UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CUSTOPHARM, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
FRESENIUS KABI USA, LLC,	)	Civil Action No: 6:21-CV-00148
	)	
Defendant.	)	
	)	

CUSTOPHARM, INC.'S DECLARATORY JUDGMENT COMPLAINT OF NONINFRINGEMENT

Plaintiff Custopharm, Inc. ("Custopharm"), by and through its undersigned counsel, files this Complaint for Declaratory Judgment of non-infringement of U.S. Patent Nos. 9,782,376 and 10,398,669 against Fresenius Kabi USA, LLC ("Fresenius Kabi" or "Defendant") as follows:

INTRODUCTION

1. This is a declaratory judgment action under 28 U.S.C. §2201(a) seeking a declaration of non-infringement of U.S. Patent Nos. 9,782,376 ("the '376 patent") (attached as **Exhibit A**) and 10,398,669 ("the '669 patent") (attached as **Exhibit B**). This action is related to and arises out of the same operative facts as Civil Action No. 20-1091 previously filed by Fresenius Kabi in this District against Custopharm for infringement of the '376 and '669 patents.

2. Custopharm's formulation cannot infringe any of the claims of the '376 and '669 patents because it uses different ingredients in a different way that results in an entirely different formulation, with different characteristics. Because Custopharm's Levothyroxine Product

formulation lacks critical claim elements required by the '376 and '669 patents, it cannot infringe either of those patents. Fresenius Kabi cannot prove otherwise.

3. Custopharm offered, on multiple occasions, to provide the formulation for its 505(b)(2) NDA Product to counsel for Fresenius Kabi on an outside counsel eye's only basis. Fresenius Kabi rejected Custopharm's offer. Without knowing what Custopharm's formulation was much less whether it infringed, on October 30, 2020, Fresenius Kabi filed lawsuits against Custopharm in three U.S. District Courts: the U.S. District Court for the Western District of Texas (1:20-cv-1091), the District of New Jersey (2:20-cv-15342), and the District of Colorado (1:20-cv-03254) alleging patent infringement of the '376 and '669 patents based on Custopharm's submission of a 505(b)(2) New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell Custopharm's levothyroxine sodium solution product.

4. On December 28, 2020, Custopharm voluntarily, on an outside counsel eyes only basis, provided counsel for Fresenius Kabi with a copy of Custopharm's NDA, which includes the formulation for Custopharm's Levothyroxine product and conclusively demonstrates that Custopharm's formulation cannot infringe the '376 or '669 patents.

5. Nevertheless, Fresenius Kabi has repeatedly refused to provide any basis for its infringement allegations, while maintaining its multiple litigations against Custopharm seeking to delay Custopharm's ability to launch its competing liquid Levothyroxine product. Through its actions, Fresenius Kabi is causing substantial injury to Custopharm in seeking to prevent the marketing of a competing levothyroxine liquid product..

6. Because Custopharm is a Texas Corporation, Fresenius Kabi's Complaint filed in the Western District of Texas was the only one of the three actions filed by Fresenius Kabi filed in

a proper venue under 28 U.S.C. §1400(b). *See Valeant Pharms. N. Am. LLC, et. al. v. Mylan Pharms., Inc., et al.,* 978 F.3d 1374, 1375 (Fed. Cir. 2020). Fresenius Kabi recently litigated against Custopharm in the Western District of Texas and knew that was and is a proper venue for its action. *See Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GMBH v. Custopharm, Inc.,* C.A. 18-0065 (W.D.Tex)). Custopharm has filed Motions to Dismiss for improper venue in both the District of New Jersey and the District of Colorado. On January 26, 2021, Magistrate Judge Hegarty issued his Recommendation of United States Magistrate Judge that Custopharm's Motion to Dismiss the Colorado Action for improper venue be granted and that the case be transferred to the Western District of Texas. **Exhibit C** (*Recommendation of United States Magistrate,* Case No. 1:20-cv-03254 (D. Colo.), ECF 43). Fresenius Kabi subsequently appealed that Recommendation. Custopharm's Motion to Dismiss is still pending in the District of New Jersey.

7. Instead of proceeding with the action filed in this District to litigate the merits of the case, on January 27, 2021, the day after the Magistrate Judge in Colorado recommended that the Colorado action be transferred to this District, Fresenius Kabi voluntarily dismissed its Complaint pending in the Western District of Texas without ever serving it and without informing this Court of the Magistrate Judge's recommendation that the case be transferred here. **Exhibit D** (*Notice of Voluntary Dismissal,* Case No. 1:20-cv-01091 (W.D. Tex.), ECF 9).

8. Fresenius Kabi's actions of dismissing the litigation it filed in the Western District of Texas, a venue all parties agree is proper, but maintaining the litigations in two districts where venue is improper is delaying the resolution of the merits of this case and preventing Custopharm from removing the cloud that Fresenius Kabi is trying to create with its objectively baseless assertion that Custopharm's 505(b)(2) Product infringes the '376 and '669 patents.

THE PARTIES

9. Custopharm is a Texas corporation with a principal place of business at 2325 Camino Vida Roble, Ste. B, Carlsbad, California 92011.

10. On information and belief, Fresenius Kabi is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

JURISDICTION AND VENUE

11. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 based upon an actual controversy between the parties for a declaration that Custopharm's Levothyroxine product that is subject of Custopharm's 505(b)(2) New Drug Application does not and will not infringe the '376 and/or '669 patents.

12. This Court has jurisdiction over Custopharm's declaratory judgment claims pursuant to 28 U.S.C. § 2201 *et seq.* based on Fresenius Kabi's suits against Custopharm for patent infringement, thereby giving rise to an actual case or controversy under 28 U.S.C. §§ 2201 and 2202.

13. A substantial controversy of sufficient immediacy and reality exists between the parties to warrant the issuance of a declaratory judgment because Fresenius Kabi has asserted the '376 and '669 patents against Custopharm in this District, in the District of New Jersey, and in the District of Colorado.

14. This Court has personal jurisdiction over Fresenius Kabi because it has a registered agent, Corporation Service Company d/b/a CSC, in Austin, Texas for service of process located at 211 E. 7th Street, Suite 620, Austin, TX 78701.

15. This Court has personal jurisdiction over Fresenius Kabi, at least because it has purposefully availed itself of the privilege of conducting activities within this District and has invoked the benefits and protections of its laws by suing Custopharm to try to enforce the same patents at issue in this Declaratory Judgment Action, and through its continuous and systematic contacts with the state of Texas, including on information and belief conducting substantial and regular business therein through marketing and sales of pharmaceutical products in Texas including but not limited to its own levothyroxine liquid product.

16. This Court has personal jurisdiction over Fresenius Kabi because Fresenius Kabi has previously submitted to the jurisdiction of this Court and has further availed itself of this Court by filing lawsuits in this jurisdiction.

17. Venue is proper in this District under 28 U.S.C. §§1391(b), (c), and/or 1400(b).

THE PATENTS-IN-SUIT

18. On its face the '376 patent entitled "Levothyroxine Liquid Formulations" indicates that it was issued by the United States Patent and Trademark Office on October 10, 2017 and is assigned to Fresenius Kabi USA, LLC. **Exhibit A**.

19. The '376 patent was filed on December 1, 2016 and assigned Application No. 15/366,864 ("the '864 Application"). The '864 Application was originally filed with 30 claims of which claims 1, 18, and 24 were the independent claims. Original claims 1, 18 and 24 are reproduced here:

> 1. A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; tromethamine; sodium iodide; and water; wherein the formulation has a pH of about 9.0 to about 11.5.
>
> 18. A liquid formulation comprising (a) levothyroxine or a pharmaceutically acceptable salt thereof in a concentration of about 20 mcg/mL to about 100 mcg/mL; (b) tromethamine in a concentration of about 5 mg/mL to about 20 mg/mL; (c) sodium

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