

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NEKTAR THERAPEUTICS,	)	
BAXALTA INCORPORATED, and	)	
BAXALTA US INC.,	)	
	)	
Plaintiffs,	)	C.A. No.
	)	
v.	)	<b>JURY TRIAL DEMANDED</b>
	)	
BAYER HEALTHCARE LLC,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Nektar Therapeutics (“Nektar”), and Baxalta Incorporated (“Baxalta Inc.”) and Baxalta US Inc. (“Baxalta US”) (collectively, “Baxalta”) (collectively, Nektar and Baxalta are “Plaintiffs”), by their attorneys, allege as follows for their Complaint for Patent Infringement against Bayer HealthCare LLC (“Bayer” or “Defendant”):

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of United States, Title 35, United States Code and Title 28, United States Code concerning U.S. Patent No. 7,026,440 (Ex. A, “the ’440 patent”); U.S. Patent No. 7,872,072 (Ex. B, “the ’072 patent”); U.S. Patent No. 8,273,833 (Ex. C, “the ’833 patent”); U.S. Patent No. 8,809,453 (Ex. D, “the ’453 patent”); and U.S. Patent No. 9,187,569 (Ex. E, “the ’569 patent”) (collectively, “the Patents-in-Suit”).

**THE PARTIES**

2. Plaintiff Nektar is a corporation organized under the laws of Delaware with its principal place of business at 455 Mission Bay Boulevard South, San Francisco, California, 94158.

3. Plaintiff Baxalta Inc. is a corporation organized under the laws of Delaware with its principal place of business at 1200 Lakeside Drive, Bannockburn, Illinois, 60015.

4. Plaintiff Baxalta US is a corporation organized under the laws of Delaware, having its principal place of business at 1200 Lakeside Drive, Bannockburn, Illinois, 60015.

5. Upon information and belief, Bayer is a corporation organized under the laws of Delaware with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey, 07891.

### **JURISDICTION AND VENUE**

6. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and 28 U.S.C. §§ 2201 *et seq.*

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

8. This Court has personal jurisdiction over Defendant because, *inter alia*, it resides in Delaware, it is doing business in Delaware, and it has continuous and systematic contacts with this Judicial District. Upon information and belief, Defendant derives substantial revenue from articles marketed, sold, distributed, and/or used in this Judicial District. Upon information and belief, Defendant maintains a registered agent for service of process in this Judicial District. Upon information and belief, Defendant has submitted to jurisdiction in this Judicial District without contesting personal jurisdiction. *See, e.g., Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, Inc.*, C.A. No. 07-753 (D. Del. Jan. 11, 2008), D.I. 41. Furthermore, Defendant has availed itself of the rights, benefits, and privileges of this Judicial District by seeking affirmative relief from this Judicial District in a litigation that is currently pending in this Judicial District. *See, e.g., Complaint, Bayer HealthCare LLC v. Baxalta Inc., et al.*, C.A. No. 16-1122-RGA (D. Del. Dec. 5, 2016), D.I. 1.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b) and (c), and/or § 1400(b).

### **FACTS AS TO ALL COUNTS**

#### **I. THE PATENTS-IN-SUIT**

10. On November 7, 2001, Nektar filed U.S. Provisional Application No. 60/337,613 (“the Nektar provisional application”).

##### **A. U.S. Patent No. 7,026,440**

11. The ’440 patent, titled “Branched Polymers and Their Conjugates,” was duly and legally issued by the USPTO on April 11, 2006.

12. The ’440 patent contains a claim of priority to the Nektar provisional application.

13. Nektar is the owner by assignment of the ’440 patent. Nektar has granted Baxalta a license to the ’440 patent, whereby Baxalta has specified rights to the ’440 patent in the United States. Pursuant to this license, Baxalta has the right to assert the ’440 patent, and Nektar and Baxalta have the right to any remedies for infringement thereof.

##### **B. U.S. Patent No. 7,872,072**

14. The ’072 patent, titled “Branched Polymers and Their Conjugates,” was duly and legally issued by the USPTO on January 18, 2011.

15. The ’072 patent is a division of U.S. patent application No. 10/290,082, filed on November 7, 2002. The ’072 patent contains a claim of priority to the Nektar provisional application.

16. Nektar is the owner by assignment of the ’072 patent. Nektar has granted Baxalta a license to the ’072 patent, whereby Baxalta has specified rights to the ’072 patent in the United States. Pursuant to this license, Baxalta has the right to assert the ’072 patent, and Nektar and Baxalta have the right to any remedies for infringement thereof.

**C. U.S. Patent No. 8,273,833**

17. The '833 patent, titled "Branched Polymers," was duly and legally issued by the USPTO on September 25, 2012.

18. The '833 patent is a continuation of U.S. patent application No. 11/336,695, filed on January 20, 2006, which is a division of U.S. patent application No. 10/290,082, filed on November 7, 2002. The '833 patent contains a claim of priority to the Nektar provisional application.

19. Nektar is the owner by assignment of the '833 patent. Nektar has granted Baxalta a license to the '833 patent, whereby Baxalta has specified rights to the '833 patent in the United States. Pursuant to this license, Baxalta has the right to assert the '833 patent, and Nektar and Baxalta have the right to any remedies for infringement thereof.

**D. U.S. Patent No. 8,809,453**

20. The '453 patent, titled "Branched Polymers," was duly and legally issued by the USPTO on August 19, 2014.

21. The '453 patent is a continuation of U.S. patent application No. 13/593,861, filed on August 24, 2012, which is a continuation of U.S. patent application No. 12/963,170, filed on December 8, 2010, which is a continuation of U.S. patent application No. 11/336,695, filed on January 20, 2006, which is a division of U.S. patent application No. 10/290,082, filed on November 7, 2002. The '453 patent contains a claim of priority to the Nektar provisional application.

22. Nektar is the owner by assignment of the '453 patent. Nektar has granted Baxalta a license to the '453 patent, whereby Baxalta has specified rights to the '453 patent in the United States. Pursuant to this license, Baxalta has the right to assert the '453 patent, and Nektar and Baxalta have the right to any remedies for infringement thereof.

**E. U.S. Patent No. 9,187,569**

23. The '569 patent, titled "Branched Polymers," was duly and legally issued by the USPTO on November 17, 2015.

24. The '569 patent is a continuation of U.S. patent application No. 13/865,912, filed on April 18, 2013, which is a continuation of U.S. patent application No. 13/593,861, filed on August 24, 2012, which is a continuation of U.S. patent application No. 12/963,170, filed on December 8, 2010, which is a continuation of U.S. patent application No. 11/336,695, filed on January 20, 2006, which is a division of U.S. patent application No. 10/290,082, filed on November 7, 2002. The '569 patent contains a claim of priority to the Nektar provisional application.

25. Nektar is the owner by assignment of the '569 patent. Nektar has granted Baxalta a license to the '569 patent, whereby Baxalta has specified rights to the '569 patent in the United States. Pursuant to this license, Baxalta has the right to assert the '569 patent, and Nektar and Baxalta have the right to any remedies for infringement thereof.

**II. Hemophilia**

26. Hemophilia A is a congenital bleeding disorder caused by deficient or defective coagulation, which requires the interaction of platelets and blood coagulation factors to coagulate or clot the blood. Patients suffering from hemophilia A are afflicted with a deficiency in the activity and/or amount of Factor VIII protein, which is a key protein in the blood coagulation pathway and is, therefore, critical for proper blood coagulation and the control of bleeding. Hemophilia A patients can experience a range of serious consequences, such as hemorrhages in the joints and muscles as well as bleeding in the digestive system and brain. Without the constant presence of functional Factor VIII in the body, hemophilia A patients can suffer severe

and even fatal bleeding episodes. Hemophilia A presently affects approximately 400 newborn babies in the United States annually and over 400,000 people worldwide.

27. Baxalta is one of the world's leading providers of products used in the treatment of hemophilia. Baxalta's products include ADVATE<sup>®</sup> [Antihemophilic Factor (Recombinant)] and ADYNOVATE<sup>®</sup> [Antihemophilic Factor (Recombinant), PEGylated].

28. Baxalta US owns BLA No. 125566, which was approved by the FDA on November 13, 2015 for the manufacture and sale of ADYNOVATE<sup>®</sup>. ADYNOVATE<sup>®</sup> is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes.

### **III. Defendant's Infringing Product**

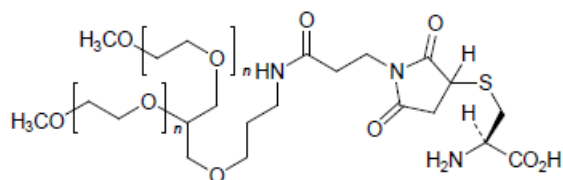
29. Upon information and belief, Defendant currently or intends to make, use, offer to sell, sell, import, export, supply, and/or cause to be supplied BAY 94-9027, also known as Jivi and/or any other trade names of BAY 94-9027, including the PEGylated Factor VIII conjugates, PEGylated Factor VIII active ingredient, PEGylated Factor VIII bulk drug substance, and/or PEGylated Factor VIII drug product composition of BAY 94-9027, BLA No. 125661, and/or any foreign regulatory filings for BAY 94-9027 in the rest of the world ("ROW") ("Jivi/BAY 94"). Upon information and belief, Jivi/BAY 94 is damoctocog alfa pegol.

30. A press release has been issued stating that Jivi/BAY 94 received FDA approval. Upon information and belief, Defendant plans to imminently launch or has already launched Jivi/BAY 94 in the United States.

31. Upon information and belief, Defendant filed BLA No. 125661 for Jivi/BAY 94 with the FDA on August 30, 2017, seeking approval for the treatment of hemophilia A.

32. Upon information and belief, the active ingredient in Jivi/BAY 94 is a pegylated form of recombinant BDD Factor VIII that is pegylated with a 60kDa PEG reagent (“PEG Reagent”). Upon information and belief, this 60 kDa PEG Reagent includes two PEG chains, each being about 30 kDa that are coupled by a linker to a reactive functional group. The PEG Reagent is attached to a cysteine residue of BDD Factor VIII, resulting in Jivi/BAY 94.

33. Upon information and belief, Jivi/BAY 94 includes BAY 1025662, which is that portion of the Jivi/BAY 94 comprising one or more attached PEG Reagent molecules attached via a linker, and a cysteine residue (“PEG60MalCys”). Upon information and belief, Jivi/BAY 94 includes PEG60MalCys, which has the following structure:



34. Upon information and belief, Jivi/BAY 94 is intended to be administered intravenously and will be available as a lyophilized powder containing 250, 500, 1000, 2000, or 3000 International Units (“IU”). Upon information and belief, Jivi/BAY 94 is produced without the addition of any exogenous human or animal derived protein in the cell culture process, purification, pegylation, or final formulation.

35. Upon information and belief, Bayer has made meaningful preparations to and/or has commenced the commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW.

36. Upon information and belief, Bayer has hired and continues to grow its sales force in order to promote the marketing and sale of Jivi/BAY 94 in the United States, including by hiring additional sales people.

37. Upon information and belief, Bayer has a manufacturing facility for the commercial manufacture of Jivi/BAY 94 to accommodate the demand for Jivi/BAY 94 following FDA approval. Upon information and belief, Bayer has the capability to manufacture Jivi/BAY 94.

38. Upon information and belief, following the approval of Bayer's BLA, Jivi/BAY 94 will be indicated for an overlapping patient population as ADYNOVATE<sup>®</sup> and will, therefore, compete with Baxalta's ADYNOVATE<sup>®</sup> product.

39. In sum, upon information and belief, Bayer has made meaningful preparations to manufacture, use, offer to sell, and/or sell Jivi/BAY 94 product in the United States and the ROW, and/or is commercially manufacturing, using, offering to sell, and/or selling the PEG Reagent and/or its Jivi/BAY 94 product in the United States and the ROW, including in this Judicial District.

40. As a direct and proximate result of Bayer's acts of infringement in the U.S. and the ROW, Plaintiffs will suffer damages in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits or a reasonable royalty.

41. Upon information or belief, Bayer knew of the existence of the Nektar's patents and/or patent applications and the risk that the PEG Reagent and/or Jivi/BAY 94 would infringe these patents since at least 2012. (*Baxalta Inc. v. Bayer HealthCare LLC*, C.A. No. 17-1316-RGA (D. Del.), D.I. 18, Decl. of Bayer Senior Counsel Alan Stevenson ¶ 2 (stating that in 2012 Bayer approached Plaintiffs "to discuss business resolutions that would avoid patent litigation involving BAY 94").) Upon information and belief, Bayer is aware of Nektar's patents directed to PEG reagents, including at least the '440 patent, the '072 patent, the '833 patent, the '453



patent, and the '569 patent, and was aware of these patents prior to commercially marketing Jivi/BAY 94, or at least no later than the filing of this Complaint. (*See id.*)

42. Upon information and belief, Bayer knew or should have known that the PEG Reagent and/or Jivi/BAY 94 infringes the Patents-in-Suit prior to seeking FDA marketing approval for and/or launching Jivi/BAY 94. Bayer's at-risk launch of the PEG Reagent and/or Jivi/BAY 94 with knowledge of the Patents-in-Suit is willful.

**FIRST COUNT**

(Infringement of the '440 patent by Bayer)

43. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

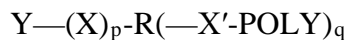
44. Upon information and belief, Bayer is using the PEG Reagent for the manufacture of Jivi/BAY 94. Upon information and belief, Bayer currently uses and intends to use the PEG Reagent when it commercially manufactures, markets, sells, offers for sale, and/or distributes Jivi/BAY 94. Upon information and belief, Bayer has commercially manufactured, used, sold, offered for sale, and/or imported the PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, or has made meaningful preparations to commercially manufacture, use sell, offer for sale, and/or import PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, upon, or in anticipation of, FDA approval.

45. Upon information and belief, Bayer was made aware of its infringement of the '440 patent prior to the commercial launch of the PEG Reagent and/or Jivi/BAY 94, or at least no later than the filing of this Complaint.

46. The PEG Reagent and/or Jivi/BAY 94 and/or its manufacture satisfies each claim element of and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '440 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

47. Claim 1 of the '440 patent recites:

A branched reactive polymer having the structure:



wherein:

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

each POLY is a water soluble and non-peptide polymer, wherein the molecular weight of each POLY is selected such that the total molecular weight of the branched reactive polymer is independently selected from the group consisting of poly(alkylene glycol), poly(oxyethylated polyol), poly(olefinic alcohol), poly(vinylpyrrolidone), poly(hydroxyalkylmethacrylamide), poly(hydroxyalkylmethacrylate), polysaccharides, poly( $\alpha$ -hydroxy acid), poly(vinyl alcohol), polyphosphazene, polyoxazoline, poly(N-acryloylmorpholine), and copolymers, terpolymers, and mixtures thereof is at least about 5,000 Da;

X' is a heteroatom linkage;

X is a linker;

p is 0 or 1;

q is 2 to about 10; and

Y is a functional group reactive with an electrophilic or nucleophilic group.

48. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “[a] branched reactive polymer.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain. Upon information and belief, a “reactive polymer” was and is used to manufacture Jivi/BAY 94.

49. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “having the structure:  $Y-(X)_p-R-(X'-POLY)_q$ .” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -

methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy.” Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

50. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “wherein: R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

51. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “each POLY is a water soluble and non-peptide polymer, wherein the molecular weight of each POLY is selected such that the total molecular weight or the branched reactive polymer is independently selected from the group consisting of poly(alkylene glycol),

poly(oxyethylated polyol), poly(olefinic alcohol), poly(vinylpyrrolidone), poly(hydroxyalkylmethacrylamide), poly(hydroxyalkylmethacrylate), polysaccharides, poly( $\alpha$ -hydroxy acid), poly(vinyl alcohol), polyphosphazene, polyoxazoline, poly(N-acryloylmorpholine), and copolymers, terpolymers, and mixtures thereof is at least about 5,000 Da.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of “poly(oxyethylene)” and satisfies the claim limitation of “poly(alkylene glycol).” Upon information and belief, Jivi/BAY 94 comprises two polyethylene glycols (“PEGs”) that are at least 5,000 Da each.

52. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “X’ is a heteroatom linkage.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X’ is represented by the Jivi/BAY 94 chemical name segment “oxy,” which is a heteroatom linkage.

53. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “X is a linker.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” which is a linker.

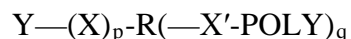
54. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “p is 0 or 1.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” wherein p is 1.

55. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “q is 2 to about 10.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is 2 to about 10 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis,” wherein q is 2.

56. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “Y is a functional group reactive with an electrophilic or nucleophilic group.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a product made after conjugation of Factor VIII with a functional group reactive with an electrophilic or nucleophilic group.

57. Claim 31 of the '440 patent recites:

A biologically active conjugate, comprising a biologically active molecule covalently attached to a branched reactive polymer having the structure:



wherein:

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

each POLY is a water soluble and non-peptide polymer, wherein the molecular weight of each POLY is selected such that the total molecular weight or the branched reactive polymer is independently selected from the group consisting of poly(alkylene glycol), poly(oxyethylated polyol), poly(olefinic alcohol), poly(vinylpyrrolidone), poly(hydroxyalkylmethacrylamide), poly(hydroxyalkylmethacrylate), polysaccharides, poly( $\alpha$ -hydroxy acid), poly(vinyl alcohol), polyphosphazene, polyoxazoline, poly(N-acryloylmorpholine), and copolymers, terpolymers, and mixtures thereof;

X' is —NH—, —O—, or —S—;

X is linker;

p is 0 or 1;

q is 2 to about 10; and

Y is a functional group.

58. Jivi/BAY 94 satisfies the claim limitation “[a] biologically active conjugate.”

Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide.

Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active conjugate.

59. Jivi/BAY 94 satisfies the claim limitation “comprising a biologically active molecule covalently attached to a branched reactive polymer.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active molecule that is covalently attached to a branched reactive polymer. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain. Upon information and belief, a “reactive polymer” was used to manufacture Jivi/BAY 94.

60. Jivi/BAY 94 satisfies the claim limitation “having the structure:  $Y-(X)_p-R-(X'-POLY)_q$ .” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy.” Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

61. Jivi/BAY 94 satisfies the claim limitation “wherein: R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

62. Jivi/BAY 94 satisfies the claim limitation “each POLY is a water soluble and non-peptide polymer, wherein the molecular weight of each POLY is selected such that the total molecular weight or the branched reactive polymer is independently selected from the group consisting of poly(alkylene glycol), poly(oxyethylated polyol), poly(olefinic alcohol), poly(vinylpyrrolidone), poly(hydroxyalkylmethacrylamide), poly(hydroxyalkylmethacrylate), polysaccharides, poly( $\alpha$ -hydroxy acid), poly(vinyl alcohol), polyphosphazene, polyoxazoline, poly(N-acryloylmorpholine), and copolymers, terpolymers, and mixtures thereof.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of “poly(oxyethylene)” and satisfies the claim limitation of “poly(alkylene glycol).”

63. Jivi/BAY 94 satisfies the claim limitation “X’ is —NH—, —O—, or —S—.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X’ is represented by the Jivi/BAY 94 chemical name segment “oxy,” which is —O—.

64. Jivi/BAY 94 satisfies the claim limitation “X is linker.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” which is a linker.



65. Jivi/BAY 94 satisfies the claim limitation “p is 0 or 1.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” wherein p is 1.

66. Jivi/BAY 94 satisfies the claim limitation “q is about 2 to 10.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is about 2 to 10 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis,” wherein q is 2.

67. Jivi/BAY 94 satisfies the claim limitation “Y is a functional group.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a functional group.

68. As a result of Bayer’s wrongful acts, Plaintiffs will be substantially and irreparably harmed if Bayer is not enjoined from infringing the ’440 patent. Plaintiffs have no adequate remedy at law.

69. As a result of Bayer’s infringement, Plaintiffs will suffer damages and are entitled to recover from Bayer the damages from Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the

ROW in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits and/or a reasonable royalty.

70. Bayer's commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 is willful, and Plaintiffs are entitled to an award of enhanced damages under 35 U.S.C. § 284.

71. As a result of Bayer's infringement, Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

### **SECOND COUNT**

(Infringement of the '072 patent by Bayer)

72. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

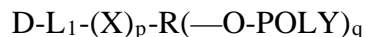
73. Upon information and belief, Bayer is using the PEG Reagent for the manufacture of Jivi/BAY 94. Upon information and belief, Bayer currently uses and intends to use the PEG Reagent when it commercially manufactures, markets, sells, offers for sale, and/or distributes Jivi/BAY 94. Upon information and belief, Bayer has commercially manufactured, used, sold, offered for sale, and/or imported the PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, or has made meaningful preparations to commercially manufacture, use sell, offer for sale, and/or import PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, upon, or in anticipation of, FDA approval.

74. Upon information and belief, Bayer was aware of its infringement of the '072 patent prior to the commercial launch of the PEG Reagent and/or Jivi/BAY 94, or at least no later than the filing of this Complaint.

75. The PEG Reagent and/or Jivi/BAY 94 and/or its manufacture satisfies each claim element of and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '072 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

76. Claim 1 of the '072 patent recites:

A biologically active conjugate comprising a branched polymer covalently attached to a biologically active molecule, wherein the conjugate has the structure:



wherein:

D is the biologically active molecule;

$L_1$  is a linkage resulting from the reaction of a functional group on the linker (X), when present, or on the aliphatic hydrocarbon having a length of at least three carbon atoms (R) of the branched polymer and a functional group of the biologically active molecule;

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

each POLY is a water soluble and non-peptidic polymer that terminates with a hydroxyl or methoxy group;

X is a linker of 1 to 10 atoms in length;

p is 0 or 1; and

q is 2 to about 10,

and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.

77. Jivi/BAY 94 satisfies the claim limitation “[a] biologically active conjugate.”

Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide.

Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active conjugate.

78. Jivi/BAY 94 satisfies the claim limitation “comprising a branched polymer covalently attached to a biologically active molecule.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active molecule that is covalently attached to a branched polymer. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain.

79. Jivi/BAY 94 satisfies the claim limitation “wherein the conjugate has the structure: D-L<sub>1</sub>-(X)<sub>p</sub>-R(—O-POLY)<sub>q</sub>.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, D is represented by the Jivi/BAY 94 chemical name segment “human coagulation factor VIII.” Upon information and belief, L<sub>1</sub> is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

80. Jivi/BAY 94 satisfies the claim limitation “wherein: D is the biologically active molecule.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-

1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, D is represented by the Jivi/BAY 94 chemical name segment “human coagulation factor VIII,” which is a biologically active molecule.

81. Jivi/BAY 94 satisfies the claim limitation “L<sub>1</sub> is a linkage resulting from the reaction of a functional group on the linker (X), when present, or on the aliphatic hydrocarbon having a length of at least three carbon atoms (R) of the branched polymer and a functional group of the biologically active molecule.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl) amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, L<sub>1</sub> is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a linkage resulting from the reaction of a functional group on the linker (X).

82. Jivi/BAY 94 satisfies the claim limitation “R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

83. Jivi/BAY 94 satisfies the claim limitation “each POLY is a water soluble and non-peptidic polymer that terminates with a hydroxyl or methoxy group.” Upon information and

belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of “poly(oxyethylene)” and satisfies the claim limitation of a water soluble, non-peptidic polymer. Upon information and belief, Jivi/BAY 94 comprises POLY that terminates with a hydroxyl or methoxy group, as is represented by the Jivi/BAY 94 chemical name segment of “methoxy.”

84. Jivi/BAY 94 satisfies the claim limitation “X is a linker of 1 to 10 atoms in length.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” which is a linker of 1 to 10 atoms in length.

85. Jivi/BAY 94 satisfies the claim limitation “p is 0 or 1.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” wherein p is 1.

86. Jivi/BAY 94 satisfies the claim limitation “q is 2 to about 10.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-

yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is 2 to about 10 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis,” wherein q is 2.

87. Jivi/BAY 94 satisfies the claim limitation “and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.” Upon information and belief, Jivi/BAY 94 comprises branched polyethylene glycols, each polyethylene glycol having a molecular weight of about 30,000 Da for a total of about 60,000 Da.

88. As a result of Bayer’s wrongful acts, Plaintiffs will be substantially and irreparably harmed if Bayer is not enjoined from infringing the ’072 patent. Plaintiffs have no adequate remedy at law.

89. As a result of Bayer’s infringement, Plaintiffs will suffer damages and are entitled to recover from Bayer the damages from Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits and/or a reasonable royalty.

90. Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 is willful, and Plaintiffs are entitled to an award of enhanced damages under 35 U.S.C. § 284.

91. As a result of Bayer’s infringement, Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

**THIRD COUNT**

(Infringement of the ’833 patent by Bayer)

92. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

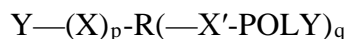
93. Upon information and belief, Bayer is using the PEG Reagent for the manufacture of Jivi/BAY 94. Upon information and belief, Bayer currently uses and intends to use the PEG Reagent when it commercially manufactures, markets, sells, offers for sale, and/or distributes Jivi/BAY 94. Upon information and belief, Bayer has commercially manufactured, used, sold, offered for sale, and/or imported the PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, or has made meaningful preparations to commercially manufacture, use sell, offer for sale, and/or import PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, upon, or in anticipation of, FDA approval.

94. Upon information and belief, Bayer was aware of its infringement of the '833 patent prior to the commercial launch of the PEG Reagent and/or Jivi/BAY 94, or at least no later than the filing of this Complaint.

95. The PEG Reagent and/or Jivi/BAY 94 and/or its manufacture satisfies each claim element of and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '833 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

96. Claim 1 of the '833 patent recites:

A branched reactive polymer having the structure:



wherein:

Y is a functional group reactive with an electrophilic or nucleophilic group,

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

X' is —O—;

X is a linker of 1 to 10 atoms in length;

P is 0 or 1;



q is 2 to about 10; and

each POLY is a water soluble and non-peptidic polyethylene glycol (PEG) polymer that terminates with a hydroxyl or methoxy group,

and further within the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.

97. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “[a] branched reactive polymer.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain. Upon information and belief, a “reactive polymer” was used to manufacture Jivi/BAY 94.

98. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “having the structure:  $Y-(X)_p-R(-X'-POLY)_q$ .” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy.” Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

99. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “Y is a functional group reactive with an electrophilic or nucleophilic group.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a product made after conjugation of Factor VIII with a functional group reactive with an electrophilic or nucleophilic group.

100. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “wherein: R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

101. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “X' is —O—.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy,” which is —O—.

102. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “X is a linker of 1 to 10 atoms in length.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” which is a linker of 1 to 10 atoms in length.

103. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “P is 0 or 1.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” wherein p is 1.

104. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “q is 2 to about 10.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is 2 to about 10 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis,” wherein q is 2.

105. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “and each POLY is a water soluble and non-peptidic polyethylene glycol (PEG) polymer.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-

oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of “poly(oxyethylene)” and satisfies the claim limitation of “polyethylene glycol.” Upon information and belief, polyethylene glycol is water soluble and non-peptidic. Upon information and belief, Jivi/BAY 94 satisfies the claim limitation of “that terminates with a hydroxyl or methoxy group,” which is represented by the Jivi/BAY 94 chemical name segment of “methoxy.”

106. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.” Upon information and belief, Jivi/BAY 94 comprises branched polyethylene glycols, each polyethylene glycol having a molecular weight of about 30,000 Da for a total of about 60,000 Da.

107. As a result of Bayer’s wrongful acts, Plaintiffs will be substantially and irreparably harmed if Bayer is not enjoined from infringing the ’833 patent. Plaintiffs have no adequate remedy at law.

108. As a result of Bayer’s infringement, Plaintiffs will suffer damages and are entitled to recover from Bayer the damages from Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits and/or a reasonable royalty.

109. Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 is willful, and Plaintiffs are entitled to an award of enhanced damages under 35 U.S.C. § 284.

110. As a result of Bayer's infringement, Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**FOURTH COUNT**

(Infringement of the '453 patent by Bayer)

111. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

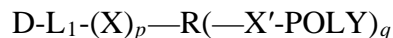
112. Upon information and belief, Bayer is using the PEG Reagent for the manufacture of Jivi/BAY 94. Upon information and belief, Bayer currently uses and intends to use the PEG Reagent when it commercially manufactures, markets, sells, offers for sale, and/or distributes Jivi/BAY 94. Upon information and belief, Bayer has commercially manufactured, used, sold, offered for sale, and/or imported the PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, or has made meaningful preparations to commercially manufacture, use sell, offer for sale, and/or import PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, upon, or in anticipation of, FDA approval.

113. Upon information and belief, Bayer was aware of its infringement of the '453 patent prior to the commercial launch of the PEG Reagent and/or Jivi/BAY 94, or at least no later than the filing of this Complaint.

114. The PEG Reagent and/or Jivi/BAY 94 and/or its manufacture satisfies each claim element of and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '453 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

115. Claim 1 of the '453 patent recites:

A biologically active conjugate comprising a branched polymer covalently attached to a biologically active molecule, wherein the conjugate has the structure:



wherein:

D is the biologically active molecule;

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

L<sub>1</sub> is a linkage resulting from the reaction of a functional group on the linker (X), when present, or on the aliphatic hydrocarbon having a length of at least three carbon atoms (R) of the branched polymer and a functional group of the biologically active molecule;

each POLY is a water soluble and non-peptidic polymer that terminates with a hydroxyl or methoxy group;

X' is —O—, —NH—, or —S—;

X is a linker of 1 to 10 atoms in length;

p is 0 or 1; and

q is 2,

and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.

116. Jivi/BAY 94 satisfies the claim limitation “[a] biologically active conjugate.”

Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide.

Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active conjugate.

117. Jivi/BAY 94 satisfies the claim limitation “comprising a branched polymer covalently attached to a biologically active molecule.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, PEGylated Factor VIII polypeptide is a biologically active molecule that is covalently attached to a branched polymer. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain.

118. Jivi/BAY 94 satisfies the claim limitation “wherein the conjugate has the structure:  $D-L_1-(X)_p-R(-X'-POLY)_q$ .” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, D is represented by the Jivi/BAY 94 chemical name segment “human coagulation factor VIII.” Upon information and belief,  $L_1$  is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy.” Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

119. Jivi/BAY 94 satisfies the claim limitation “wherein: D is the biologically active molecule.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, D is represented by the Jivi/BAY 94 chemical name segment “human coagulation factor VIII,” which is a biologically active molecule.

120. Jivi/BAY 94 satisfies the claim limitation “R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

121. Jivi/BAY 94 satisfies the claim limitation “L<sub>1</sub> is a linkage resulting from the reaction of a functional group on the linker (X), when present, or on the aliphatic hydrocarbon having a length of at least three carbon atoms (R) of the branched polymer and a functional group of the biologically active molecule.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)]propoxy}propyl) amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, L<sub>1</sub> is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a linkage resulting from the reaction of a functional group on the linker (X).

122. Jivi/BAY 94 satisfies the claim limitation “each POLY is a water soluble and non-peptidic polymer that terminates with a hydroxyl or methoxy group.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of



“poly(oxyethylene)” and satisfies the claim limitation of a water soluble, non-peptidic polymer. Upon information and belief, Jivi/BAY 94 comprises POLY that terminates with a hydroxyl or methoxy group, as is represented by the Jivi/BAY 94 chemical name segment of “methoxy.”

123. Jivi/BAY 94 satisfies the claim limitation “X’ is —O—, —NH—, or —S—.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X’ is represented by the Jivi/BAY 94 chemical name segment “oxy,” which is —O—.

124. Jivi/BAY 94 satisfies the claim limitation “X is a linker of 1 to 10 atoms in length.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” which is a linker of 1 to 10 atoms in length.

125. Jivi/BAY 94 satisfies the claim limitation “p is 0 or 1.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl},” wherein p is 1.

126. Jivi/BAY 94 satisfies the claim limitation “q is 2.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-

cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

127. Jivi/BAY 94 satisfies the claim limitation “and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.” Upon information and belief, Jivi/BAY 94 comprises branched polyethylene glycols, each polyethylene glycol having a molecular weight of about 30,000 Da for a total of about 60,000 Da.

128. As a result of Bayer’s wrongful acts, Plaintiffs will be substantially and irreparably harmed if Bayer is not enjoined from infringing the ’453 patent. Plaintiffs have no adequate remedy at law.

129. As a result of Bayer’s infringement, Plaintiffs will suffer damages and are entitled to recover from Bayer the damages from Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits and/or a reasonable royalty.

130. Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 is willful, and Plaintiffs are entitled to an award of enhanced damages under 35 U.S.C. § 284.

131. As a result of Bayer’s infringement, Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

**FIFTH COUNT**

(Infringement of the ’569 patent by Bayer)

132. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

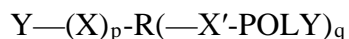
133. Upon information and belief, Bayer is using the PEG Reagent for the manufacture of Jivi/BAY 94. Upon information and belief, Bayer currently uses and intends to use the PEG Reagent when it commercially manufactures, markets, sells, offers for sale, and/or distributes Jivi/BAY 94. Upon information and belief, Bayer has commercially manufactured, used, sold, offered for sale, and/or imported the PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, or has made meaningful preparations to commercially manufacture, use sell, offer for sale, and/or import PEG Reagent alone, or attached to Factor VIII, resulting in a biologically active Jivi/BAY 94, upon, or in anticipation of, FDA approval.

134. Upon information and belief, Bayer was aware of its infringement of the '569 patent prior to the commercial launch of the PEG Reagent and/or Jivi/BAY 94, or at least no later than the filing of this Complaint.

135. The PEG Reagent and/or Jivi/BAY 94 and/or its manufacture satisfies each claim element of and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '569 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

136. Claim 1 of the '569 patent recites:

A branched reactive polymer having the structure:



wherein:

R is an aliphatic hydrocarbon having a length of at least three carbon atoms;

each POLY is a poly(ethylene glycol) that terminates with a hydroxyl or methoxy group;

X' is a heteroatom linkage selected from —NH—, —O— or —S—;

X is a linker of 1 to ten atoms;

p is 0 or 1;

q is 2 to about 10; and

and Y is a maleimide,

and further wherein the branched reactive polymer has a molecular weight of about 500 Da to about 100,000 Da.

137. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “[a] branched reactive polymer.” Upon information and belief, Jivi/BAY 94 is comprised of a PEGylated Factor VIII polypeptide. Upon information and belief, the PEG Reagent used in Jivi/BAY 94 is branched and each branch contains a 30 kDa PEG chain. Upon information and belief, a “reactive polymer” was used to manufacture Jivi/BAY 94.

138. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “having the structure: Y—(X)<sub>p</sub>-R(—X'-POLY)<sub>q</sub>.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin.” Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, p is 1 as represented by the Jivi/BAY 94 chemical name segment “propyl)amino]-3-oxopropyl}.” Upon information and belief, R is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms. Upon information and belief, X' is represented by the Jivi/BAY 94 chemical name segment “oxy.” Upon information and belief, POLY is represented by the Jivi/BAY 94 chemical name segment “poly(oxyethylene.” Upon information and belief, q is 2 as represented by the Jivi/BAY 94 chemical name segment “2,3-bis.”

139. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “wherein: R is an aliphatic hydrocarbon having a length of at least three carbon atoms.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, R is an aliphatic hydrocarbon having a length of at least three carbon atoms and is represented by the Jivi/BAY 94 chemical name segment “propoxy,” which contains an aliphatic hydrocarbon having a length of at least three carbon atoms.

140. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “each POLY is a poly(ethylene glycol) that terminates with a hydroxyl or methoxy group.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, each POLY is polyethylene glycol, which is represented by the Jivi/BAY 94 chemical name segment of “poly(oxyethylene)” and satisfies the claim limitation of a “poly(ethylene glycol).” Upon information and belief, Jivi/BAY 94 comprises POLY that terminates with a hydroxyl or methoxy group, as is represented by the Jivi/BAY 94 chemical name segment of “methoxy.”

141. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “X’ is a heteroatom linkage selected from —NH—, —O— or —S—.” Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ $\omega$ -methoxypoly(oxyethylene)] propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and

belief, X' is represented by the Jivi/BAY 94 chemical name segment "oxy," which is —O—, a heteroatom linkage.

142. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation "X is a linker of 1 to ten atoms." Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, X is represented by the Jivi/BAY 94 chemical name segment "propyl)amino]-3-oxopropyl}," which is a linker of 1 to ten atoms.

143. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation "p is 0 or 1." Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, p is 0 or 1 as represented by the Jivi/BAY 94 chemical name segment "propyl)amino]-3-oxopropyl}," wherein p is 1.

144. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation "q is 2 to about 10." Upon information and belief, Jivi/BAY 94 has the chemical name of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy}propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, q is 2 to about 10 as represented by the Jivi/BAY 94 chemical name segment "2,3-bis," wherein q is 2.

145. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation "Y is a maleimide." Upon information and belief, Jivi/BAY 94 has the chemical name

of des-(743-1636)-[1804-[S-(1-{3-[(3-{2,3-bis[ω-methoxypoly(oxyethylene)]propoxy)propyl)amino]-3-oxopropyl}-2,5-dioxopyrrolidin-3-yl)-L-cysteine](K>C)]human coagulation factor VIII. Upon information and belief, Y is represented by the Jivi/BAY 94 chemical name segment “2,5-dioxopyrrolidin,” which is a group resulting from conjugation of maleimide to Factor VIII.

146. Bayer uses a compound to manufacture Jivi/BAY 94 that satisfies the claim limitation “and further wherein the branched polymer has a molecular weight of about 500 Da to about 100,000 Da.” Upon information and belief, Jivi/BAY 94 comprises a branched polymer, polyethylene glycol, and each polyethylene glycol has a molecular weight of about 30,000 Da for a total of about 60,000 Da. Upon information and belief, a “reactive polymer” was used to manufacture Jivi/BAY 94.

147. As a result of Bayer’s wrongful acts, Plaintiffs will be substantially and irreparably harmed if Bayer is not enjoined from infringing the ’569 patent. Plaintiffs have no adequate remedy at law.

148. As a result of Bayer’s infringement, Plaintiffs will suffer damages and are entitled to recover from Bayer the damages from Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW in an amount to be determined through discovery and/or trial, but in an amount no less than lost profits and/or a reasonable royalty.

149. Bayer’s commercial manufacture, marketing, use, sale, offer for sale, and/or distribution of the PEG Reagent and/or Jivi/BAY 94 is willful, and Plaintiffs are entitled to an award of enhanced damages under 35 U.S.C. § 284.

150. As a result of Bayer's infringement, Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs Nektar, Baxalta Inc., and Baxalta US pray for judgment against Defendant Bayer, and respectfully request the following relief:

1. A judgment that the '440 patent, the '072 patent, the '833 patent, the '453 patent, and the '569 patent have been infringed and will be infringed by Bayer under 35 U.S.C.

§§ 271(a), (b), (c), (f), and/or (g);

2. A judgment for an injunction enjoining Bayer, and its officers, agents, servants, and employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the PEG Reagent and/or Jivi/BAY 94 within the United States, or importing the PEG Reagent and/or Jivi/BAY 94 into the United States, prior to the expiration of the '440 patent, the '072 patent, the '833 patent, the '453 patent, and/or the '569 patent pursuant to 35 U.S.C. § 283;

3. To the extent that Defendant has or will commercially manufacture, market, use, sell, offer for sale, and/or distribute the PEG Reagent and/or Jivi/BAY 94 in the U.S. and the ROW prior to the expiration of the '440 patent, the '072 patent, the '833 patent, the '453 patent, and/or the '569 patent, including any extensions, a judgment pursuant to 35 U.S.C. § 284 awarding Plaintiffs monetary relief together with interest, costs, expenses and disbursements;

4. An award of all other damages as are appropriate under 35 U.S.C. § 284;

5. A judgment that this is an exceptional case and that Plaintiffs be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

6. Costs and expenses in this action; and

7. Such other and further relief as the Court deems just and appropriate.



**DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all claims and issues so triable.

*Of Counsel:*

Edgar H. Haug  
Angus Chen  
Porter F. Fleming  
Richard F. Kurz  
HAUG PARTNERS LLP  
745 Fifth Avenue  
New York, New York 10151  
(212) 588-0800  
ehaug@haugpartners.com  
achen@haugpartners.com  
pfleming@haugpartners.com  
rkurz@haugpartners.com

/s/ Kelly E. Farnan

Frederick L. Cottrell, III (#2555)  
Kelly E. Farnan (#4395)  
RICHARDS, LAYTON & FINGER, P.A.  
One Rodney Square  
920 North King Street  
Wilmington, Delaware 19801  
(302) 651-7700  
cottrell@rlf.com  
farnan@rlf.com

*Attorneys for Plaintiffs*  
*Nektar Therapeutics, Baxalta Incorporated,*  
*and Baxalta US Inc.*

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