IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK HEALTHCARE AG and NOVO NORDISK INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
	)	**JURY TRIAL DEMANDED**
LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES S.A. and HEMA BIOLOGICS, LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novo Nordisk Healthcare AG and Novo Nordisk Inc. (together, "Novo Nordisk"), by their undersigned attorneys, for their Complaint, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 9,102,762 (the "'762 patent" or the "Asserted Patent," Exhibit A) under the patent laws of the United States, Title 35 of the United States Code by Novo Nordisk against Laboratoire Francais du Fractionnement et des Biotechnologies S.A. and Hema Biologics, LLC (together, "Defendants"). The invention of the '762 patent relates to a novel method for improving the viral safety of liquid Factor VII compositions, particularly those comprising active Factor VII ("FVIIa") polypeptides. Exhibit A at Abstract.

2. This action arises from the Defendants' current and/or imminent manufacture, use, sale, offer to sell within the United States, and/or importation into the United States of

Defendants' medicinal product "SEVENFACT®." Exhibit B. According to its Highlights of Prescribing Information, SEVENFACT® uses recombinant activated Factor VII ("rFVIIa") to promote hemostasis in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX, respectively. Exhibit B at 2. On information and belief, Defendants use the novel method of the '762 patent in the manufacture of SEVENFACT®.

THE PARTIES

3. Plaintiff Novo Nordisk Healthcare AG ("NNHAG") is an entity organized and existing under the laws of Switzerland, and has its principal place of business at Thurgauerstrasse 36-38, Zurich, Switzerland.

4. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

5. On information and belief, Laboratoire Francais du Fractionnement et des Biotechnologies S.A. ("LFB S.A.") is a corporation organized and existing under the laws of France, having a principal place of business at 3 avenue des Tropiques, BP 40 305, 91 958 Courtaboeuf Cedex, Les Ulis, France. On April 1, 2020, the FDA granted approval of SEVENFACT® to LFB S.A. Exhibit C at 2. LFB S.A. developed and manufactures and/or will imminently manufacture SEVENFACT® for sale in the United States. Exhibit C at 2; *see also* Exhibit B at 23.

6. On information and belief, Hema Biologics, LLC ("Hema") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 4441 Springdale Road, Louisville, Kentucky, 40241. Hema has commercialization and distribution rights for SEVENFACT® in the United States and sells

and/or will imminently sell SEVENFACT® in the United States. Exhibit C at 2; *see also* Exhibit B at 23.

SUBJECT MATTER JURISDICTION

7. This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, generally, and 35 U.S.C. § 271(a) and (g), specifically. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

PERSONAL JURISDICTION AND VENUE

8. On information and belief, LFB S.A., directly or indirectly through its affiliates and agents, including but not limited to Hema, markets and sells, or will imminently market and sell, SEVENFACT® throughout the United States, including in this judicial district. Further, on information and belief, LFB S.A., the manufacturer of SEVENFACT®, will import the product into the United States for Hema to immediately or imminently sell throughout the United States, including in this judicial district. Moreover, LFB S.A. has placed, and/or will imminently place, the infringing SEVENFACT® into the stream of commerce, with the knowledge and/or understanding that such product will be sold in the State of Delaware providing the LFB Defendants with substantial revenues.

9. This Court has personal jurisdiction over LFB S.A. because, inter alia, LFB S.A., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute infringing products to residents of this State directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys or imminently will enjoy substantial income from sales of its pharmaceutical products in this State on its own and through Hema, a Delaware limited liability company; and (4) is a partner in Hema.

10. In the alternative, this Court may exercise jurisdiction over LFB S.A. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Novo Nordisk's claims arise under federal law; (b) LFB S.A. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) LFB S.A. has sufficient contacts with the United States as a whole, including, but not limited to, filing a BLA with the FDA and conducting clinical trials throughout the United States, such that this Court's exercise of jurisdiction over LFB S.A. satisfies due process. *See, e.g.*, Exhibit C.

11. On information and belief, Hema, directly or indirectly through its affiliates and agents, markets and sells, or will imminently market and sell, SEVENFACT® throughout the United States, including in this judicial district.

12. This Court has personal jurisdiction over Hema because, inter alia, Hema, on information and belief: (1) is organized under the laws of the State of Delaware and (2) intends to market, sell, and/or distribute the infringing SEVENFACT® to residents of this State directly or through at least one of its wholly-owned subsidiaries or agents.

13. This Court additionally has personal jurisdiction over Hema because, on information and belief, Hema has knowingly induced and/or contributed to, and/or will imminently knowingly induce and/or contribute to, infringement within this District by advertising, marketing, offering for sale, and/or selling infringing SEVENFACT® within this District, to consumers, customers, distributors, resellers, partners, and/or end users, and providing instructions, advertising, and/or marketing materials that facilitate, direct, or encourage the use of infringing products with knowledge thereof.

14. Venue is proper in this Court because, inter alia, 1) Hema resides in this judicial district (28 U.S.C. § 1400(b)) and 2) LFB S.A. is a foreign corporation not residing in any United States district and may be sued in any judicial district (28 U.S.C. § 1391(c)).

THE ASSERTED PATENT

15. On August 11, 2015, the United States Patent and Trademark Office issued the '762 patent, entitled "Virus Filtration of Liquid Factor VII Compositions." Exhibit A. NNHAG is the owner of all right, title, and interest in the '762 patent.

16. The '762 patent explains that the purification and handling of Factor VII must be done carefully, due to the possibility for degradation of the molecule. Exhibit A at col.1 ll.45-51. Accordingly, the prior art processes for manufacturing Factor VII involved the step of virus-filtration of a solution comprising inactive Factor VII. Exhibit A at col.1 l.66-col.2 l.3.

17. Contrary to the prior art processes and conventional wisdom, the inventors of the '762 patent nanofiltered a partially-activated recombinant Factor VII solution. Exhibit A at Example 5, col.17-18. Recombinant activated Factor VII is used to promote hemostasis in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX, respectively. Surprisingly they found that degradation barely increased following filtration of rFVIIa. Exhibit A at Example 5, col.17-18. This led them to conclude that nanofiltration may be applied even after the Factor VII polypeptide has been partially or fully activated and, thereafter, they applied for and obtained the '762 patent. Exhibit A at col.3 ll.46-48.

18. Claim 1 of the '762 patent claims:

> A method for removing viruses from a liquid composition of recombinant Factor VII comprising one or more Factor VII polypeptides having a concentration in the range of 0.01 to 5 mg/mL, the method comprising subjecting the liquid composition to nanofiltration using a nanofilter having a pore size of 80 nm or less, wherein 50-100% of the Factor VII polypeptides in the composition subjected to the nanofilter are in an activated form (FVIIa) prior to nanofiltration.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.