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.

19. The claimed processes of the ’762 patent are used in the manufacture of Novo Nordisk’s medicinal product NovoSeven®. NovoSeven® is composed of recombinant human coagulation Factor VIIa (rFVIIa) and has multiple indications, including promoting hemostasis in hemophilia A or B patients with inhibitors. The manufacture of NovoSeven® includes a chromatographic purification process, during which recombinant Factor VII is converted to the active form. Exhibit D. This purification process for NovoSeven® removes viruses. *Id.*

DEFENDANTS’ INFRINGING PRODUCT AND ACTIVITIES

20. LFB S.A. developed the medicinal product SEVENFACT® using recombinant activated Factor VII (rFVIIa) and intends to begin commercial manufacture of the product as promoting hemostasis in hemophilia A or B patients with inhibitors. Exhibit E at 37; *see also* Exhibit B at 2.

21. SEVENFACT® is a sterile, white to off-white lyophilized powder in a single-use vial containing either 1 mg or 5 mg of rFVIIa as the active ingredient. SEVENFACT® is produced by recombinant DNA technology using genetically engineered rabbits into which the DNA coding sequence for human Factor VII has been introduced. During purification and processing, Factor VII is enzymatically converted to activated Factor VII. The manufacturing process of SEVENFACT® includes specific steps to reduce impurities. Exhibit B at 12-13. Defendants have indicated that the purification process for SEVENFACT® also includes steps that are validated to inactivate or remove viruses. *Id.*

22. LFB S.A. has acknowledged that its manufacturing facility in France “is capable of carrying out the process claimed in the ’762 patent for producing products using rFVIIa,” as well as acknowledged its desire to manufacture products by carrying out the process claimed in the ’762 patent. *See* Exhibit E at 38.

23. Upon information and belief, Defendants have infringed and/or will imminently infringe (literally and/or under the doctrine of equivalents), directly, and/or through agents or intermediaries, one or more claims of the '762 patent, including at least claim 1 of the '762 patent, by making, using, offering for sale, and/or selling in the United States, SEVENFACT®.

24. On information and belief, LFB S.A. manufactures SEVENFACT® using the method set forth in claim 1 of the '762 patent. Specifically, LFB S.A., in manufacturing SEVENFACT®, removes viruses from a liquid composition of rFVIIa; the rFVIIa polypeptides in the liquid composition have a concentration in the rage of 0.01-5 mg/mL; nanofiltration of the liquid composition is performed using a nanofilter having a pore size of 80 nm or less; and at least about 50% of the Factor VII polypeptides in the composition subjected to the nanofilter are activated prior to nanofiltration.

25. Unless enjoined by this Court, now that SEVENFACT® has been approved by the FDA, Defendants will immediately make, use, offer to sell, or sell SEVENFACT® within the United States, and/or will immediately import SEVENFACT® into the United States.

26. LFB S.A. has announced that it is building new industrial facilities in France "to substantially increase [LFB S.A.'s] bioproduction capacities for recombinant medicinal products, particularly for [LFB S.A.'s] activated Factor VII." *See* Exhibit F at 3.

27. LFB S.A. has also announced that it "continued the extension of its cell culture plant [], giving it the capacities to meet needs for activated Factor VII production. . . ." Exhibit F at 6.

28. LFB S.A. has also announced that it began construction of a plant in the United States in 2016 for the purification process of recombinant products resulting from its claimed proprietary rPRO technology with which it makes SEVENFACT®. *See* Exhibit F at 6.

29. On October 7, 2016, LFB S.A. filed a petition with the Patent Trial and Appeal Board ("PTAB") seeking *inter partes* review of the '762 patent. On April 5, 2018, the PTAB issued its Final Written Decision on the initially instituted grounds, rejecting LFB S.A.'s validity challenges as to all claims of the '762 patent. Still pending is the Final Written Decision on the grounds that were originally rejected by the PTAB, then instituted, fully briefed, and argued following and in view of the Supreme Court's decision in *SAS Institute, Inc. v. Iancu.*

30. Defendants' infringement has been willful. They have engaged in the claimed methods of the '762 patent with knowledge of the '762 patent and its validity and without a license or permission to practice the inventions claimed therein.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,102,762

31. Novo Nordisk realleges and incorporates by reference the allegations of paragraphs 1-30 as if fully set forth herein.

32. Upon information and belief, as set forth above, Defendants' sale, offer for sale or commercial manufacture of SEVENFACT® within the United States, or importation of SEVENFACT® into the United States, during the term of the '762 patent infringes and will infringe at least claim 1 of the '762 patent under 35 U.S.C. § 271(a) and/or (g).

33. As a result of Defendants' infringement of the '762 patent, Novo Nordisk will suffer damages in an amount to be determined, but no less than a reasonable royalty.

34. Defendants' infringement of the '762 patent was willful, wanton, and deliberate, justifying an award to Novo Nordisk of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

35. Novo Nordisk will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '762 patent.

COUNT FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,102,762

36. Novo Nordisk realleges and incorporates by reference the allegations of paragraphs 1-35 as if fully set forth herein.

37. On information and belief, the FDA approval of SEVENFACT® to market in the United States, coupled with Defendants' intent to launch SEVENFACT® for sale in the United States soon following that approval, create an actual, immediate, and real controversy under the Declaratory Judgment Act that Defendants will directly or indirectly infringe the '762 patent prior to its expiration.

38. Defendants' infringement of the '762 patent will be willful. LFB S.A. challenged the validity of the '762 patent before the PTAB, yet continued to develop and seek to commercialize SEVENFACT® knowing that its practice of the claimed invention of the '762 patent in manufacturing SEVENFACT® and subsequent sale and offer for sale would constitute infringement.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed the '762 patent;

B. A judgment, pursuant to 35 U.S.C. § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling SEVENFACT® within the United States, or importing SEVENFACT® into the United States, prior to the expiration of the '762 patent, including any extensions, adjustments, and exclusivities;

C. A judgment awarding monetary damages, in the form of lost profits, but in no event less than a reasonable royalty, on past and future infringing sales, together with interest for Defendants' sale, offer to sell, use, and/or commercial manufacture of SEVENFACT® within the United States, or importation of SEVENFACT® into the United States, prior to the expiration of the '762 patent, including any extensions, adjustments, and exclusivities;

D. A judgment that the infringement has been willful and an enhancement of damages;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of Novo Nordisk's costs and expenses in this action; and

G. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Novo Nordisk requests a trial by jury on all issues properly triable by jury.

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