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12
13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA
15 SAN JOSE DIVISION

16
17 BAYER HEALTHCARE LLC

18 Plaintiff,

19 vs.

20 NEKTAR THERAPEUTICS,
21 BAXALTA INCORPORATED, and
BAXALTA US INC.,

22 Defendants.
23

) Case No. 3:17-cv-05055 (LHK)

) **AMENDED COMPLAINT FOR
DECLARATORY JUDGMENT OF
PATENT NON-INFRINGEMENT**

) **DEMAND FOR JURY TRIAL**
24

25 Plaintiff Bayer HealthCare LLC (“Bayer”), by and through its undersigned attorneys,
26 hereby files the following Amended Complaint for declaratory relief against Defendants
27 Nektar Therapeutics (“Nektar”), Baxalta Incorporated (“Baxalta Inc.”), and Baxalta US Inc.
28 (“Baxalta US”) (collectively, “Defendants”) pursuant to Federal Rule of Civil Procedure
15(a)(1)(A) and alleges as follows:

1 **NATURE OF ACTION**

2 1. This is an action arising under the Declaratory Judgment Act, 28 U.S.C. § 2201,
3 *et seq.*, and the United States Patent Act, 35 U.S.C. § 1, *et seq.* Bayer seeks a declaratory
4 judgment that U.S. Patent No. 7,199,223 (Ex. 1, the “’223 patent”); U.S. Patent No. 7,863,421
5 (Ex. 2, the “’421 patent”); U.S. Patent No. 8,143,378 (Ex. 3, the “’378 patent”); U.S. Patent No.
6 8,247,536 (Ex. 4, the “’536 patent”); U.S. Patent No. 8,519,102 (Ex. 5, the “’102 patent”); U.S.
7 Patent No. 8,618,259 (Ex. 6, the “’259 patent”); and U.S. Patent No. 8,889,831 (Ex. 7, the “’831
8 patent”) (collectively, the “Nektar Patents-in-Suit”) are not infringed by Bayer’s Factor VIII
9 replacement product BAY 94-9027 (“BAY 94”).

10 2. The allegations set forth herein arise out of the same conduct, transaction, and/or
11 occurrence set out in the original complaint that sought declaratory relief with respect to Bayer’s
12 BAY 94 product and Nektar’s U.S. Patent No. 7,858,749 (the “’749 patent”). The originally
13 asserted ’749 patent and the Nektar Patents-in-Suit all derive from Provisional Patent
14 Application No. 60/450,578 (the “Provisional Application”), share a common specification, and
15 belong to the same family of patents and patent applications. The terms of the ’421, ’378, ’536,
16 ’102, ’259, and ’831 patents, along with the ’749 patent, are all terminally disclaimed over the
17 term of the ’223 patent.

18 **THE PARTIES**

19 3. Plaintiff Bayer is organized under the laws of the State of Delaware, having its
20 principal place of business at 100 Bayer Boulevard, Whippany, New Jersey, 07981, and
21 substantial facilities in this District at 800 Dwight Way, Berkeley, California, 94710.

22 4. Defendant Nektar is a corporation organized under the laws of the State of
23 Delaware, having its principal place of business at 455 Mission Bay Boulevard South, San
24 Francisco, California, 94158.

25 5. Defendant Baxalta Inc. is a corporation organized under the laws of the State of
26 Delaware, having its principal place of business at 1200 Lakeside Drive, Bannockburn, Illinois,
27 60015.

1 and systematic contacts with this District, and therefore, have purposefully availed themselves of
2 the privilege of conducting activities within this District. Upon information and belief, Baxalta
3 Inc. and Baxalta US employ individuals and have multiple manufacturing facilities in California,
4 including in this District at 1978 West Winton Avenue, Hayward, California, 94545.

5 15. Upon information and belief, Baxalta Inc. and Baxalta US are parties to an
6 exclusive license agreement with Nektar, pursuant to which Nektar granted Baxalta Inc. and
7 Baxalta US exclusive rights to the family of patents and applications that includes the Nektar
8 Patents-in-Suit and the originally asserted '749 patent. Upon information and belief, under the
9 terms of the exclusive license agreement, Nektar expressly or impliedly transferred its rights in
10 the Nektar Patents-in-Suit and '749 patent to Baxalta Inc. and Baxalta US in at least the field of
11 treatment of hemophilia A or pegylated Factor VIII.

12 16. Upon information and belief, pursuant to the exclusive agreement, Baxalta Inc.
13 and Baxalta US purchase materials (e.g., polyethylene glycol polymers ("PEG")) from Nektar
14 that are manufactured in this District for a portion of the product supply chain for Adynovate[®],
15 Baxalta Inc. and Baxalta US's pegylated Factor VIII replacement product. In exchange, Baxalta
16 Inc. and Baxalta US are responsible for development and commercialization of Adynovate[®] and
17 remit substantial royalty payments to Nektar in this District in the form of: escalating royalties
18 between 4-6 percent on global net revenue of Adynovate[®] up to \$1.2 billion in revenue, 13%
19 royalty for revenue above \$1.2 billion, and additional tiered revenue milestone payments based
20 upon global net revenue of Adynovate[®].

21 17. Baxalta Inc. and Baxalta US have also purposefully directed their activities at
22 consumer-residents of this forum in a systematic and continuous manner. Upon information and
23 belief, Baxalta Inc. and/or Baxalta US sell and market their products, including Adynovate[®],
24 throughout this District and the State of California.

25 18. Baxalta US has appointed a registered agent in this state to accept service of
26 process on its behalf and is therefore subject to service in California.

1 **VENUE**

2 19. Venue is proper in this District under 28 U.S.C. §§ 1391(a), (b), (c), and (d)
3 because Nektar, Baxalta Inc., and Baxalta US are subject to this Court’s personal jurisdiction by
4 virtue of their continuous and systematic contacts with this District. In addition, the Nektar
5 Patents-in-Suit state on their face that they are situated by assignment to Nektar at its
6 headquarters in this District in San Francisco, California.

7 20. Venue is also proper in this District because Bayer maintains a substantial site for
8 research, development, and manufacture of biological products in Berkeley, California.

9 **INTRADISTRICT ASSIGNMENT**

10 21. This action was assigned previously to the San Jose Division.

11 **FACTUAL BACKGROUND**

12 22. Plaintiff Bayer is a global life science company whose lineage traces back over
13 150 years. Bayer is a leader in the field of research and development of innovative drug
14 treatments in numerous therapeutic areas, including hematology.

15 23. Bayer has focused its innovative research and development in the hematology
16 field on the treatment of hemophilia A, a genetic blood coagulation disorder that affects
17 approximately 400 newborn babies each year in the United States and over 400,000 people
18 worldwide. Patients suffering from hemophilia A are afflicted with a deficiency of the
19 functional human Factor VIII, a complex protein that is critical for proper blood coagulation and
20 control of bleeding. Hemophilia A patients can experience a range of serious consequences,
21 such as hemorrhages in the joints and muscles as well as bleeding in the digestive system and
22 brain. Without the constant presence of functional Factor VIII in the body, hemophilia A
23 patients can suffer severe and even fatal bleeding episodes. Hemophilia A treatment includes
24 both prophylactic administration of Factor VIII replacement products as well as intravenous
25 injections in response to a bleeding episode.

26 24. Bayer is a leader in the research and development efforts related to understanding
27 the role of Factor VIII and treatments for hemophilia A. Bayer has developed several Factor
28 VIII replacement therapies in the United States, including its recombinant antihemophilic Factor

1 VIII products Kogenate[®], Kogenate[®] FS, and Kovaltry[®]. Kogenate[®] was one of the first
2 recombinant Factor VIII products approved in the United States by the U.S. Food and Drug
3 Administration (“FDA”) in 1993. Kogenate[®] FS, an improved Kogenate[®] product formulation,
4 was approved by the FDA in 2000. Kovaltry[®], which provides for less frequent prophylactic
5 dosing in certain patients, was approved by the FDA in March 2016.

6 25. In humans, Factor VIII has a relatively short half-life of approximately 11 hours.
7 Because of this short half-life, patients who require prophylactic Factor VIII replacement therapy
8 are required to receive Factor VIII infusions up to three times per week, and sometimes as often
9 as every day. Such frequent dosing limits the ability of hemophilia A patients to lead dynamic,
10 active lifestyles, especially for adolescents and young adults. The demanding nature of
11 prophylactic Factor VIII treatment may also contribute to patient noncompliance, which can lead
12 to serious adverse consequences, including fatal bleeding episodes. Therefore, increasing the
13 half-life of Factor VIII treatments to reduce the frequency of infusions is of utmost importance to
14 hemophilia A patients, their treating physicians, and researchers.

15 26. Since introducing Kogenate[®] in 1993, Bayer has continued to devote substantial
16 research and development resources to improving hemophilia A treatments, including by
17 implementing pegylation technology to increase the half-life of Factor VIII replacement products
18 in order to reduce the frequency of infusions and reduce immunogenicity. Pegylation is a
19 method by which PEG molecules are attached to active biologic or chemical entities in an effort
20 to impart certain unique properties, such as potentially preventing degradation of the therapeutic
21 product to extend its half-life.

22 27. Factor VIII, however, is a very large and complex protein that is unique in
23 structure and function. As a result, it has presented challenging issues related to extending its
24 half-life through pegylation. Factor VIII interacts with a host of additional enzymes and proteins
25 in a particular sequence of biochemical events that leads to blood coagulation. To begin this
26 cascade of reactions, thrombin, a plasma enzyme, must first activate Factor VIII; thereafter, the
27 activated Factor VIII interacts sequentially with a number of additional enzymes leading
28 eventually to the generation of fibrin, which forms the lattice responsible for blood clotting.

1 Therefore, if a PEG molecule is attached to Factor VIII at a location that must interact with any
2 of the other chemicals involved in the clotting cascade, the pegylated Factor VIII may lose a
3 significant amount of coagulation activity.

4 28. In the 1990s, small PEG molecules (e.g., ≤ 5 kDa) were known to extend the half-
5 life of therapeutic candidates that were less complex and much smaller than Factor VIII. At that
6 time it was generally believed that Factor VIII, due to its complexity and large size, would
7 require many small (e.g., ≤ 5 kDa) PEG molecules to shield it from degradation in order to
8 extend its half-life. However, this approach resulted in a loss of Factor VIII's coagulation
9 activity and did not extend the active Factor VIII's half-life by a satisfactory amount of time.

10 **BAYER'S CONFIDENTIAL FACTOR VIII**
11 **PEGYLATION RESEARCH AND DISCLOSURE TO NEKTAR**

12 29. Despite the failure of others to achieve success with pegylated Factor VIII, Bayer
13 in the early 1990s began its own program to develop a pegylated Factor VIII replacement
14 product with the goal of improving half-life and reducing immunogenicity while retaining
15 coagulation activity. This work occurred at Bayer's biologics research center in Berkeley,
16 California.

17 30. By 1993, Bayer became the first to discover and make a pegylated Factor VIII
18 using only one large PEG (e.g., ≥ 20 kDa) that provided an extended half-life while retaining
19 coagulation activity, an unexpected result that ran contrary to conventional wisdom.

20 31. For this work, Bayer sought out PEG suppliers who could provide large PEGs
21 because such large PEG molecules were not readily available. One such supplier of PEGs was
22 Nektar's predecessor in interest, Shearwater Corporation ("Shearwater"), located in Huntsville,
23 Alabama. Shearwater manufactured and sold small PEG molecules as catalog items, but was
24 capable of providing by custom order the large PEG molecules that Bayer needed.

25 32. Upon information and belief, Bayer (at this time known as Miles Laboratories in
26 the United States) and Shearwater entered into a confidentiality agreement in 1993, and
27 Shearwater began providing Bayer with custom-made larger PEG molecules in consultation with
28

1 Shearwater's founder, Dr. J. Milton Harris, who was a scientist knowledgeable about pegylation
2 chemistry.

3 33. The same year, Bayer and Dr. Harris entered into a consulting agreement so that
4 Bayer could disclose its confidential research on Factor VIII to Dr. Harris. The term of the
5 consulting agreement between Bayer and Dr. Harris continued through at least 1995.

6 34. Over the course of the consultancy, Dr. Harris and Bayer scientists regularly
7 spoke by phone and in person. During these discussions, Bayer disclosed to Dr. Harris the
8 details of its pegylated Factor VIII research and discoveries. As a result, Dr. Harris learned, for
9 example, of Bayer's discovery that attaching large PEG molecules (e.g., ≥ 20 kDa) at fewer
10 binding sites (e.g., one) increases Factor VIII's half-life while coagulation activity is retained.

11 35. Upon information and belief, Dr. Michael Bentley joined Shearwater in 1997 as
12 the head of its research and drug development program while Dr. Harris was still serving as
13 president of the company.

14 36. Upon information and belief, Dr. Bentley became aware of certain details of
15 Bayer's Factor VIII pegylation research and development while employed at Shearwater with
16 Dr. Harris.

17 37. In its ongoing effort to perfect its Factor VIII pegylation technology, on June 17,
18 1998, Bayer entered into a second Mutual Non-Disclosure Agreement with Shearwater, which
19 Dr. Harris signed on behalf of Shearwater. Upon information and belief, Dr. Bentley remained
20 employed by Shearwater at this time.

21 38. Around the same time, Bayer began consulting with another supplier of PEGs,
22 PolyMASC Pharmaceuticals PLC ("PolyMASC"). Bayer met and corresponded with
23 PolyMASC concerning Bayer's pegylation work on Factor VIII and entered into a Research
24 Agreement with PolyMASC in 1999 in furtherance thereof. The PolyMASC Research
25 Agreement confidentiality provisions limited the use of all information and materials provided
26 by Bayer to uses solely contemplated under the Agreement. Over the course of this business
27 relationship, Bayer shared with PolyMASC its confidential information and discoveries
28 concerning Bayer's long-standing research and discoveries concerning pegylated Factor VIII.

1 39. Upon information and belief, Bayer's confidential information concerning its
2 pegylated Factor VIII research and discoveries was disclosed to the PolyMASC Director of
3 Commercial Development, Dr. Stephen Charles, a scientist and inventor on several pegylation
4 patents.

5 40. Upon information and belief, after learning the details of Bayer's pegylation work
6 on Factor VIII, Dr. Charles left PolyMASC to join Drs. Harris and Bentley at Shearwater as Vice
7 President of Corporate Development.

8 41. Upon information and belief, Drs. Harris, Bentley, and Charles all had scientific
9 knowledge of pegylation technology and would have had a keen interest in understanding and
10 making use of the confidential Bayer discoveries concerning extending the half-life of Factor
11 VIII through pegylation.

12 42. In 2001, Inhale Therapeutics Systems, Inc. ("Inhale") acquired Shearwater.

13 43. Upon information and belief, Dr. Mary Bossard joined Shearwater in early
14 October of 2002.

15 44. Upon information and belief, Drs. Harris, Bentley, Charles, and Bossard worked
16 together for Shearwater in Huntsville, Alabama, from 2002 to at least 2003.

17 45. Upon information and belief, Dr. Bossard had not worked with Factor VIII or on
18 pegylating Factor VIII prior to joining Shearwater.

19 46. Upon information and belief, Dr. Bossard's early work with Shearwater (and
20 eventually Nektar) involved traveling with business teams to sell Shearwater's catalog of small
21 PEG molecules.

22 47. In 2003, Inhale changed its name to Nektar Therapeutics ("Nektar"), while
23 Shearwater changed its name to Nektar Therapeutics AL Corporation and later merged into its
24 parent corporation, Nektar.

25 48. Dr. Harris served as president and later as chief scientific officer of Nektar, and
26 Dr. Bentley headed Nektar's research group and started its drug development program. Dr.
27 Charles became vice president of business development & alliance management at Nektar. Dr.
28 Bossard's title at Nektar was senior director of science and technology.

1 49. Upon information and belief, while Nektar was knowledgeable about pegylation
2 generally, it had very limited, if any, expertise with pegylating Factor VIII prior to at least
3 February 26, 2003, independent of the knowledge that Drs. Harris, Bentley, and Charles learned
4 from Bayer.

5 50. As of 2003, Bayer continued working to refine its process to commercialize a
6 long-acting pegylated Factor VIII replacement therapy. As a result, Bayer once again renewed
7 its relationship with Shearwater (now known as Nektar) to build on Bayer's own extensive
8 confidential research work on pegylating Factor VIII.

9 51. On February 12, 2003, Bayer's legal predecessor-in-interest, Bayer Corporation,
10 signed a confidential disclosure agreement ("CDA") with Nektar to enable Bayer once again to
11 share its proprietary research information with Nektar. Dr. Charles, who had been employed by
12 PolyMASC and then Shearwater with Drs. Harris, Bentley, and Bossard, signed the non-
13 disclosure agreement on behalf of Nektar.

14 52. Upon information and belief, Nektar, like its predecessor Shearwater since 1993,
15 was primarily a catalog business that provided PEG reagents to pharmaceutical companies for
16 conjugation work but did not carry out de novo drug discovery.

17 **NEKTAR'S MISAPPROPRIATION OF BAYER'S**
18 **CONFIDENTIAL INFORMATION FOR PATENT FILINGS**

19 53. Within only a few months after Dr. Bossard joined Shearwater and only two
20 weeks after signing the CDA with Bayer, on February 26, 2003, Nektar secretly filed its
21 Provisional Application, to which the Nektar Patents-in-Suit claim priority. Drs. Bossard and
22 Bentley are listed as the only inventors of the Provisional Application. Nektar did not inform
23 Bayer of this secret filing.

24 54. Upon information and belief, this Provisional Application is based on information
25 learned from Bayer by Drs. Harris, Charles, Bentley, and Bossard pursuant to Bayer's
26 confidential collaborations with Shearwater, PolyMASC, and/or Nektar over a period of years,
27 including Bayer's discovery of the efficacy of using fewer (e.g., one) large PEG molecules (e.g.,
28 ≥ 20 kDa) to pegylate Factor VIII.

1 55. Upon information and belief, Nektar did not have access to Factor VIII at the time
2 it filed its Provisional Application.

3 56. Evidencing Nektar's lack of practical expertise with pegylating the complex
4 Factor VIII protein, the Provisional Application does not contain any data for any of the
5 examples disclosed therein, which are drafted in the present tense as opposed to the past tense,
6 demonstrating that the disclosed experiments had not been performed.

7 57. On December 11, 2003, Bayer entered into a Research Agreement (the
8 "Agreement") with Nektar, which described the object of the parties' work as increasing the
9 half-life of Factor VIII while at the same time preserving its activity levels. The Agreement
10 contained provisions to protect Bayer's confidential information and limit the use and disclosure
11 of any such confidential information to activities contemplated under the Agreement on a need-
12 to-know basis. Dr. Charles again signed this Agreement on behalf of Nektar. Nektar designated
13 Dr. Bossard as its official correspondent for the project, such that all communications between
14 Bayer and Nektar were to be with Dr. Bossard.

15 58. Despite having secretly filed the Provisional Application claiming the efficacy of
16 pegylating Factor VIII with larger PEG molecules at fewer binding sites, Nektar sought to
17 deceive Bayer by stating in the Plan of Research attached to the Agreement that more than one
18 small PEG attached to "multiple subunits" on the complex Factor VIII protein may be required
19 to meet Bayer's stated goals i.e., to extend half-life of Factor VIII while retaining its coagulation
20 activity.

21 59. Notwithstanding Nektar's misrepresentations about the number and size of PEGs
22 required to achieve Bayer's goals, Bayer instructed Nektar to pegylate Factor VIII according to
23 Bayer's preferences as set forth in the Agreement and Plan of Research, including, *inter alia*,
24 attachment of a large PEG (≥ 30 kDa) to Factor VIII, consistent with Bayer's earlier discoveries
25 regarding the efficacy of mono-pegylated Factor VIII using a large PEG.

26 60. Pursuant to the Agreement, in early 2004, Bayer sent Nektar batches of
27 recombinant Factor VIII, including B-domain deleted ("BDD") and full-length Factor VIII.
28 Recombinant technology allows for production of proteins in large quantities using cells

1 engineered to contain the gene encoding the protein of interest. BDD Factor VIII is a type of
2 Factor VIII in which most or all of a segment of Factor VIII, known as the “B domain” has been
3 removed, whereas full-length Factor VIII refers to a Factor VIII protein in which the B domain
4 has been retained.

5 61. During this time, Bayer was in regular communication with Nektar about the
6 agreed-upon work and testing through Nektar’s designated correspondent, Dr. Bossard.

7 62. In February 2004, Nektar updated Bayer regarding its efforts to achieve Factor
8 VIII pegylation using a large PEG molecule. On February 26, 2004, Nektar indicated that the
9 PEGylation of Factor VIII was not very promising with regard to binding a large PEG molecule
10 to the amino acid cysteine of Factor VIII. Notwithstanding this representation, on the same day,
11 unbeknownst to Bayer, Nektar secretly filed Patent Application No. 10/789,956 (“the ‘956
12 Application”), which is a continuation of the secret Provisional Application.

13 63. The ‘956 Application included new data and examples absent from the original
14 Provisional Application and, upon information and belief, is based on the discoveries that Nektar
15 learned from Bayer, e.g., the use of fewer (e.g., one) large PEG molecules (e.g., ≥ 20 kDa) to
16 pegylate Factor VIII. Claim 1 of the ‘956 Application recited “[a] composition comprising a
17 plurality of conjugates each conjugate having one to three water-soluble polymers covalently
18 attached to a Factor VIII moiety, wherein each water-soluble polymer has a nominal average
19 molecular weight in the range of greater than 5,000 Daltons to about 150,000 Daltons.”

20 64. Subsequently, beginning in late-March through August 2004, Nektar provided to
21 Bayer certain samples of recombinant human Factor VIII (full length and BDD) purportedly
22 pegylated at cysteine and lysine amino acids, as well as a report corresponding to the work
23 performed. The report included pegylation yield and degree of pegylation. The report did not
24 include any information regarding Nektar’s pegylation techniques.

25 65. The report indicated that Nektar’s pegylation technology and the resulting
26 samples suffered from, *inter alia*, deficient purification, unsatisfactory characterization of the
27 degree of pegylation, and low pegylation yield. Because of Nektar’s inability to provide a
28 reliable pegylation technique for Factor VIII and Bayer’s own successful Factor VIII pegylation

1 research carried out independently of Nektar, Bayer elected not to renew the Agreement and
2 instead discontinued the relationship with Nektar upon conclusion of the work contemplated
3 under the Agreement.

4 **BAYER'S SUCCESSFUL DEVELOPMENT**
5 **OF ITS LONG-ACTING, PEGYLATED FACTOR VIII**

6 66. Bayer independently pursued its own Factor VIII pegylation research and
7 development before, during, and after its multiple interactions with Shearwater and Nektar,
8 dating back to the early 1990s when it began its Factor VIII pegylation research. Bayer filed its
9 own patent applications in the United States and Europe based on its Factor VIII pegylation
10 research and was granted, *inter alia*, U.S. Patent No. 9,364,520 in 2016.

11 67. Bayer's efforts culminated in the development of BAY 94, a pegylated
12 recombinant human Factor VIII with extended half-life engineered to prolong duration of effect
13 while preserving full coagulation activity. Bayer filed its Biologics License Application
14 ("BLA") No. 125661 for BAY 94 with the FDA on August 30, 2017, seeking approval for the
15 treatment of hemophilia A.

16 68. Bayer invented and developed BAY 94 in this District at its Berkeley, California
17 research facility.

18 69. The sustained therapeutic effect of BAY 94 allows for less frequent dosing, thus
19 reducing treatment burden and the potential to improve quality of life for hemophilia A patients.
20 Early preclinical analysis of BAY 94 showed promising results, such as retained Factor VIII
21 activity *in vitro* and improved half-life in animal models, which were later confirmed in clinical
22 trials. Ex. 8 at 272-74 (referring to "K1804C," the BDD Factor VIII cysteine variant that is
23 pegylated to make BAY 94); Ex. 9 at 490, 494. A recent clinical trial of BAY 94 demonstrated
24 protection against bleeding with dosing intervals as infrequent as once per week, a marked
25 improvement over currently available Factor VIII treatments in the U.S.

26 70. The active ingredient in BAY 94 is the recombinant BDD form of Factor VIII
27 pegylated with a large 60 kDa PEG molecule, consistent with Bayer's discoveries in the 1990s.
28 Ex. 8 at 271-272; Ex. 10 at 82 (entry for damoctocog alpha pegol, the nonproprietary name for

1 BAY 94). The BAY 94 manufacturing process entails, *inter alia*, introduction of a cysteine and
2 pegylation of a BDD Factor VIII protein with a 60 kDa PEG molecule attached via a thioether
3 linkage to the introduced cysteine. Ex. 8 at 271; Ex. 10 at 82.

4 71. BAY 94 is to be administered intravenously and will be available as a lyophilized
5 powder containing 250, 500, 1000, 2000, or 3000 International Units. BAY 94 is produced
6 without the addition of any exogenous human or animal derived protein in the cell culture
7 process, purification, pegylation, or final formulation.

8 72. After a quarter century of research, development, and testing requiring the
9 expenditure of significant resources and commitments by Bayer, its groundbreaking Factor VIII
10 product, BAY 94, will offer a new treatment option for patients and potentially save lives
11 worldwide.

12 **NEKTAR, BAXALTA US, AND/OR BAXALTA INC. BENEFIT FROM**
13 **THE MISAPPROPRIATION OF BAYER'S CONFIDENTIAL INFORMATION**

14 73. Upon information and belief, while Bayer was paying Nektar to assist Bayer's
15 efforts to perfect a commercially viable pegylated Factor VIII product, Nektar secretly sought
16 out a partnership with Baxter, Baxalta Inc.'s corporate predecessor, to develop its own pegylated
17 Factor VIII replacement therapy. At this time, Baxter and Bayer had competing Factor VIII
18 replacement products.

19 74. Upon information and belief, Baxalta US Inc. and Baxalta Inc. are exclusive
20 licensees of the Nektar Patents-in-Suit and '749 patent by virtue of an Exclusive Research,
21 Development, License and Manufacturing and Supply Agreement as amended and granted by
22 Nektar to Baxter-related entities, originally executed on September 26, 2005, and transferred by
23 assignment to Baxalta Inc. and/or Baxalta US on April 30, 2015.

24 75. Upon information and belief, Nektar worked with Baxalta Inc., Baxalta US,
25 and/or Baxter to develop, manufacture, and/or market Adynovate[®], an extended half-life
26 recombinant Factor VIII (rFVIII) treatment for hemophilia A.

1 76. Upon information and belief, Nektar, its predecessors, and/or its employees
2 improperly used and/or disclosed Bayer's confidential information to Baxalta Inc., Baxalta US,
3 and/or Baxter to develop, commercialize, and/or manufacture Adynovate®.

4 77. Baxalta US currently owns BLA No. 125566 for Adynovate® (Antihemophilic
5 Factor (Recombinant), PEGylated), which was approved by the FDA on November 13, 2015.
6 Adynovate® is indicated in children and adults for on-demand treatment and control of bleeding
7 episodes, perioperative management, and routine prophylaxis to reduce the frequency of
8 bleeding episodes.

9 78. Upon information and belief, Adynovate® is a full-length recombinant Factor VIII
10 pegylated with a 20 kDa PEG, the same size PEG that Bayer disclosed to Dr. Harris in 1993.

11 79. Upon information and belief, Baxalta Inc. and/or Baxalta US are currently
12 responsible for development and commercialization of Adynovate®, and Nektar supplies
13 manufacturing materials for a portion of the supply chain to manufacture Adynovate®.

14 80. Upon information and belief, Baxalta Inc. and/or Baxalta US are recipients and
15 beneficiaries of the confidential research work that Bayer performed beginning in the early
16 1990s through 2004 that was disclosed to Nektar, its predecessors, and/or its employees under
17 confidentiality agreements that Nektar, its predecessors, and/or employees subsequently
18 misrepresented as their own.

19 81. Upon information and belief, Nektar is a recipient and beneficiary of Bayer's
20 confidential and proprietary research and discoveries that Bayer disclosed to Nektar, its
21 predecessors, and/or its employees under confidentiality agreements that Nektar, its
22 predecessors, and/or employees subsequently misrepresented as their own.

23 **A DECLARATORY JUDGMENT IS WARRANTED BECAUSE THERE IS A**
24 **SUBSTANTIAL CONTROVERSY OF SUFFICIENT IMMEDIACY AND REALITY**

25 82. The totality of the circumstances demonstrate that there is a substantial
26 controversy between Bayer and Defendants, whose legal interests are adverse to Bayer. The
27 controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory
28 judgment that Bayer has not infringed and will not infringe any valid claim of the Nektar

1 Patents-in-Suit. In addition, Bayer has made meaningful preparations to manufacture, use, offer
2 to sell, and/or sell its BAY 94 product in the United States.

3 83. Bayer publicly described BAY 94 in 2010, including publication of Bayer's
4 pegylation procedures and the results of various analyses of BAY 94. *See generally* Ex. 8.

5 84. Bayer and Nektar have litigated the rights to Factor VIII pegylation technology
6 for many years. In 2013, Bayer filed an action in civil court in Munich, Germany, seeking
7 ownership rights in certain of Nektar's pending European patent filings, which claim priority to
8 the same Provisional Application from which the Nektar Patents-in-Suit derive. These European
9 filings are based on Bayer's confidential Factor VIII research from the 1990s and 2000s that
10 Nektar, its predecessors, and/or employees obtained through confidential communications with
11 Bayer. In connection with this German action, Bayer filed an *ex parte* Application for Discovery
12 in Aid of Foreign Litigation Pursuant to 28 U.S.C. § 1782 in this Court, Docket No. 3:14-mc-
13 80138, which was granted in May 2014.

14 85. After Bayer filed its action in Germany, Nektar filed its own action against Bayer
15 in 2015 in the courts of Munich, Germany, seeking rights to certain Bayer patent applications
16 pending in the European Patent Office related to Bayer's Factor VIII pegylation research.

17 86. Bayer contacted Nektar in an effort to come to an agreement that would avoid
18 potential future litigation concerning BAY 94 and Nektar's patent portfolio, including the Nektar
19 Patents-in-Suit and the '749 patent, for which Bayer initially asserted declaratory claims of non-
20 infringement and invalidity (*see generally* Dkt. No. 1), but Nektar refused. Upon information
21 and belief, Baxalta Inc. and Baxalta US, as the exclusive licensees of this patent family, likewise
22 refused to negotiate with Bayer. While Defendants' conduct strongly suggested that they would
23 sue Bayer, they never identified the specific Nektar Patents-in-Suit, nor did they rule out the '749
24 patent.

25 87. Bayer has actively researched and developed BAY 94, including through publicly
26 known clinical trials. In 2010, Bayer announced its Phase 1 study to describe the
27 pharmacokinetics of BAY 94. *See* Ex. 9. Based on the results of the Phase 1 study, Bayer
28 designed and carried out an open-label, partially randomized Phase 2/3 trial, titled the

1 “PROTECT VIII” trial, in 2012 to assess the effectiveness and safety of BAY 94 in previously
2 treated patients at least 12 years of age with severe hemophilia A (ClinicalTrials.gov identifier:
3 NCT01580293). The results of these studies were published and have been presented at
4 numerous conferences. Upon information and belief, Baxalta Inc., Baxalta US, and Nektar are
5 aware that Bayer has undertaken BAY 94 clinical trials to support its BLA submission.

6 88. In 2016, Bayer filed an action for patent infringement in the District of Delaware
7 against Defendants, alleging that Adynovate[®] infringes Bayer’s U.S. Patent No. 9,364,520.

8 89. In 2016, Bayer announced that it intended to file a BLA seeking regulatory
9 approval of BAY 94 in mid-2017. Upon information and belief, Baxalta Inc., Baxalta US, and
10 Nektar are aware of Bayer’s plans to seek FDA approval of BAY 94 and that Bayer intended to
11 do so before the end of 2017.

12 90. Bayer has hired and continues to grow its sales force in order to promote the
13 marketing and sale of BAY 94 in the United States upon FDA approval, including by hiring
14 additional sales people. For example, Bayer has posted publicly available job postings for the
15 position of Director of Sales Hematology as recently as August 16, 2017. Bayer’s sales force
16 will begin actively marketing BAY 94 immediately upon receiving FDA approval.

17 91. It was announced publicly that Bayer submitted a BLA for BAY 94:

18 Bayer AG today announced the submission of a Biologics
19 License Application (BLA) with the U.S. Food and Drug
20 Administration (FDA) for its long-acting site-specifically
21 PEGylated recombinant human Factor VIII ([BAY 94]) for the
22 treatment of Hemophilia A. The regulatory submission is
essentially based on the results from the PROTECT VIII trial.
In that trial, [BAY 94] showed protection from bleeds with
dosing intervals when used prophylactically once every seven
days, once every five days, and twice per week.

23 “Since introducing Kogenate around 25 years ago, Bayer has
24 been committed to continuously improving disease management
25 for people living with Hemophilia A,” said Dr. Joerg Moeller,
26 member of the Executive Committee of Bayer AG’s
27 Pharmaceutical Division and Head of Development. “The filing
28 of [BAY 94] brings us one step closer to providing a therapeutic
option with additional benefits for patients who decided to have
a more active lifestyle.”

1 News Release: Bayer Submits Biologics License Application in the U.S. for BAY94-9027 – a
2 Long-Acting Factor VIII for the Treatment of Hemophilia A, Bayer AG Communications and
3 Public Affairs (Berlin, Aug. 31, 2017) (available at <http://press.bayer.com>). Upon information
4 and belief, Defendants know of Bayer’s submission of a BLA for BAY 94.

5 92. Bayer has a manufacturing facility in Berkeley, California, for the commercial
6 manufacture of BAY 94 to accommodate the demand for BAY 94 following FDA approval.
7 Upon information and belief, Defendants are aware of Bayer’s manufacturing facility and
8 capability to manufacture BAY 94 upon FDA approval.

9 93. According to standard industry practice, the FDA typically takes about one year
10 to complete its review of a BLA. FDA approval of BAY 94 would permit Bayer to immediately
11 offer to sell and sell the treatment within the United States, and Bayer expects to launch BAY 94
12 in the United States in the fourth quarter of 2018. Upon information and belief, Defendants are
13 aware of the standard timeline for FDA approval and Bayer’s intent to launch BAY 94 in the
14 fourth quarter of 2018.

15 94. Upon information and belief, following approval of Bayer’s BLA, BAY 94 will
16 be indicated for overlapping patient population as Adynovate® and will, therefore, compete with
17 Baxalta’s Adynovate® product, especially because BAY 94 and Adynovate® are both extended
18 half-life pegylated Factor VIII products. Upon information and belief, Defendants are aware that
19 BAY 94 will compete with Adynovate® for new patients.

20 95. Upon information and belief, Baxalta Inc. and Baxalta US have a strong interest
21 in maintaining the market position of Adynovate®. Upon information and belief, Baxalta Inc.
22 characterizes Adynovate® as a “blockbuster” treatment, which has been predicted to exceed \$1
23 billion in sales by 2020.

24 96. Upon information and belief, Nektar has a strong interest in maintaining the
25 market position of Adynovate®. Upon information and belief, Nektar receives the following
26 payments from Baxalta Inc. and Baxalta US under their exclusive licensing agreement:
27 escalating royalties of between 4-6% on global net revenue of Adynovate® up to \$1.2 billion in
28

1 revenue; a flat 13% royalty for revenue above \$1.2 billion; and additional tiered revenue
2 milestone payments based upon global net revenue of Adynovate[®].

3 97. Upon information and belief, as the exclusive licensees of the Nektar Patents-in-
4 Suit, Baxalta Inc. and Baxalta US intend to seek a declaration that Bayer's BAY 94 infringes the
5 Nektar Patents-in-Suit before the FDA approves Bayer's BLA. Baxalta Inc. has a history of
6 asserting its patents against competitors in the hemophilia A treatment market even before the
7 competitor has completed submission of its BLA to the FDA. *See, e.g., Complaint, Baxalta Inc.*
8 *v. Genentech, Inc.*, No. 1:17-cv-00509 (D. Del. May 4, 2017) (ECF No. 1) (alleging infringement
9 of U.S. Patent No. 7,033,590 based on "Defendants' current and/or imminent manufacture, use,
10 sale, offer to sell within the United States, and/or importation into the United States of
11 Defendants' humanized bispecific antibody that binds Factor IX/IXa and Factor X to treat
12 hemophilia A."); *see also Answer, Baxalta Inc. v. Genentech, Inc.*, No. 1:17-cv-00509 (D. Del.
13 June 30, 2017) (ECF No. 9) ("As of [the date of Baxalta Inc.'s complaint], Genentech had not
14 completed filing its Biologics License Application ('BLA') for emicizumab with FDA").

15 98. On September 15, 2017, sixteen days after Bayer commenced this action on the
16 '749 patent, Defendants filed *Baxalta Incorporated, et al. v. Bayer HealthCare LLC*, Case No.
17 1:17-cv-01316, in the District of Delaware. Defendants' September 15, 2017 complaint asserts
18 that BAY 94 infringes the related Nektar Patents-in-Suit: the '223, '421, '378, '536, '102, '259,
19 and '831 patents.

20 99. On September 19, 2017, Defendants served a "Notice of Covenant Not to Sue on
21 U.S. Patent No. 7,858, 749." The Notice states that "Defendants, on behalf of themselves and
22 any successors-in-interest to the '749 patent, hereby unconditionally and irrevocably covenant
23 not to make any claim(s) or demand(s) against Bayer, or any of its related business entities,
24 employees of such entities, distributors, and customers, for infringement of the '749 patent only,
25 based on Bayer's manufacture, importation, use, sale, and/or offer for sale of its BAY 94
26 product, which Bayer is seeking U.S. Food and Drug Administration ('FDA') marketing
27 approval for under Biologics License Application No. 125661 filed on August 30, 2017, that is
28 pegylated via a thioether linkage to a cysteine residue, whether before or after the date of this

1 Covenant.” (Dkt. No. 25-2.) Defendants have not provided any covenant not to sue on any other
2 patents, including the Patents-in-Suit.

3 100. Based on, *inter alia*: the exclusive right granted by Nektar to Baxalta Inc. and
4 Baxalta US to enforce the Nektar Patents-in-Suit; the history of litigation between the parties
5 over the rights to Factor VIII pegylation technology, both in the United States and abroad;
6 Defendants’ past refusals to resolve disputes over the right to Factor VIII pegylation technology;
7 Bayer’s publicly known, extensive, and meaningful preparations to obtain FDA approval to
8 manufacture, use, offer to sell, and/or sell BAY 94, including its clinical trials and recent BLA
9 submission; Bayer’s publicly known intention to launch BAY 94 immediately upon obtaining
10 FDA approval; Baxalta Inc.’s practice of seeking declarations of infringement against its
11 competitors in the hemophilia A treatment market even before they have completed their FDA
12 submissions; Defendants’ strong interest in maintaining their position in the Factor VIII
13 replacement therapy market, including Defendants’ collaboration to develop, manufacture,
14 and/or market Adynovate[®] and Defendants’ financial interest in maintaining Adynovate’s[®]
15 market position, there is a real, immediate, and substantial controversy between the parties that
16 warrants a declaratory judgment.

17 101. Defendants stated in their September 15 Delaware complaint that “[t]here is a
18 substantial controversy between Defendant [Bayer] and Plaintiffs [Nektar, Baxalta Inc., and
19 Baxalta US], whose legal interests are adverse. The controversy is of sufficient immediacy and
20 reality to warrant the issuance of a judgment.” Compl. ¶ 64, *Baxalta Inc. v. Bayer HealthCare*
21 *LLC*, Case No. 1:17-cv-01316 (Sept. 15, 2017 D. Del.) (Dkt. No. 1).

22 102. The challenge to Bayer’s BAY 94 has cast uncertainty over the commercialization
23 of BAY 94 and created a justiciable controversy.

24 **THE ’223 PATENT**

25 103. The ’223 patent, titled “Polymer-Factor VIII Moiety Conjugates,” states on its
26 face that it issued on April 3, 2007.

27 104. The ’223 patent lists on its face the following inventors: Mary J. Bossard and
28 Michael D. Bentley.

1 a water-soluble polymer covalently attached to a Factor VIII
2 polypeptide via a thiol group of a cysteine residue contained
within the Factor VIII polypeptide,

3 wherein the Factor VIII polypeptide is selected from the group
4 consisting of Factor VIII, Factor VIIIa, Factor VIII:C, Factor
VIII:vWF and B-domain deleted Factor VIII, and

5 wherein the water-soluble polymer is selected from the group
6 consisting of poly(alkylene glycol), poly(vinyl pyrrolidone),
7 poly(vinyl alcohol), polyoxazoline, and poly(N-
acryloylmorpholine).

8 THE '378 PATENT

9 115. The '378 patent, titled "Polymer-Factor VIII Moiety Conjugates," states on its
10 face that it issued on March 27, 2012.

11 116. The '378 patent lists on its face the following inventors: Mary J. Bossard, Michael
12 D. Bentley, and Ping Zhang.

13 117. The '378 patent lists on its face Nektar Therapeutics as the assignee.

14 118. The '378 patent states on its face that it issued from Application No. 12/636,635,
15 filed on December 11, 2009, which is a continuation of Application No. 11/702,302, filed on
16 February 5, 2007, now the '749 patent, which is a continuation of the '956 Application filed on
17 February 26, 2004, now the '223 Patent, which claims the benefit of priority to the original
18 Provisional Application filed on February 26, 2003.

19 119. The '378 patent contains one independent claim and 26 dependent claims.

20 120. Independent claim 1 of the '378 patent recites:

21 A composition comprising

22 a plurality of conjugates, each conjugate comprising one, two or
23 three water-soluble polymers each covalently attached to a
Factor VIII moiety polypeptide via a hydrolytically stable
24 linkage,

25 wherein: (i) the Factor VIII polypeptide is selected from the
group consisting of Factor VIII, Factor VIIIa, Factor VIII:C,
Factor VIII:vWF and B-domain deleted Factor VIII;

26 (ii) the water-soluble polymer is selected from the group
27 consisting of a poly(alkylene glycol), a poly(oxyethylated
polyol), a poly(olefinic alcohol), a poly(vinylpyrrolidone), a
28 poly(hydroxyalkylmethacrylamide), a

1 poly(hydroxyalkylmethacrylate), a poly(saccharide), a poly(α -
2 hydroxy acid), a poly(vinyl alcohol), a polyphosphazene, a
3 polyoxazoline, a poly(N-acryloylmorpholine), and
4 combinations thereof; and

5 (iii) the composition is bioactive, comprising an in-vitro activity
6 of at least 15% compared to that of a Factor VIII polypeptide
7 composition in unconjugated form.

8 **THE '536 PATENT**

9 121. The '536 patent, titled "Factor VIII Compositions," states on its face that it issued
10 on August 21, 2012.

11 122. The '536 patent lists on its face the following inventors: Mary J. Bossard, Michael
12 D. Bentley, and Ping Zhang.

13 123. The '536 patent lists on its face Nektar Therapeutics as the assignee.

14 124. The '536 patent states on its face that it issued from Application No. 12/636,594,
15 filed on December 11, 2009, and is a continuation of Application No. 11/702,302, filed on
16 February 5, 2007, now the '749 Patent, which is a continuation of the '956 Application, filed on
17 February 26, 2004, now the '223 Patent, which claims the benefit of priority to the original
18 Provisional Application filed on February 26, 2003.

19 125. The '536 patent contains one independent claim and 26 dependent claims.

20 126. Independent claim 1 of the '536 patent recites:

21 A composition that is free from albumin comprising:

22 a conjugate that comprises one, two or three water-soluble
23 polymers selected from the group consisting of a poly(alkylene
24 glycol), a poly(oxyethylated polyol), a poly(olefinic alcohol), a
25 poly(vinylpyrrolidone), a poly(hydroxyalkylmethacrylamide), a
26 poly(hydroxyalkylmethacrylate), a poly(saccharide), a poly(α -
27 hydroxy acid), a poly(vinyl alcohol), a polyphosphazene, a
28 polyoxazoline, a poly(N-acryloylmorpholine), and
combinations thereof, covalently attached to a Factor VIII
polypeptide selected from the group consisting of Factor VIII,
Factor VIIIa, Factor VIII:C, Factor VIII:vWF and B-domain
deleted Factor VIII.

29 **THE '102 PATENT**

30 127. The '102 patent, titled "Polymer-Factor VIII Moiety Conjugates," states on its
31 face that it issued on August 27, 2013.

1 128. The '102 patent lists on its face the following inventors: Mary J. Bossard, Michael
2 D. Bentley, and Ping Zhang.

3 129. The '102 patent lists on its face Nektar Therapeutics as the assignee.

4 130. The '102 patent states on its face that it issued from Application No. 13/431,872,
5 filed on March 27, 2012, and is a continuation of Application No. 12/636,594, filed on December
6 11, 2009, now the '536 patent, which is a continuation of Application No. 11/702,302, filed on
7 February 5, 2007, now the '749 patent, which is a continuation of the '956 Application, filed on
8 February 26, 2004, now the '223 patent, which claims the benefit of priority to the original
9 Provisional Application filed on February 26, 2003.

10 131. The '102 patent contains one independent claim and 28 dependent claims.

11 132. Independent claim 1 of the '102 patent recites:

12 A conjugate comprising

13 a water-soluble polymer covalently attached to a Factor VIII
14 polypeptide via a thiol group of a cysteine residue that has been
added to or substituted in the Factor VIII polypeptide,

15 wherein the conjugate comprises an in-vitro activity that is at
16 least 15% of the in-vitro activity of the unconjugated Factor VIII
polypeptide, and

17 wherein the water-soluble polymer is selected from the group
18 consisting of poly(alkylene glycol), poly(oxyethylated polyol),
poly(olefinic alcohol), poly(vinylpyrrolidone),
19 poly(hydroxyalkylmethacrylamide),
poly(hydroxyalkylmethacrylate), poly(saccharide), poly(α -
20 hydroxy acid), poly(vinyl alcohol), polyphosphazene,
polyoxazoline, poly(N-acryloylmorpholine), and combinations
21 thereof.

22 **THE '259 PATENT**

23 133. The '259 patent, titled "Polymer-Factor VIII Conjugate Compositions," states on
24 its face that it issued on December 31, 2013.

25 134. The '259 patent lists on its face the following inventors: Mary J. Bossard, Michael
26 D. Bentley, and Ping Zhang.

27 135. The '259 patent lists on its face Nektar Therapeutics as the assignee.
28

1 136. The '259 patent states on its face that it issued from Application No. 13/431,862,
2 filed on March 27, 2012, and is a continuation of Application No. 12/636,594, filed on December
3 11, 2009, now the '536 patent, which is a continuation of Application No. 11/702,302, filed on
4 February 5, 2007, now the '749 patent, which is a continuation of the '956 Application, filed on
5 February 26, 2004, now the '223 patent, which claims the benefit of priority to the original
6 Provisional Application filed on February 26, 2003.

7 137. The '259 patent contains one independent claim and 32 dependent claims.

8 138. Independent claim 1 of the '259 patent recites:

9 A composition that is at least 85% free from albumin, the
10 composition comprising

11 a conjugate comprising a water-soluble polymer covalently
12 attached to a Factor VIII polypeptide via a thiol group of a
13 cysteine residue that has been added to or substituted in the
14 Factor VIII polypeptide,

15 wherein the water-soluble polymer is selected from the group
16 consisting of poly(alkylene glycol), poly(oxyethylated polyol),
17 poly(olefinic alcohol), poly(vinylpyrrolidone),
18 poly(hydroxyalkylmethacrylamide),
19 poly(hydroxyalkylmethacrylate), poly(saccharide), poly(α -
20 hydroxy acid), poly(vinyl alcohol), polyphosphazene,
21 polyoxazoline, poly(N-acryloylmorpholine), and combinations
22 thereof.

23 THE '831 PATENT

24 139. The '831 patent, titled "Unit Dosage Forms of Pharmaceutical Compositions
25 Comprising a Polymer-Factor VII Polypeptide Conjugate," states on its face that it issued on
26 November 18, 2014.

27 140. The '831 patent lists on its face the following inventors: Mary J. Bossard, Michael
28 D. Bentley, and Ping Zhang.

141. The '831 patent lists on its face Nektar Therapeutics as the assignee.

142. The '831 patent states on its face that it issued from Application No. 13/431,844,
filed on March 27, 2012, and is a continuation of Application No. 12/636,594, filed on December
11, 2009, now the '536 patent, which is a continuation of Application No. 11/702,302, filed on
February 5, 2007, now the '749 Patent, which is a continuation of the '956 Application, filed on

1 February 26, 2004, now the '223 patent, which claims the benefit of priority to the original
2 Provisional Application filed on February 26, 2003.

3 143. The '831 patent contains one independent claim and 39 dependent claims.

4 144. Independent claim 1 of the '831 patent recites:

5 A unit dose of a pharmaceutical composition, the
6 pharmaceutical composition comprising:

7 (i) a conjugate comprising one, two or three water-soluble
8 polymers, each covalently attached to a Factor VIII polypeptide
9 via a thiol group of a cysteine residue that has been added to or
10 substituted in the Factor VIII polypeptide, and

11 (ii) a pharmaceutically acceptable excipient, wherein the Factor
12 VIII polypeptide is present in the unit dose in an amount ranging
13 from 0.001 mg to 100 mg, and further wherein the one, two or
14 three water soluble polymers are selected from the group
15 consisting of poly(alkylene glycol), poly(oxyethylated polyol),
16 poly(olefinic alcohol), poly(vinylpyrrolidone),
17 poly(hydroxyalkylmethacrylamide),
18 poly(hydroxyalkylmethacrylate), poly(saccharide), poly(α -
19 hydroxy acid), poly(vinyl alcohol), polyphosphazene,
20 polyoxazoline, poly(N-acryloylmorpholine), and combinations
21 of any of the foregoing.

22 **COUNT 1: DECLARATORY JUDGMENT**
23 **OF NON-INFRINGEMENT OF THE '223 PATENT**

24 145. Bayer repeats and realleges each of the foregoing paragraphs as if fully set forth
25 herein.

26 146. There is a real, immediate, substantial, and justiciable controversy between Bayer
27 and Defendants concerning, inter alia, infringement of the '223 patent.

28 147. This controversy is amenable to specific relief through a decree of a conclusive
character.

148. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
contributorily, any valid claim of the '223 patent.

149. For example, BAY 94 does not satisfy at least the following element of
independent claim 1 of the '223 patent: “conjugate comprising one, two or three water-soluble

1 polymers covalently attached to a Factor VIII moiety.” This element is required by every claim
2 of the ’223 patent because claims 2-31 all depend on claim 1.

3 150. BAY 94 does not contain “a Factor VIII moiety” according to the disclosures
4 and/or definitions of that term in the ’223 patent because BAY 94 contains a cysteine muterin
5 instead.

6 151. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
7 ’223 patent.

8 **COUNT 2: DECLARATORY JUDGMENT**
9 **OF NON-INFRINGEMENT OF THE ’421 PATENT**

10 152. Bayer repeats and realleges each of the foregoing paragraphs as if fully set forth
11 herein.

12 153. There is a real, immediate, substantial, and justiciable controversy between Bayer
13 and Defendants concerning, *inter alia*, infringement of the ’421 patent.

14 154. This controversy is amenable to specific relief through a decree of a conclusive
15 character.

16 155. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
17 infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
18 contributorily, any valid claim of the ’421 patent.

19 156. For example, BAY 94 does not satisfy at least the following element of
20 independent claim 1 of the ’421 patent: “wherein the Factor VIII polypeptide is selected from the
21 group consisting of Factor VIII, Factor VIIIa, Factor VIII:C, Factor VIII:vWF and B-domain
22 deleted Factor VIII.” This element is required by every claim of the ’421 patent because claims
23 2-19 all depend on claim 1.

24 157. BAY 94 does not contain “Factor VIII, Factor VIIIa, Factor VIII:C, Factor
25 VIII:vWF [or] B-domain deleted Factor VIII” according to the disclosures and/or definitions of
26 those terms in the ’421 patent because BAY 94 contains a cysteine muterin instead.

27 158. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
28 ’421 patent.

1 168. This controversy is amenable to specific relief through a decree of a conclusive
2 character.

3 169. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
4 infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
5 contributorily, any valid claim of the '536 patent.

6 170. For example, BAY 94 does not satisfy at least the following element of
7 independent claim 1 of the '536 patent: “a Factor VIII polypeptide selected from the group
8 consisting of Factor VIII, Factor VIIIa, Factor VIII:C, Factor VIII:vWF and B-domain deleted
9 Factor VIII.” This element is required by every claim of the '536 patent because claims 2-19 all
10 depend on claim 1.

11 171. BAY 94 does not contain “Factor VIII, Factor VIIIa, Factor VIII:C, Factor
12 VIII:vWF [or] B-domain deleted Factor VIII” according to the disclosures and/or definitions of
13 those terms in the '536 patent because BAY 94 contains a cysteine mutein instead.

14 172. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
15 '536 patent.

16 **COUNT 5: DECLARATORY JUDGMENT**
17 **OF NON-INFRINGEMENT OF THE '102 PATENT**

18 173. Bayer repeats and realleges each of the foregoing paragraphs as if fully set forth
19 herein.

20 174. There is a real, immediate, substantial, and justiciable controversy between Bayer
21 and Defendants concerning, *inter alia*, infringement of the '102 patent.

22 175. This controversy is amenable to specific relief through a decree of a conclusive
23 character.

24 176. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
25 infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
26 contributorily, any valid claim of the '102 patent.

27 177. For example, BAY 94 does not satisfy at least the following element of
28 independent claim 1 of the '102 patent: “a water-soluble polymer covalently attached to a Factor

1 VIII polypeptide via a thiol group of a cysteine residue that has been added to or substituted in
2 the Factor VIII polypeptide.” This element is required by every claim of the ’102 patent because
3 claims 2-19 all depend on claim 1.

4 178. BAY 94 does not contain a “Factor VIII polypeptide” according to the disclosures
5 and/or definitions of those terms in the ’102 patent because BAY 94 contains a cysteine muterin
6 instead.

7 179. BAY 94 does not contain a thiol group that “that has been added to or substituted
8 in” according to the disclosures and/or definitions of those terms in the ’102 patent because BAY
9 94 contains a cysteine muterin whose thiol group has not been so added or substituted.

10 180. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
11 ’102 patent.

12 **COUNT 6: DECLARATORY JUDGMENT**
13 **OF NON-INFRINGEMENT OF THE ’259 PATENT**

14 181. Bayer repeats and realleges each of the foregoing paragraphs as if fully set forth
15 herein.

16 182. There is a real, immediate, substantial, and justiciable controversy between Bayer
17 and Defendants concerning, *inter alia*, infringement of the ’259 patent.

18 183. This controversy is amenable to specific relief through a decree of a conclusive
19 character.

20 184. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
21 infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
22 contributorily, any valid claim of the ’259 patent.

23 185. For example, BAY 94 does not satisfy at least the following element of
24 independent claim 1 of the ’259 patent: “a conjugate comprising a water-soluble polymer
25 covalently attached to a Factor VIII polypeptide via a thiol group of a cysteine residue that has
26 been added to or substituted in the Factor VIII polypeptide.” This element is required by every
27 claim of the ’259 patent because claims 2-19 all depend on claim 1.

1 186. BAY 94 does not contain a “Factor VIII polypeptide” according to the disclosures
2 and/or definitions of those terms in the ’259 patent because BAY 94 contains a cysteine mutein
3 instead.

4 187. BAY 94 does not contain a thiol group that “that has been added to or substituted
5 in” according to the disclosures and/or definitions of those terms in the ’259 patent because BAY
6 94 contains a cysteine mutein whose thiol group has not been so added or substituted.

7 188. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
8 ’259 patent.

9 **COUNT 7: DECLARATORY JUDGMENT**
10 **OF NON-INFRINGEMENT OF THE ’831 PATENT**

11 189. Bayer repeats and realleges each of the foregoing paragraphs as if fully set forth
12 herein.

13 190. There is a real, immediate, substantial, and justiciable controversy between Bayer
14 and Defendants concerning, *inter alia*, infringement of the ’831 patent.

15 191. This controversy is amenable to specific relief through a decree of a conclusive
16 character.

17 192. The manufacture, use, offer for sale, sale, and/or import of BAY 94 has not
18 infringed and will not infringe, literally or under the doctrine of equivalents, by inducement or
19 contributorily, any valid claim of the ’831 patent.

20 193. For example, BAY 94 does not satisfy at least the following element of
21 independent claim 1 of the ’831 patent: “a conjugate comprising one, two or three water-soluble
22 polymers, each covalently attached to a Factor VIII polypeptide via a thiol group of a cysteine
23 residue that has been added to or substituted in the Factor VIII polypeptide.” This element is
24 required by every claim of the ’831 patent because claims 2-19 all depend on claim 1.

25 194. BAY 94 does not contain a “Factor VIII polypeptide” according to the disclosures
26 and/or definitions of those terms in the ’831 patent because BAY 94 contains a cysteine mutein
27 instead.

1 195. BAY 94 does not contain a thiol group that that has been “added to or substituted
2 in” according to the disclosures and/or definitions of those terms in the ’831 patent because BAY
3 94 contains a cysteine muterin whose thiol group has not been so added or substituted.

4 196. Therefore, BAY 94 has not infringed and will not infringe any valid claim of the
5 ’831 patent.

6 **PRAYER FOR RELIEF**

7 WHEREFORE, Bayer requests that the Court enter judgment in its favor and against
8 Defendant Nektar as follows:

- 9 A. Declare that the manufacture, use, offer for sale, sale, and/or import of Bayer’s
10 BAY 94 product has not infringed and will not infringe, literally or under the doctrine
11 of equivalents, by inducement or contributorily, any valid claim of the Nektar
12 Patents-in-Suit;
- 13 B. Award Bayer its costs and reasonable attorney’s fees to the extent permitted by law;
14 and
- 15 C. Award Bayer such other and further relief as the Court deems just and proper.

16 **DEMAND FOR JURY TRIAL**

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

19
20 Dated: September 25, 2017

SIDLEY AUSTIN LLP

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