IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

GLOBAL CURE MEDICINE, LLC, a foreign limited liability company, Plaintiff, v. ALFA PHARMA, LLC, a Washington limited liability company. Defendant.	NO.: COMPLAINT FOR BREACH OF CONTRACT, BREACH OF WARRANTY, FRAUD, VIOLATION OF RCW 19.86.020.

JURISDICTION AND VENUE

1. This court has original jurisdiction over this action under 28 U.S.C. §1332, diversity of citizenship, and the matter in controversy exceeds the sum of $75,000.00 exclusive of interest and costs. The Plaintiff is a legal entity of a foreign country and has its principal place of business there. The Defendant is a citizen of the State of Washington.

2. The Defendant is a Washington limited liability company with its principal place of business in the Western District of Washington. Venue is proper in this court pursuant to 28 U.S.C. §1391.

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

THE PARTIES

3. Global Cure Medicine, LLC is a limited liability company, located in the Sultanate of Oman, engaged in the business of wholesale trade of pharmaceuticals in the Middle East.

4. Alfa Pharma, LLC is a limited liability company organized in the State of Washington with its principal place of business in Renton, Washington, engaged in the business of sourcing pharmaceuticals and selling them to resellers.

DESCRIPTION OF EVENTS

5. In September 2016, the Ministry of Health for Supply of Pharmaceuticals to the Royal Hospital of the Sultanate of Oman requested proposals to supply vials of injectable solution Eculizumab from Alexion Pharmaceuticals, Inc., headquartered in Boston, Massachusetts. The brand name for the drug is "Soliris." Alexion developed, manufactures, and markets the drug, which is protected by patent. Alexion started selling Soliris in 2007. It is the first and only therapy for the treatment of atypical hemolytic uremic syndrome ("aHUS"), a blood disease characterized by low levels of circulating red blood cells. Soliris is a life-saving medication for aHUS, but a single dose containing an impurity or an improper quantity of the active ingredient could pose immediate life-threatening danger. Soliris was the most expensive drug in the world in 2010 and the fourth most expensive medication in the United States in 2015.

6. On November 5, 2016, Defendant Alfa Pharma, LLC ("Alfa") sent a quotation to Global Cure Medicine, LLC ("GCM") to provide 150 units of Soliris 300 mg vials at a cost of $705,000.00. (Ex. 1 – Price Quote from Alfa). The quotation contains a guarantee that all

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

items would be delivered to the destination in excellent condition and that original Certificates of Analysis ("COA") and Certificates of Origin ("COO") would be supplied.

7. On January 29, 2017 the Ministry of Health of the Sultanate of Oman confirmed an order placed with GCM for 75 vials of Soliris together with 200 units of Myozyme 50mg (Alglucosidase Alfa infusion concentrate) manufactured by Genzyme. (Ex. 2 – P.O. from Ministry of Health). Genzyme corporation is located in Cambridge, Massachusetts and is a wholly-owned subsidiary of Sanofi. The order was priced at OMR 172,500.00 (Oman rial) for the Soliris and OMR 62,000.00 for the Myozyme for a total of OMR 234,500. Each rial converts to approximately 2.6 U.S. dollars, for a total of approximately $609,700.00.

8. GCM and Alfa had further communications about reducing the original quotation of 150 vials to 75 and to supply the Myozyme as well. The Defendant confirmed that it could supply both products at competitive prices and that the products would be accompanied by an original COA and an original COO. (Ex. 3 – Emails between GCM & Alfa on 2/10/17). Ultimately GCM issued purchase orders dated February 20, 2017 and March 1, 2017 to Alfa for collectively 200 units of Myozyme for $126,000.00 and 75 units of Soliris for $352,500 ($178,600+$173,900) to be sourced respectively from Genzyme, U.S.A and Alexion, U.S.A. (Ex. 4 – GCM POs to Alfa). The total amount of the purchase orders came to $478,500.00. The purchase orders included as required documentation the COA and COO.

9. Alfa invoiced GCM in accordance with the purchase orders and again stated on its invoice that "Original Certificates of Analysis & Certificates of Origin will be supplied." (Exs. 5 & 5A – Invoices from Alfa to GCM) GCM through its affiliate Global Industrial Services, LLC paid Defendant for the Soliris the amount of $353,850 (which included a $1,350 shipping fee) plus $12,400 for stainless steel containers for the medication. GCM sent a wire

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

transfer in March 2017 for the total $366,250 from the Oman Arab Bank to Alfa's Bank of America, New York branch. (Ex. 6 –Wire Transfer Request)

10. Defendant sent some of the product the third week of April, 2017. The packing slip showed France as the country of origin rather than the U.S.A. In addition, the products were delivered from Alfa Pharma Medikal Sandtic, located in Ankara, Turkey. (Ex. 7 – Alpha packing slip and related documents).

11. GCM immediately delivered 40 units to the Royal Hospital of Oman. (Ex. 8 – Delivery Note, Soliris to Royal Hospital). On May 11, 2017, Defendant sent 11 vials by separate shipment to GCM. (Ex. 9 – Alpha packing slip and related documents) The invoice for that shipment stated that the manufacturer was Alexion Europe SAS. Defendant sent 6 batches of "Soliris," but provided only four COAs. The COAs sent to GCM were facsimile copies of certificates of analysis purporting to be from ALMAC Pharma Services, located in the United Kingdom. At least one was dated June 9, 2016, which was nearly a year before the shipment from Alfa to GCM.

12. Because the COAs were not from Alexion, the Royal Hospital sent the Certificates of Analysis to Alexion for verification. Alexion responded on May 17, 2017 that it conducted an internal review of each of the four certificates of analysis and its assessment concluded that none of the COAs was authentic. (Ex. 10 – RH fax to GCM with letters from Alexion to Royal Hospital). Not one of the COAs matched Alexion records and in some cases the batch numbers referenced did not exist. Alexion's response also included the following statement:

> It is imperative that all such packages and their contents be quarantined and not administered to any patients. We have no confidence that the product which you procured is authentic Soliris, and it may pose a substantial hazard to patients who rely on our therapy.

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

> Further, as the COAs have been submitted in support of a sale to your institution, there appears to have been a fraud committed, and we strongly request that you immediately refer this matter to relevant law enforcement authorities. Assuming that this precipitates an investigation and if the authorities allow, we would like to obtain samples in as much quantity as possible of the subject product, if possible, for further investigation and testing. (Ex. 10 p. 2).

13. Almac Pharma Services is a contract service provider to Alexion, providing secondary packaging and market release services. (Ex. 10, p. 3-4 – Alexion Letter to RH). By letter dated June 13, 2017, Almac confirmed to Alexion that the batches of "Soliris" were not packaged by Almac, that the COA for each was not issued by Almac, and the COAs were not authentic. (Ex. 11 –Letter from Alexion Ireland (ALMAC) stating it did not package Soliris). It appears that Defendant Alfa, or someone on its behalf, modified one or more previously issued genuine COAs from Almac for other Soliris shipments in order to make the COAs provided by Alfa to GCM appear to be authentic, when in fact they were counterfeit, forged documents. As a result, on July 6, 2017 the Royal Hospital formally rejected the "Soliris-Eculizumab" supplied to it by GCM and instructed GCM to retrieve the vials in the Royal Hospital's possession. (Ex. 12 – RH letter rejecting Soliris).

14. Despite requests from GCM, Alfa did not authenticate the product as genuine Soliris and did not obtain original, valid COAs. Alfa instead sent an email dated July 24, 2017 to GCM from a Michael Stone, JD, Vice President, Legal Department, AlfaPharma LLC, that stated the "Soliris" was obtained from the Turkish Ministry of Health via a third party named Xerox Pharma, but that Alpha did "not have any means of obtaining definitive proof" of the product's source and authenticity. (Ex. 13 - Emails between GCM and Alfa Pharma). GCM contacted the Turkish Ministry of Health, which informed GCM by letter that the batch numbers were not registered in Turkey. (Ex. 14 – Letter from Turkish MOH). Therefore, the

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

product could not have come from the Turkish Ministry of Health or any reputable source in Turkey.

15. GCM has been left with four counterfeit, facsimile COAs for four batches, and no COAs for the other two batches of "Soliris." The Royal Hospital obtained 75 vials of Soliris from another source and formally canceled the OMR 172,500 ($448,500) GCM contract on April 30, 2018. (Ex. 15 – Letter from Ministry of Health cancelling PO w/GCM). The Royal Hospital imposed its administrative fees and cancelation penalty in the amount of OMR 20,624.475, or approximately $53,624. (Ex. 15).

BREACH OF CONTRACT

16. Defendant Alfa contracted to provide 75 vials of Soliris to GCM for GCM to deliver to the Royal Hospital in the Sultanate of Oman. The contract required Alfa to provide original Certificates of Authenticity and Certificates of Origin. Alfa failed to provide the required certificates, which resulted in GCM's contract with the Royal Hospital to be canceled and GCM penalized. As a result of Alfa's breach of contract, GCM has been damaged in the amount of $448,500 for its lost sales price and $53,624 in cancellation penalties, for a total of $502,124.

BREACH OF WARRANTY

17. In its contract with GCM, Alfa warranted that the product sold and delivered would be genuine Soliris manufactured by Alexion, the Massachusetts company Alexion Pharmaceuticals, Inc. Alfa also warranted that the product would be accompanied by original Certificates of Authenticity and Certificates of Origin. Alfa provided no original certificates of any kind, but only facsimile documents. Alfa provided no Certificates of Origin. Alfa provided

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

4 out of a required 6 COAs for 6 batches of product. The COAs provided were not authentic, but were counterfeit, forged documents. Alfa has breached the express warranties in its contract with GCM, in violation of RCW 62A.2-313.

18. Without the Certificates, the product is unsafe to use and is worthless; it cannot legitimately be resold. To be merchantable, the goods must be able to pass without objection in the trade and fit for the purposes for which such goods are used. Alfa is a merchant with respect to goods of the kind sold. Alfa's delivery of unmerchantable goods that are unfit for the purpose intended violates warranties of merchantability and fitness for purpose, in violation of RCW 62A.2-314 and 315.

19. Alfa's breach of express and implied warranties has damaged GCM in the amount of $502,124, representing the lost revenue from GCM's sale to the Royal Hospital in the Sultanate of Oman together with penalties assessed by the Royal Hospital. The damages were foreseeable and directly result from the breaches of warranty.

FRAUD

20. Alfa represented to GCM that it had access and the ability to deliver 75 units of Soliris from the United States to the Sultanate of Oman, that Alfa would deliver the Soliris to the Sultanate of Oman upon placement of the order, and that the deliveries would be accompanied by original Certificates of Authenticity and Certificates of Origin for the Soliris.

21. The representations were material to GCM's ordering Soliris from Alfa. GCM would not have placed the order or paid Alfa, but for Alfa's representations.

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

22. The representations were false. The product delivered was not from the United States, was not verifiably Soliris, and was not accompanied by valid or original COAs and COOs.

23. Alfa knew when it made the representations that it did not have accessible Soliris in the United States and knew that no other source had reliably represented to Alfa that it had valid, original COAs and COOs for 75 vials of Soliris for Alfa to obtain.

24. Alfa intended GCM to rely on Alfa's representations for GCM to enter into a sale contract with the Royal Hospital in the Sultanate of Oman and to purchase Soliris from Alfa.

25. GCM did not know Alfa's representations were false.

26. GCM relied on Alfa's representations in entering GCM's contracts with Alfa and with the Royal Hospital in the Sultanate of Oman.

27. GCM had the right to rely on Alfa's representations.

28. As a result, GCM has suffered damages from Alfa's fraud in the amount of $502,124.

VIOLATION OF CONSUMER PROTECTION ACT

28. The International Federation of Pharmaceutical Manufacturers & Associations states on its website (https://www.ifpma.org/topics/falsified-medicines/) that "Falsified medicines deliberately and deceitfully attempt to pass themselves off as genuine approved medicines. They represent a serious threat to patients around the globe." And further "Fake medicines put patients and the general public at risk. Patients believe they are receiving genuine treatment, but instead they are getting potentially dangerous products that could

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

increase their resistance to real treatments, and cause further illness, disability or even death. Though it is a challenge to measure the scope of these dangerous products, the World Health Organization (WHO) estimates that fake medicines could account for up to 10% of medicines in the supply chain globally, and up to 30% of the drug supply chain in parts of Asia, Africa and Latin America. Fake medicines may contain the wrong ingredients, the wrong dose, or no active ingredients at all; they can be long-standing or new medicines, over-the-counter or prescription, branded or generic. In some cases, they contain dangerous substances and poisons including mercury, antifreeze, paint and rat poison." (at https://www.ifpma.org/partners-2/1236/)

29. Alfa engaged in unfair or deceptive acts or practices in violation of RCW 19.86.020 by selling drugs labeled as a prescription drug that in fact were not the prescription drug and not an authenticated equivalent, legal generic. Such drugs are considered contraband in Washington State under RCW 69.41.230 and their sale is in violation of RCW Ch. 69.04 for intrastate sales and the Federal Food, Drug and Cosmetic Act as well as the Federal Trade Commission Act for interstate sales.

30. Alfa's unfair or deceptive acts or practices occurred in trade or commerce, and were capable of deceiving numerous potential consumers of the counterfeit drugs.

31. Alfa's unfair or deceptive acts or practices impact the public interest because the sale of counterfeit drugs affects a stated public interest of Washington State law as expressed in RCW 69.41.230 declaring such drugs as contraband and as expressed in RCW 69.04.001[1] declaring sale of such drugs as contrary to public health and welfare.

[1] This chapter is intended to enact state legislation (1) which safeguards the public health and promotes the public welfare by protecting the consuming public from (a) potential injury by product use; (b) products that are adulterated; or (c) products that have been produced under unsanitary conditions, and the purchasing public from injury by merchandising deceit flowing from intrastate commerce in food,

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

32. Alfa's unfair or deceptive acts or practices adversely affect the public interest because the sale and distribution of counterfeit drugs to hospitals will impact numerous consumers and is an act capable of repetition.

33. Alfa's acts caused damage to GCM for which GCM is entitled to an injunction to enjoin further violations, and to recover actual damages, and treble damages up to $25,000, and to recover its costs of suit, including reasonable attorney's fees.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

1. That Alfa Pharma, LLC be found liable to Global Cure Medicine, LLC for breach of contract.

2. That Alfa Pharma, LLC be found liable to Global Cure Medicine, LLC for breach of warranty.

3. That Alfa Pharma, LLC be found liable to Global Cure Medicine, LLC for fraud.

4. That Alfa Pharma, LLC be found liable to Global Cure Medicine, LLC for its violation of the Washington State Consumer Protection and Unfair Business Practices Act.

5. That Global Cure Medicine be awarded the sum of $502,124 plus interest at the Washington State prejudgment interest rate of 12% per annum from April 30, 2017, when

---

drugs, devices, and cosmetics; and (2) which is uniform, as provided in this chapter, with the federal food, drug, and cosmetic act; and with the federal trade commission act, to the extent it expressly outlaws the false advertisement of food, drugs, devices, and cosmetics; and (3) which thus promotes uniformity of such law and its administration and enforcement, in and throughout the United States.

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929

GCM delivered and was otherwise entitled to payment from the Royal Hospital in the Sultanate of Oman.

6. That Global Cure Medicine's damages be trebled up to $25,000.

7. That Global Cure Medicine be awarded its reasonable attorney's fees.

8. That a permanent injunction be entered against Alfa Pharma, LLC restraining it from further sales of pharmaceutical products.

5. That interest on the judgment in favor of Global Cure Medicine, LLC continue to accrue at 12% per annum.

6. That the Court order such other relief as would be just and equitable.

Dated this 18th day of April, 2019.

Simburg, Ketter, Sheppard & Purdy, LLP

By: _____
Melvyn J. Simburg, WSBA #4773

999 Third Avenue, Suite 2525
Seattle, WA 98104
Telephone: (206) 382-2600
Fax: (206) 223-3929
E-mail: msimburg@sksp.com

Attorneys for Plaintiff

VERIFICATION

Based on personal knowledge and information, about which I am competent to testify, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 1 day of April, 2019, at Muscat, Oman.

Sultanate of Oman
Ministry of Foreign Affairs
APOSTILLE
(Convention de La Haye du 5 October 1961)
1. Country Sultanate of Oman
This Public document.
2. Has been signed by Registrar
3. Acting in the Capacity of Director
4. Bears the Seal / Stamp of
Certified
5. At Muscat 6. The 14-2019
7. By Ministry of Foreign Affairs
8. No 962
9. Seal / Stamp: 10. Signature

GLOBAL CURE MEDICINE L.L.C

OCCI attests the signature of the authorized signatory of Global Cure Medicine registered under No. 18728 in grade 1 without any responsibility on the contents of the document.
Legalization No.: 214138 Date: 01-04-2019
Muscat Signature:

SIMBURG, KETTER, SHEPPARD & PURDY, LLP
999 THIRD AVENUE, SUITE 2525
SEATTLE, WASHINGTON 98104-4089
(206) 382-2600 FAX: (206) 223-3929