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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____)	
NOVO NORDISK INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
BAXTER HEALTHCARE CORPORATION,)	JURY TRIAL DEMANDED
BAXTER INNOVATIONS GmbH, and)	
BAXTER AKTIENGESELLSCHAFT,)	
)	
Defendants.)	
)	
_____)	

COMPLAINT

Plaintiff Novo Nordisk Inc. (“Novo”), by its undersigned attorneys, as and for its Complaint against defendants Baxter Healthcare Corp. (“Baxter Healthcare”), Baxter Innovations GmbH (“Baxter Innovations”), and Baxter Aktiengesellschaft (“Baxter AG”; together with Baxter Healthcare and Baxter Innovations, “Baxter”), hereby alleges on knowledge as to itself and upon information and belief as to all other matters as follows:

Introduction

1. Novo brings this action under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* Novo seeks a declaratory judgment that it has not infringed and is not infringing any valid claim of U.S. Patent No. 6,100,061 (the “’061 Patent”) or any other Baxter patent relating to cell cultures and processes used to make Factor VIII protein for the treatment of hemophilia from recombinant Chinese Hamster Ovary (“CHO”) cells (what Baxter has called “Baxter’s Factor VIII Portfolio”). On information and belief, in addition to the ’061 Patent, Baxter’s Factor VIII Portfolio may also include, but is not necessarily limited to, U.S. Patent Nos. 6,475,725, 6,936,441, 7,094,574, 8,080,414, 8,084,251, 8,084,252, and 8,329,465.

2. This action is brought at this time because on March 23, 2015, on the eve of Novo’s launch in the United States of Novoeight[®]—which will compete with Baxter’s Advate[®] product—Baxter made baseless allegations of infringement which Novo believes are intended to interfere with Novo’s lawful competition with Baxter.

Parties

3. Plaintiff Novo is a corporation organized and existing under the laws of Delaware and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

4. Defendant Baxter Healthcare is a corporation organized under the laws of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter Healthcare is a wholly-owned subsidiary of Baxter International Inc. (“Baxter International”), which is a corporation organized under the laws of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

5. Baxter Innovations is a company organized under the laws of Austria with its principal place of business at 67 Industriestrasse, Vienna, Austria A-122. Baxter Innovations is a wholly-owned subsidiary of Baxter International.

6. Baxter AG is a company organized under the laws of Austria with its principal place of business at 67 Industriestrasse, Vienna, Austria A-122. Baxter AG is a wholly-owned subsidiary of Baxter International. Prior to July 1, 1999, when its name was changed, Baxter AG was called Immuno Aktiengesellschaft (“Immuno AG”)

Jurisdiction and Venue

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Baxter is subject to personal jurisdiction in this District because it maintains continuous and systematic contacts with the State of New Jersey and directly and indirectly derives substantial revenue from business transacted within this State and District. Baxter Healthcare maintains offices in New Jersey, including in Cherry Hill, New Providence, and North Brunswick. Baxter Healthcare and Baxter International have invoked the jurisdiction of this Court by bringing claims as plaintiffs in patent infringement actions at least three times in the past two years. In addition, as described below, Baxter sent a letter to Novo in New Jersey asserting that Novo is infringing or will infringe patents in Baxter’s Factor VIII Portfolio. Further, Baxter sells products throughout the United States, including in New Jersey, under trademarks owned by Baxter AG. Such products include Advate[®], which, like Novo’s Novoeight[®] product, is indicated for the treatment of hemophilia in certain patients.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)-(c).

The Patents

10. The '061 Patent is entitled "Recombinant Cell Clone Having Increased Stability in Serum and Protein-Free Medium and a Method of Recovering the Stable Cell Clone and the Production of Recombinant Proteins by Using a Stable Cell Clone." It issued on August 8, 2000. The inventors named on the '061 Patent are Manfred Reiter, Wolfgang Mundt, and Friedrich Dorner. A copy of the '061 Patent is attached as Exhibit A.

11. The '061 Patent was assigned to Immuno AG.

12. Upon information and belief, Baxter currently owns the '061 Patent and has the right to sue for its infringement.

13. Upon information and belief, Baxter currently owns and asserts that Novo infringes patents that form Baxter's Factor VIII Portfolio.

14. Upon information and belief, the Baxter Factor VIII Portfolio includes, among other patents, U.S. Patent Nos. 6,475,725, 6,936,441, 7,094,574, 8,080,414, 8,084,251, 8,084,252, and 8,329,465 (the "Family Patents"), which are all entitled "Recombinant Cell Clones Having Increased Stability and Methods of Making and Using the Same" and were issued on, respectively, November 5, 2002, August 30, 2005, August 22, 2006, December 20, 2011, December 27, 2011, December 27, 2011, and December 11, 2012. Copies of these patents are attached as Exhibits B-H. All of the Family Patents (i) name as inventors Manfred Reiter, Wolfgang Mundt, and Friedrich Dorner (the same inventors named on the '061 Patent), (ii) claim priority to the application from which the '061 Patent issued, and (iii) were assigned to Baxter Innovations.

15. Upon information and belief, Baxter currently owns each of the patents in its Baxter Factor VIII Portfolio, including the Family Patents, and has the right to sue for their infringement.

Background

16. Novo has developed a product under the trade name Novoeight[®] (turoctocog alfa), which is a type of blood-clotting protein known as a “Factor VIII” protein. Novoeight[®] was approved in October 2013 by the Food and Drug Administration (“FDA”) under Biologic License Application No. BL125466 for the treatment of patients with hemophilia A for (i) the control and prevention of bleeding episodes, (ii) perioperative management, and (iii) routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Novo announced in October 2013 that it planned to commence sales of Novoeight[®] in the United States in early April 2015. Novo currently anticipates that the product will be available in the United States sometime in April 2015.

17. Baxter currently sells Advate[®], which is a product that is approved for treating indications similar to Novoeight[®]. Novo’s introduction of Novoeight[®] would provide U.S. consumers with a choice they currently do not have for medication to treat certain symptoms.

18. Novoeight[®] is manufactured, packaged, and labeled by Novo’s parent company, Novo Nordisk A/S, in Denmark. The European counterpart patent to the ’061 Patent and Family Patents, EP 1200561, was revoked by the European Patent Office in a decision dated October 22, 2010. That decision is currently on appeal. Novoeight[®] was approved for marketing in the European Union in November 2013, and has been sold there since January 2014.

Information regarding the process by which Novoeight[®] is manufactured has been available on the website of the European Medicines Agency since at least November 2013.

19. On March 23, 2015, Baxter sent a letter to Novo concerning what Baxter stated was the planned April 1, 2015 U.S. launch of the Novoeight[®] product. A copy of that letter is attached as Exhibit I.

20. In its March 23 letter, Baxter stated that it “is the owner of certain patents related to cell cultures and processes used to make Factor VIII protein from recombinant CHO cells (collectively, ‘Baxter’s Factor VIII Portfolio’),” a “representative” of which is the ’061 Patent. Baxter further stated that, based on its “extensive[] analy[sis of] the information publicly available for the Novoeight[®] product,” it “believe[s] that the information strongly suggests that at least the process Novo Nordisk uses for manufacturing Novoeight[®] infringes one or more claims of Baxter’s Factor VIII Portfolio.”

21. Baxter’s letter requested that Novo disclose confidential information about the manufacturing process for Novoeight[®] to Baxter’s outside counsel and their unnamed “expert consultants” so that they could “evaluate infringement.” Baxter further requested that, “to avoid interrupting patient supply,” Novo (i) respond to Baxter’s letter by March 30, 2015 (two days before the stated U.S. launch date), and (ii) refrain from its launch.

22. Novo intends to commence sales of its Novoeight[®] product in the United States in April 2015. Novo has not infringed, is not infringing, and will not infringe any valid claim of the ’061 Patent, the Family Patents, or any other patent in Baxter’s Factor VIII Portfolio.

23. Baxter's conduct and assertion of its patent rights against Novo's imminent launch demonstrates that Baxter intends to enforce its alleged patent rights against Novo.

24. An actual and substantial controversy has arisen and exists between Novo and Baxter within the meaning of 28 U.S.C. § 2201.

COUNT I
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 6,100,061)

25. Novo repeats and realleges paragraphs 1 through 21 of its Complaint as though fully set forth in this paragraph.

26. As to each and every claim of the '061 Patent, (a) any Novo development, manufacture, importation, sale and/or offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT II
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 6,475,725)

27. Novo repeats and realleges paragraphs 1 through 23 of its Complaint as though fully set forth in this paragraph.

28. As to each and every claim of U.S. Patent No. 6,475,725, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United

States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT III
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 6,936,441)

29. Novo repeats and realleges paragraphs 1 through 25 of its Complaint as though fully set forth in this paragraph.

30. As to each and every claim of U.S. Patent No. 6,936,441, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT IV
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 7,094,574)

31. Novo repeats and realleges paragraphs 1 through 27 of its Complaint as though fully set forth in this paragraph.

32. As to each and every claim of U.S. Patent No. 7,094,574, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT V
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 8,080,414)

33. Novo repeats and realleges paragraphs 1 through 29 of its Complaint as though fully set forth in this paragraph.

34. As to each and every claim of U.S. Patent No. 8,080,414, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT VI
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 8,084,251)

35. Novo repeats and realleges paragraphs 1 through 31 of its Complaint as though fully set forth in this paragraph.

36. As to each and every claim of U.S. Patent No. 8,084,251, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT VII
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 8,084,252)

37. Novo repeats and realleges paragraphs 1 through 33 of its Complaint as though fully set forth in this paragraph.

38. As to each and every claim of U.S. Patent No. 8,084,252, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight[®] product has not

infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT VIII
(Declaration of Noninfringement and Invalidity of U.S. Patent No. 8,329,465)

39. Novo repeats and realleges paragraphs 1 through 35 of its Complaint as though fully set forth in this paragraph.

40. As to each and every claim of U.S. Patent No. 8,329,465, (a) any Novo development, manufacture, importation, sale and offer for sale of the Novoeight® product has not infringed, is not infringing, and will not in the future infringe any such claim, and/or (b) the claim is invalid for failure to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112 and the rules, regulations, and laws pertaining thereto.

COUNT IX
(Declaration of Noninfringement and/or Invalidity of
Other Patents in Baxter's Factor VIII Portfolio)

41. Novo repeats and realleges paragraphs 1 through 37 of its Complaint as though fully set forth in this paragraph.

42. Upon information and belief, Novo has not infringed, is not infringing, and will not infringe any valid claim of any other patent in Baxter's Factor VIII Portfolio.

Prayer for Relief

WHEREFORE, Novo demands judgment as follows:

- A. As to Count I, adjudging, finding, and declaring that Novo has not infringed, is not infringing and will not infringe any claim of U.S. Patent No. 6,100,061;
- B. As to Count I, adjudging, finding, and declaring that each and every claim of U.S. Patent No. 6,100,061 as to which infringement is asserted is invalid;
- C. As to Counts II through IX, adjudging, finding, and declaring that Novo has not infringed, is not infringing and will not infringe any claim of the patents in Baxter's Factor VIII Portfolio, including but not limited to U.S. Patent Nos. 6,475,725, 6,936,441, 7,094,574, 8,080,414, 8,084,251, 8,084,252, and 8,329,465;
- D. As to Counts II through IX, adjudging, finding, and declaring that each and every claim of the patents in Baxter's Factor VIII Portfolio, including but not limited to U.S. Patent Nos. 6,475,725, 6,936,441, 7,094,574, 8,080,414, 8,084,251, 8,084,252, and 8,329,465, as to which infringement is asserted is invalid;
- E. Adjudging, finding, and declaring this to be an exceptional case entitling Novo to reasonable attorneys' fees, costs, and disbursements under 35 U.S.C. § 285; and
- F. Granting Novo such other and further relief as this Court may deem just and proper.

Jury Demand

Novo demands a trial by jury on all issues so triable.

Dated: Newark, New Jersey
March 26, 2015

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