendency of the action, which will be contrary to the law. Reliance is placed on *Islamic Republic of Pakistan through Secretary, Establishment Division, Islamabad and others v. Muhammad Zaman Khan*, 1997 SCMR 1508. In the present case, Defendant Nos.2,

vide its impugned decision cancelled Plaintiff's import licence as his DA had expired. At this stage, withdrawing the impugned decision of Defendant No.2 is likely to create an entirely new situation, i.e., the continuing distribution of medical devices during the trial proceedings. Further, at present, the outcome of the interim relief sought by Plaintiff regarding the dispute between Plaintiff and Defendant No.1 arising out of the expired DA is yet to be taken up by this Court (CMA No.4505/2023). Moreover, Defendant No.1's counteraction is also not known. Court proceedings will take their own time, whereas the medical devices of Defendant No.1 in circulation have a limited shelf life. A court should be mindful that when granting discretionary relief, its decision may not create a potential risk to the public. Therefore, this Court should avoid creating a new situation from a public health perspective too and is not inclined to withdraw the impugned decision on this score too.

8. It may be noted that an importer of medical devices in Pakistan, as part of the registration process under Rules 14(a), 16(1), and 17(2) of MDR, 2017, is required to submit to Defendant Nos.2&3 the Original Agency Agreement/Letter of Authorization from the foreign manufacturer. Thereafter, importers are mandated to essentially keep Defendant Nos.2&3 informed of any changes in the particulars provided about such registration (Rules 17(1) and 48 of MDR, 2017). Expiration of an Agency Agreement, such as the DA in this case, would also constitute a reportable item to Defendant Nos.2&3. Thus, even though Plaintiff has always been under obligation to inform Defendant Nos.2&3 regarding the expiration of the DA on 31.03.2022, he did not promptly notify Defendant Nos.2&3. It took Plaintiff almost seven (7) months from the date of expiration of the DA to inform Defendant No.2, and that too as a part of the Show-Cause proceedings when he submitted his detailed (but belated) Reply of 12 January 2023 to Defendant No.2 that Plaintiff was in talks with M/s Terumo [Defendant No.1] for the ongoing dispute and would take the matter to the competent forum for resolution.

9. The Plaintiff has prayed in this CMA for withdrawal of the impugned decision of Defendant No.2, whereas Rule 60 of the MDR 2017 provides a right of appeal to the Plaintiff. Rule 60 states as follows:

> "Rule 60. Appeal against the decision of the MDB.— The aggrieved person or party may prefer appeal before the Appellate Board of the Authority against the decision of MDB within a period of sixty days."

It appears that Plaintiff, instead of preferring an appeal and exhausting his remedy before the proper forum, i.e. the Appellate Board of the Authority, has moved the instant application in this lis. The Court withdrawing the impugned decision as pleaded by Plaintiff in this application will suspend the machinery of adjudication provided under the law. Stakeholders should be encouraged to invoke due process of law. The Court is not inclined to exercise its discretion and withdraw the impugned decision when Plaintiff has an existing right to file an appeal against the impugned decision under Rule 60 of MDR, 2017.

10. It may not be out of place to mention here that no interim relief can be granted, which is not prayed in the main suit. Plaintiff has prayed to this Court to restrain Defendant No.2 for transfer of registration. The prayer clause in the main suit seeks orders to restrain Defendants from transferring the Plaintiff's licence to another person. But the impugned decision of Defendant No.2 does not relate to the transfer of the import license. The impugned decision is for the cancellation of the import license of Plaintiff and not transfer. The impugned decision does not deal with transferring the import license of Defendant No.1 from Plaintiff to anyone else. Further, the impugned decision does not mention the name of any future distributor of Defendant No.1's medical devices in Pakistan. Therefore CMA No.9885/2023, which seeks withdrawal of cancellation of an import license, is beyond the pleadings which seek restraint of the transfer of the import license. As per the impugned decision, there is no order to transfer. Thus, the interim relief sought by Plaintiff in CMA No.9885/2023 is not pleaded in the main suit. Hence no interim relief can be granted to the Plaintiff for withdrawal of the impugned decision, which decision does not deal with the transfer of the import licence.

11. It is common ground that the DA has stood expired on 01.04.2022. The position has not changed till today, and Defendant's medical devices have a limited shelf life of 36 months. It is also apparent from documents filed by Plaintiff that as and when he secured any tender after the expiration of the DA, he did so at his own risk. Plaintiff knew that there was no DA in place after 01.04.22. Further, he received an email in March 2022 from Defendant No.1 not to commit to any further tenders. Finally, Defendant No.2 had also issued a show cause notice in May 2022 regarding the cancellation of his import license. In the circumstances, Plaintiff always knew that Defendant Nos.2&3, which regulates the health and safety of medical devices in Pakistan, would not allow Plaintiff to continue distributing and market medical devices

endlessly. Defendant No.2 could not have been expected to wait for the parties to resolve their dispute when clearly the DA stood expired on 31.03.2022. No further update as to the renewal of the DA was submitted by Plaintiff. Continuing delay would endanger the general public with expired medical devices circulating in the country. Therefore, it was inevitable for Defendant No.2 to conclude its show-cause hearing of cancellation of Plaintiff's import license, holding in the impugned decision that the import licence stood cancelled on account of the expiration of the DA in 2022.

12. Regarding Plaintiff's claim for a personal hearing, based on the detailed written Reply of Plaintiff of 12.01.2023, it cannot be pleaded that Plaintiff has been condemned unheard by Defendant No.2's impugned decision of 19.06.2023. Defendant No.2 appears to have considered Plaintiff's admission in paragraph 8 of the said Reply that the DA was cancelled. Defendant No.2 concluded in the impugned decision that "the agreement [with Defendant No.1] was not renewed in 2022. . . ". Be that as it may, it is apparent that Defendant No.2 did not accord a personal hearing to Plaintiff before announcing its impugned decision. Plaintiff's Counsel has submitted that a personal hearing before Defendant No.2 would have enabled Plaintiff to apparently work out a plan for the next steps in the matter given its ongoing negotiations with Defendant No.1 as well as devise a program for the existing tenders and stock/inventory of medical devices lying with Plaintiff. Plaintiff Counsel pleads that Plaintiff had no such opportunity of discussion with Defendant No.2. While it may be true that a personal hearing was not afforded to Plaintiff yet an opportunity to be heard before the Appellate Board of the Authority of Respondent Nos.2&3 remains in place. Plaintiff is at liberty to claim the right of a personal hearing before the appellate forum, and this Court is minded to provide him such opportunity.

13. For the above reasons, CMA No.9885/2023 is dismissed with directions to the Appellate Board of the Authority that if the Plaintiff prefers an appeal to the impugned decision before the Board, then the Board will give the Plaintiff an opportunity to be heard, including a personal hearing before passing any final order in the appeal.

14. It is clarified that the observations made herein pertain to Defendant No.2's impugned decision of 19.06.2023, are confined to provide a background to decide CMA No.9885/2023, and are without prejudice to

parties' claims and defence, in the main suit and/or any future interlocutory proceedings.

Order accordingly.

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