

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

RIGSHOSPITALET,

Plaintiff,

v.

SHIRE-NPS PHARMACEUTICALS,
INC.

and

TAKEDA PHARMACEUTICALS
U.S.A., INC.,

Defendants.

Case No. 21cv11602

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Rigshospitalet, a hospital located in Denmark that is affiliated with the University of Copenhagen, by and through its undersigned counsel, files this Complaint against Shire-NPS Pharmaceuticals, Inc. (“Shire-NPS”) and Takeda Pharmaceuticals U.S.A., Inc. (“Takeda USA”; collectively with Shire-NPS, “Defendants”), and alleges as follows:

NATURE OF THE SUIT

1. Rigshospitalet brings this action to remedy Defendants’ theft of inventions relating to the revolutionary treatment of short bowel syndrome (“SBS”) in patients with colon-incontinuity using GLP-2 receptor agonists. By misappropriating Rigshospitalet’s inventions, Defendants have earned *more than \$2 billion* in revenue on sales of Gattex[®] without paying any royalties to Rigshospitalet — a revenue stream that Rigshospitalet could have re-invested in researching and developing other groundbreaking medical treatments.

2. The revolutionary inventions that Defendants stole were developed by Dr. Per Brøbech Mortensen and Dr. Palle Bekker Jeppesen at Rigshospitalet — a hospital located in

Denmark that is affiliated with the University of Copenhagen. Dr. Mortensen is Chief Physician and Head of the Department of Medicine, Gastroenterology Section at Rigshospitalet.

Dr. Jeppesen is Head of Research in the Department of Medicine, Gastroenterology Section at Rigshospitalet.

3. Drs. Mortensen and Jeppesen invented the treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists at Rigshospitalet as part of clinical trials involving the treatment of SBS patients with teduglutide, a dipeptidyl peptidase IV resistant GLP-2 receptor agonist (“Teduglutide Study”). The Teduglutide Study was sponsored by Shire-NPS’s then wholly-owned subsidiary NPS Allelix Corporation (“NPS Allelix”).

4. Shire-NPS (by and through NPS Allelix), Rigshospitalet, and Dr. Mortensen struck a clear and unequivocal agreement regarding intellectual property resulting from the Teduglutide Study. They agreed that Rigshospitalet owned any intellectual property (including patents) resulting from the Teduglutide Study provided that Shire-NPS had a one-year option to obtain a worldwide, royalty-bearing, exclusive license to any such patents.

5. As they worked on the Teduglutide Study, Drs. Mortensen and Jeppesen discovered that GLP-2 receptor agonists could be used to effectively treat SBS patients with colon-in-continuity — a discovery that was surprising and contrary to the conventional belief that such patients could not be helped using GLP-2 receptor agonists. Drs. Mortensen and Jeppesen reported their findings in a manuscript that was published in the scientific journal *Gut* in August 2005: *Teduglutide (ALX-0600), a dipeptidyl peptidase IV resistant glucagon-like peptide 2 analogue, improves intestinal function in short bowel syndrome patients* (“GLP-2 SBS Article”).

6. But unbeknownst to Drs. Mortensen and Jeppesen, just before submitting the manuscript to *Gut* journal, Shire-NPS submitted a near-final draft of the GLP-2 SBS Article as Provisional Patent Application No. 60/623,233 (“’233 Application”) to the United States Patent and Trademark Office (“Patent Office”). Shire-NPS did not name Drs. Mortensen and Jeppesen as inventors. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS had filed the ’233 Application.

7. Shire-NPS continued to file non-provisional patent applications claiming priority to the ’233 Application (collectively, the “GLP-2 SBS Applications”) and has obtained almost 30 United States and foreign patents claiming priority to that application (collectively, the “GLP-2 SBS Patents”; collectively with the GLP-2 SBS Applications, the “GLP-2 SBS Applications and Patents”). Shire-NPS did not name Drs. Mortensen and Jeppesen as inventors on any of the GLP-2 SBS Applications and they are not therefore named as inventors on any of the issued GLP-2 SBS Patents. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS had filed the GLP-2 SBS Applications and obtained the GLP-2 SBS Patents.

8. In fact, pursuant to their agreement with Shire-NPS, Rigshospitalet owns all rights, title, and interests in the GLP-2 SBS Applications and Patents. Moreover, Drs. Mortensen and Jeppesen are inventors of the inventions claimed in the GLP-2 SBS Applications and Patents.

9. Rigshospitalet only recently learned about Defendants’ theft of its inventions and that Defendants have earned billions of dollars on royalty-free sales of Gattex — a parenteral therapeutic containing GLP-2 receptor agonists indicated for use in the treatment of adult and pediatric SBS patients, including patients with colon-in-continuity.

10. Rigshospitalet brings this action to remedy Defendants' theft of Drs. Mortensen and Jeppesen's inventions, wrongful prosecution of the GLP-2 SBS Applications, and misuse of the GLP-2 SBS Patents to protect the royalty-free profits that Defendants have illicitly earned by exploiting Drs. Mortensen and Jeppesen's inventions.

THE PARTIES

11. Plaintiff Rigshospitalet is located at Blegdamsvej 9, 2100 Copenhagen Ø, Denmark. Rigshospitalet is the most specialized hospital in Copenhagen and one of the largest hospitals in Denmark. Rigshospitalet is the owner of all rights, title, and interests in Drs. Mortensen and Jeppesen's inventions described in the '233 Application and all applications and patents claiming priority thereto, including the GLP-2 SBS Applications and Patents.

12. Shire-NPS is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 300 Shire Way, Lexington, Massachusetts. Shire-NPS is a wholly owned direct or indirect subsidiary of Takeda USA and is held out as "a Takeda company" on the Gattex website (www.gattex.com). Shire-NPS was formerly known as NPS Pharmaceuticals, Inc. ("NPS Pharmaceuticals"), then-parent of NPS Allelix. In 2008, NPS Allelix sold its intellectual property and substantially all of its other assets to its parent NPS Pharmaceuticals. Shire-NPS, together with Takeda USA, manufactures, distributes, markets, offers for sale, and sells Gattex in the United States.

13. Takeda USA is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 95 Hayden Avenue, Lexington, Massachusetts. Takeda USA wholly owns, directly or indirectly, Shire-NPS and holds Shire-NPS out as "a Takeda company" on the Gattex website (www.gattex.com). Takeda USA, together with Shire-NPS, manufactures, distributes, markets, offers for sale, and sells Gattex in the United States.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over Rigshospitalet's claims pursuant to 28 U.S.C. §§ 1331, 1332(a), 1338, 1367, 2201, and 2202. This Court has subject matter jurisdiction over Rigshospitalet's claims for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, fraudulent nondisclosure, conversion, and unfair and deceptive trade practices, each having a value exceeding \$75,000, under 28 U.S.C. §§ 1332(a) and 1367. This Court has subject matter jurisdiction over Rigshospitalet's claim to quiet title to the GLP-2 SBS Applications and Patents, which has a value exceeding \$75,000, pursuant to 28 U.S.C. §§ 1332(a), 1367, 2201, and 2202. This Court has subject matter jurisdiction over Rigshospitalet's claim for correction of inventorship pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. This Court has jurisdiction over Rigshospitalet's claims for patent infringement pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Shire-NPS because Shire-NPS maintains its principal place of business in the Commonwealth of Massachusetts; is licensed to do business in Massachusetts; and regularly, systematically, and continuously transacts business within Massachusetts. Shire-NPS has also committed the wrongful acts alleged herein, and benefited from those acts, within Massachusetts. Those wrongful acts include filing and prosecuting the GLP-2 SBS Applications despite the fact that Shire-NPS does not own the inventions claimed therein; deliberately misrepresenting the inventors on the GLP-2 SBS Applications and Patents; wrongfully recording in the Patent Office Shire-NPS's alleged ownership of all rights, title, and interests in the GLP-2 SBS Applications and Patents; wrongfully listing the GLP-2 SBS Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") which misrepresented that Shire-NPS owns and/or is

the exclusive licensee to the GLP-2 SBS Patents; and infringing the GLP-2 SBS Patents by its unauthorized marketing, distribution, offer for sale, and sale of Gattex in Massachusetts and elsewhere in the United States. Shire-NPS took, directed, and oversaw those wrongful acts from its Massachusetts headquarters and has reaped the benefits of royalty-free revenues on sales of Gattex at that headquarters.

16. This Court has personal jurisdiction over Takeda USA because Takeda USA maintains its principal place of business in the Commonwealth of Massachusetts; is licensed to do business in Massachusetts; and regularly, systematically, and continuously transacts business within Massachusetts. Takeda USA has also committed wrongful acts giving rise to this action, and benefited from those acts, within Massachusetts. Those wrongful acts include overseeing Shire-NPS's filing and prosecution of the GLP-2 SBS Applications despite the fact that Shire-NPS does not own the inventions; knowingly supporting Shire-NPS's deliberate misrepresentation of the inventors on the GLP-2 SBS Applications; wrongfully coordinating with Shire-NPS to list the pediatric extensions to the GLP-2 SBS Patents in the Orange Book, which listings misrepresent that Shire-NPS owns and/or is the exclusive licensee to the GLP-2 SBS Patents; and infringing the GLP-2 SBS Patents by its unauthorized marketing, distribution, offer for sale, and sale of Gattex in Massachusetts and elsewhere in the United States. Takeda USA took, directed, and oversaw all of those wrongful acts from its Massachusetts headquarters and has reaped the benefits of royalty-free revenues on sales of Gattex at that headquarters.

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

A. Drs. Mortensen and Jeppesen Are Experts in the Treatment of SBS Patients and Oversee an Internationally Recognized Practice at Rigshospitalet

18. Rigshospitalet is one of the largest hospitals in Denmark and the most highly specialized hospital in Copenhagen. Rigshospitalet is affiliated with the University of Copenhagen and part of the framework organization Copenhagen University Hospital.

19. Dr. Mortensen, M.D., D.M.Sc., is Chief Physician and Head of the Department of Medicine, Section of Gastroenterology at Rigshospitalet.

20. Dr. Jeppesen, M.D., Ph.D. is Head of Research at the Department of Gastroenterology of Rigshospitalet.

21. Drs. Mortensen and Jeppesen are experts in conducting metabolic balance studies and have worked for years with SBS patients. SBS is a malabsorption disorder caused by a lack of functional small intestine. There are two distinct subgroups of SBS patients: those with no functional colon and those with colon-in-continuity with their remnant small intestine. Patients with no functional colon have low basal GLP-2 levels and limited meal-stimulated GLP-2 secretions, which significantly impedes the intestinal absorption of nutrients. By contrast, patients with colon-in-continuity have elevated basal endogenous GLP-2 levels.

22. Drs. Mortensen and Jeppesen worked for years exploring the efficacy of treating SBS patients using GLP-2 receptor agonists. GLP-2 is of interest for SBS patients because it acts to slow gastric emptying, reduce gastric secretions, increase intestinal blood flow, and stimulate growth of the small and large intestines. By July 1999, Drs. Mortensen and Jeppesen had prepared a formulation for the first human GLP-2 study in eight SBS patients with no colon.

23. Drs. Mortensen and Jeppesen also shared their research and development regarding the treatment of SBS patients by publishing their research findings in several well-

known medical journals in the field of gastroenterology, including *Gut*, *Journal of Parenteral and Enteral Nutrition*, *The Journal of Nutrition*, and *Gastroenterology*. For example, in April 1999, Drs. Mortensen and Jeppesen published their research regarding postprandial endogenous GLP-2 secretion in SBS patients with no functional colon in *Gut*. In 2001, Drs. Mortensen and Jeppesen published an article describing the positive benefits of GLP-2 in SBS patients with no functional colon in *Gastroenterology*.

B. Shire-NPS Recruited Drs. Mortensen and Jeppesen to Oversee Clinical Trials Investigating the Treatment of SBS Patients at Rigshospitalet

24. In light of their expertise in this area, and Rigshospitalet's access to patients with rare SBS conditions, Drs. Mortensen and Jeppesen were recruited by Shire-NPS to oversee a clinical study of teduglutide at Rigshospitalet. Teduglutide is a type of GLP-2 receptor agonist that can help stimulate GLP-2 secretions in SBS patients.

25. The Teduglutide Study was conducted in accordance with the Clinical Research Protocol titled "Open-Label Multicenter, Dose-Ranging, Pilot Study to Examine the Safety, Tolerability and Efficacy of a 21 Day, Ascending, Multidose Subcutaneous Treatment with ALX-0600 in Patients with Short Bowel Syndrome" ("Clinical Study Protocol").

26. Rigshospitalet, Dr. Mortensen, and NPS Allelix on behalf of itself and its affiliates (including Shire-NPS), also entered into a Clinical Study Agreement, dated April 1, 2000 ("Clinical Study Agreement"). The Clinical Study Agreement provided that Rigshospitalet owns any intellectual property resulting from the Teduglutide Study subject to Shire-NPS's option to license any patents.

27. The Clinical Study Agreement provided, *inter alia*, that "[Rigshospitalet] shall own its medical records, research notebooks and related documentation and any intellectual

property resulting from the [Teduglutide] Study subject to the option granted to [Shire-NPS] to license Inventions described below.” (Section 8, Clinical Study Agreement.)

28. The Clinical Study Agreement further provided that Shire-NPS would notify Rigshospitalet (and Dr. Mortensen) if Shire-NPS believed that any proposed publication concerning their work on the Teduglutide Study disclosed any invention for which a patent application should be filed:

The Investigator shall furnish Sponsor with a copy of any proposed publication for review and comment at least thirty (30) days prior to submission for publication. At the expiration of such thirty (30) day period, Investigator may proceed with the submission for publication provided, however, that upon notice by Sponsor that Sponsor reasonably believes a patent application claiming an Invention (such as the term is defined in Section 8 below) should be filed, such publication shall be delayed for an additional ninety (90) days or until any patent application or applications have been filed.

(Section 7, Clinical Study Agreement.)

29. The Clinical Study Agreement also provided that Shire-NPS would notify Rigshospitalet if it believed that a patent application relating to inventions resulting from Rigshospitalet’s (and Dr. Mortensen’s) work on the Teduglutide Study should be filed:

Within sixty (60) days of such disclosure, [Shire-NPS] shall notify institution in writing if it wishes Institution to file a patent application claiming the Invention at [Shire-NPS’s] expense. For one (1) year after Institution’s disclosure of each Invention, [Shire-NPS] shall have the option to obtain a worldwide, royalty-bearing exclusive license to [Rigshospitalet’s] rights under any such patent application and any patent that issues on it.

(Section 8, Clinical Study Agreement.)

30. The Clinical Study Agreement also provided that the terms of any such license by Rigshospitalet to Shire-NPS for any issued patents would be negotiated in good faith:

The terms of such license shall be negotiated in good faith, and shall include terms standard for agreements between academic research institutions and industry including, without limitation, clauses providing for reasonable royalties and/or other payments to [Rigshospitalet], objective time-limited due diligence

provisions and product liability indemnification and insurance requirements which are acceptable to [Rigshospitalet's] liability insurance carrier.

(Section 8, Clinical Study Agreement.)

31. Drs. Mortensen and Jeppesen were Principal Investigators on the Teduglutide Study. Drs. Mortensen and Jeppesen enrolled the first Danish SBS patients in the Teduglutide Study in October 2000.

32. Per the Clinical Study Protocol, the Teduglutide Study initially included only patients with no functional colon. Drs. Mortensen and Jeppesen analyzed the data for the Teduglutide Study in real time and recognized a beneficial effect in SBS patients with no functional colon. As they continued analyzing the results, Drs. Mortensen and Jeppesen conceived that GLP-2 receptor agonists should also have a beneficial effect in SBS patients with colon-in-continuity. This was contrary to the then widely held belief that GLP-2 receptor agonists would not help SBS patients with colon-in-continuity. In fact, the potential benefit of teduglutide in patients with colon-in-continuity had never before been studied.

33. After conceiving of the idea of treating SBS patients with colon-in-continuity with GLP-2 receptor agonists, Drs. Mortensen and Jeppesen began recruiting and treating such patients as part of the Teduglutide Study. Drs. Mortensen and Jeppesen's analysis of the data confirmed their hypothesis that treating SBS patients with colon-in-continuity using GLP-2 receptor agonists provided significant benefits.

34. Drs. Mortensen and Jeppesen drafted an article describing the positive impacts associated with treating SBS patients with colon-in-continuity using GLP-2 receptor agonists. Drs. Mortensen and Jeppesen provided the first draft for comment to Shire-NPS by early 2004. Drs. Mortensen and Jeppesen continued to work to finalize the GLP-2 SBS Article throughout the year, in connection with their ongoing work on the Teduglutide Study.

35. In September 2004, Shire-NPS solicited final approvals of the draft article before submitting it for publication and asked that the co-authors “join me in thanking Palle [Jeppesen] and Per [Mortensen] for the work they did on preparing the core of this manuscript.” Shire-NPS did not reveal that it intended to submit the final manuscript (or any draft) to the Patent Office as a provisional patent application or otherwise seek patent protection of the inventions described in the GLP-2 SBS Article. Shire-NPS did not notify Rigshospitalet that the GLP-2 SBS Article included any invention for which a patent application should be filed.

36. The manuscript was submitted for publication to *Gut* on November 22, 2004, and accepted for publication on March 31, 2005. The GLP-2 SBS Article was published in the August 2005 issue of *Gut*.

C. Shire-NPS Stole Drs. Mortensen and Jeppesen’s Invention and Built a Substantial Patent Portfolio Based on Their Invention

37. Just days before submitting the GLP-2 SBS Article for publication, and unbeknownst to Drs. Mortensen and Jeppesen or Rigshospitalet, Shire-NPS filed a near-final draft of the GLP-2 SBS Article with the Patent Office as the ’233 Application. The ’233 Application included the data and results from Drs. Mortensen and Jeppesen’s study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. Shire-NPS did not name Drs. Mortensen and Jeppesen as inventors. Instead, Shire-NPS named one of its own employees as the sole inventor. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS had filed the ’233 Application.

38. In November 2005, Shire-NPS, by and through its wholly owned subsidiary NPS-Allelix, filed a non-provisional application claiming priority to the ’233 Application: U.S. Patent Application No. 11/262,980 (the “’980 Application”). The ’980 Application was a near

copy of the '233 Application, *i.e.*, a near-final draft of the GLP-2 SBS Article. The '980 Application again included the data and results from Drs. Mortensen and Jeppesen's study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. Shire-NPS did not name Drs. Mortensen and Jeppesen as inventors on the '980 Application. Instead, Shire-NPS named four of its own employees. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS had filed the '980 Application.

39. Shire-NPS kept Drs. Mortensen and Jeppesen and Rigshospitalet in the dark as it filed and prosecuted the GLP-2 SBS Applications and Patents, even as Drs. Mortensen and Jeppesen steadfastly continued their work on the Teduglutide Study — work that Shire-NPS later used to obtain marketing approval for Gattex.

40. Shire-NPS continued to file additional non-provisional patent applications claiming priority to the '233 Application. These GLP-2 SBS Applications were near copies of the '233 Application, *i.e.*, near-final drafts of the GLP-2 SBS Article. The GLP-2 SBS Applications included the data and results from Drs. Mortensen and Jeppesen's study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS was continuing to file and prosecute the GLP-2 SBS Applications claiming priority to the '233 Application. Shire-NPS's prosecution of the GLP-2 SBS Applications led to the issuance of numerous United States and foreign patents claiming priority to the original '233 Application.

41. The first GLP-2 SBS Patent that issued was U.S. Patent No. 7,847,061 (the "'061 Patent"). The '061 Patent issued on December 7, 2010 from the '980 Application, and

was titled “Treatment Of Short Bowel Syndrome Patients With Colon-In-Continuity.” The ’061 Patent specification was a near copy of the ’233 Application, *i.e.*, a near-final draft of the GLP-2 SBS Article. The ’061 Patent included the data and results from Drs. Mortensen and Jeppesen’s study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. The ’061 Patent claimed methods for treating patients with SBS with colon-in-continuity using GLP-2 receptor agonists.

42. Since the issuance of the ’061 Patent, Shire-NPS has obtained almost thirty United States and foreign patents claiming priority to the ’233 Application. The specifications of these GLP-2 SBS Patents are all near copies of the ’233 Application, *i.e.*, a near-final draft of the GLP-2 SBS Article. The GLP-2 SBS Patents all include the data and results from Drs. Mortensen and Jeppesen’s study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. The GLP-2 SBS Patents claim methods for treating patients with SBS with colon-in-continuity using GLP-2 receptor agonists. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that its prosecution of the GLP-2 SBS Applications led to the issuance of the GLP-2 SBS Patents.

43. The GLP-2 SBS Patents include the following issued United States patents: 7,847,061; 9,060,992; 9,545,434; 9,981,014; 9,987,334; 9,993,528; 9,974,835; 9,974,836; 9,545,435; 9,968,655; 9,539,310; 9,572,867; 9,592,273; 9,592,274; 9,555,079; 9,981,015; 9,968,656; 9,974,837; 9,987,335; 9,974,838; 9,999,656; 9,981,016; 9,968,657; and 9,968,658. Copies of these patents are attached hereto as Exhibits A through X, respectively. The GLP-2 SBS Patents also include the following foreign counterparts: CA 258542; JP 5197012; EP 1809318; and HK 1107026.

44. Even today, Shire-NPS, at the direction and under the control of parent Takeda USA, is continuing to prosecute patent applications claiming priority to the '233 Application and is misrepresenting to the Patent Office the inventors and ownership of the inventions claimed therein. Shire-NPS has six such pending patent applications in the United States alone. As with the other GLP-2 SBS Applications, the pending applications are near copies of the '233 Application, *i.e.*, a near-final draft of the GLP-2 SBS Article. The pending applications include the data and results from Drs. Mortensen and Jeppesen's study reflecting the effective treatment of SBS patients with colon-in-continuity using GLP-2 receptor agonists. Shire-NPS did not tell Drs. Mortensen and Jeppesen or Rigshospitalet, and concealed from them, that Shire-NPS had filed these applications and that it is continuing to prosecute them.

45. The GLP-2 SBS Applications that are currently pending include the following United States patent applications: 16/732,545; 16/992,751; 17/206,513; 17/213,534; 17/215,036; and 17/224,761.

46. Rigshospitalet owns all rights, title, and interests in the GLP-2 SBS Applications and Patents. Moreover, Drs. Mortensen and Jeppesen are inventors of the inventions claimed in the GLP-2 SBS Applications and Patents.

D. Shire-NPS Launches Gattex and Earns Billions of Dollars of Royalty-Free Revenues

47. In 2012, Shire-NPS obtained marketing approval from the United States Food and Drug Administration ("FDA") for its subcutaneous teduglutide treatment for SBS patients.

48. By 2013, Shire-NPS launched the approved product in the United States as Gattex (teduglutide), indicated for the treatment of adults with SBS who are dependent on parenteral support, including SBS patients with colon-in-continuity. The administration of Gattex to SBS patients was the first significant long-term treatment for SBS in nearly 40 years.

49. In 2015, Shire plc acquired NPS Pharmaceuticals in a stock acquisition for total consideration of approximately \$5.2 billion. At that time, Gattex was NPS Pharmaceuticals' only approved therapeutic. Shire plc subsequently changed the name of NPS Pharmaceuticals Inc. to Shire-NPS.

50. On January 8, 2019, Takeda USA acquired Shire plc in a stock acquisition worth approximately \$62 billion. On information and belief, Takeda USA reviewed the Clinical Study Agreement and knew before closing on the acquisition about all of the GLP-2 SBS Applications and Patents; that Rigshospitalet (not Shire-NPS) owned the GLP-2 SBS Applications and Patents; that Drs. Mortensen and Jeppesen should have been but were not named as inventors on the GLP-2 SBS Applications and Patents; that Shire-NPS had been misrepresenting the inventorship and ownership on the GLP-2 SBS Applications and Patents; and that Shire-NPS had been wrongfully listing the GLP-2 SBS Patents in the Orange Book and wrongfully asserting the GLP-2 SBS Patents against generics in litigation to protect its multi-billion dollar revenue stream.

51. In May 2019, the FDA approved extending the indication of Gattex to pediatric patients one year and older with SBS who are dependent on parenteral support, including pediatric SBS patients with colon-in-continuity.

52. Defendants have earned more than \$2 billion in revenue on sales of Gattex in the United States so far — including more than \$500 million in revenue last year alone. Defendants have earned these billions of dollars in royalty-free revenues on the backs of Drs. Mortensen and Jeppesen's pioneering inventions at Rigshospitalet.

53. Shire-NPS has also protected its royalty-free profits and discouraged competitors from entering the market by listing the GLP-2 SBS Patents for Gattex in the Orange Book.

Nineteen of the twenty patents listed for Gattex in the Orange Book are GLP-2 SBS Patents — the only other listed patent is a patent on the active ingredient set to expire in 2023. Shire-NPS listed these GLP-2 SBS Patents in the Orange Book despite knowing that it does not own those patents and is not licensed to use the inventions claimed therein.

54. Shire-NPS has also filed suit against competitors to block their entry into the market by asserting GLP-2 SBS Patents against them, despite the fact that Shire-NPS does not own and is not licensed to use those patents. For example, in April 2017, Shire-NPS filed suit against Par Pharmaceuticals to block entry of a generic teduglutide treatment into the market. Shire-NPS alleged, *inter alia*, that Par Pharmaceuticals' generic teduglutide treatment would infringe twenty different GLP-2 SBS Patents. Shire-NPS and Par Pharmaceuticals ultimately resolved the suit pursuant to a stipulation by which Par Pharmaceuticals was permanently enjoined from manufacturing, marketing, distributing, and selling generic teduglutide until the patent on the active ingredient (U.S. Patent No. 7,056,886) expires. That patent is set to expire in early 2023 at the conclusion of a pediatric extension.

55. The entire time that Defendants earned billions of dollars in royalty-free profits and used the GLP-2 SBS Applications and Patents to keep competitors out of the market, they continued to knowingly, intentionally, and willfully keep Drs. Mortensen and Jeppesen and Rigshospitalet in the dark.

56. Drs. Mortensen and Jeppesen and Rigshospitalet did not know, and in the exercise of reasonable diligence could not have known, of Defendants' wrongful conduct or the factual basis for the claims asserted herein. Drs. Mortensen and Jeppesen and Rigshospitalet also did not have enough information to suggest that they had suffered any injury based on Defendants' misconduct described herein and giving rise to those claims.

57. For example, Drs. Mortensen and Jeppesen and Rigshospitalet did not know that Shire-NPS submitted the GLP-2 SBS Article to the Patent Office, filed any of the GLP-2 SBS Applications, or obtained any of the GLP-2 SBS Patents.

58. Drs. Mortensen and Jeppesen and Rigshospitalet also had no reason to believe or even suspect that Shire-NPS submitted the GLP-2 SBS Article to the Patent Office, filed any of the GLP-2 SBS Applications, or obtained any of the GLP-2 SBS Patents.

59. Defendants also concealed the existence of the claims asserted herein through affirmative acts done with the specific intent to deceive Drs. Mortensen and Jeppesen and Rigshospitalet. For example, Shire-NPS took the lead on finalizing Drs. Mortensen and Jeppesen's GLP-2 SBS Article and submitting it to *Gut* knowing and intending that Shire-NPS would first file it with the Patent Office as a provisional patent application — without telling Drs. Mortensen and Jeppesen or Rigshospitalet and without naming Drs. Mortensen and Jeppesen as inventors.

60. Shire-NPS also deliberately, and with the intent to deceive Drs. Mortensen and Jeppesen and Rigshospitalet, filed the near-final GLP-2 SBS Article with the Patent Office as the '233 Application without telling Drs. Mortensen and Jeppesen and Rigshospitalet and, in fact, continued to work with them on the Teduglutide Study and to lead them to believe that Shire-NPS had not sought patent protection for their invention.

61. Shire-NPS also deliberately and with the intent to deceive Drs. Mortensen and Jeppesen and Rigshospitalet, did not name Drs. Mortensen and Jeppesen as inventors on the '233 Application or any of the GLP-2 SBS Applications claiming priority thereto — ensuring that they could not identify the GLP-2 SBS Applications, or issued GLP-2 SBS Patents, by searching for applications and patents on which they were named as inventors.

62. Shire-NPS also deliberately and with the intent to deceive Drs. Mortensen and Jeppesen and Rigshospitalet, did not name Rigshospitalet as an owner or assignee of any rights on the '233 Application or any of the GLP-2 SBS Applications claiming priority thereto — ensuring that Rigshospitalet could not identify the GLP-2 SBS Applications, or issued GLP-2 SBS Patents, by searching for applications and patents on which they were identified as an assignee.

63. Shire-NPS took all of these wrongful actions in violation of moral, contractual, and legal obligations to inform and involve Drs. Mortensen and Jeppesen and Rigshospitalet. The Clinical Study Agreement required that Shire-NPS notify Rigshospitalet (and Dr. Mortensen) if it believed that the GLP-2 SBS Article disclosed inventions for which a patent application should be filed. (Section 7, Clinical Study Agreement.) The Clinical Study Agreement further required that Shire-NPS “shall notify [Rigshospitalet] in writing if it wishes [Rigshospitalet] to file a patent application claiming the Invention [resulting from the Teduglutide Study].” (Section 8, Clinical Study Agreement.) Shire-NPS brazenly ignored its contractual obligations and instead secretly filed and prosecuted the GLP-2 SBS Applications and Patents.

64. Defendants’ actions were designed to prevent, and did for years prevent, Drs. Mortensen and Jeppesen and Rigshospitalet from discovering Defendants’ wrongful acts and the facts giving rise to the claims asserted herein.

COUNT I
(Breach of Contract – Against Shire-NPS)

65. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–64 of this Complaint.

66. The Clinical Study Agreement is a valid and enforceable agreement by and between Rigshospitalet, Dr. Mortensen, and Shire-NPS (and its affiliates).

67. Rigshospitalet and Dr. Mortensen performed all of their obligations under the Clinical Study Agreement.

68. Shire-NPS breached the Clinical Study Agreement.

69. The Clinical Study Agreement provided, *inter alia*, that Rigshospitalet “shall own . . . any intellectual property resulting from the [Teduglutide] Study subject to the option granted to Sponsor [Shire-NPS] to license Inventions described below.” (Section 8, Clinical Study Agreement.)

70. The Clinical Study Agreement further provided that Shire-NPS would notify Rigshospitalet (and Dr. Mortensen) if it believed that the GLP-2 SBS Article disclosed inventions for which a patent application should be filed. (Section 7, Clinical Study Agreement.)

71. The Clinical Study Agreement also provided that “[w]ithin sixty (60) days of such disclosure [of an Invention], [Shire-NPS] shall notify Rigshospitalet in writing if it wished [Rigshospitalet] to file a patent application claiming the Invention at [Shire-NPS’s] expense.” (*Id.*)

72. Shire-NPS breached all of these contractual obligations. Shire-NPS breached these contractual obligations by, *inter alia*, filing and prosecuting the GLP-2 SBS Applications without telling Rigshospitalet and while concealing the filings and prosecutions from Rigshospitalet; recording its alleged ownership of all rights, title, and interests in the GLP-2 SBS Applications and Patents with the Patent Office; holding itself out as owning the GLP-2 SBS Patents by listing them in the Orange Book; representing, in collaboration with Takeda USA,

that it owns several of the GLP-2 SBS Patents on the Takeda USA website (www.takeda.com/en-us/patents); and asserting that it “owns” several of the GLP-2 SBS Patents in patent infringement litigation against prospective generic suppliers of Gattex.

73. In fact, Rigshospitalet is the sole and exclusive owner of the GLP-2 SBS Applications and Patents, which claim inventions conceived of by Drs. Mortensen and Jeppesen in connection with their work on the Teduglutide Study.

74. Shire-NPS is not and never has been the sole and exclusive owner of all rights, title, and interests in the GLP-2 SBS Applications and Patents. Shire-NPS is not and has never been licensed to use the inventions claimed in the GLP-2 SBS Applications and Patents and has never held any right, title, or interest in those applications and patents.

75. Shire-NPS’s breaches of the Clinical Study Agreement were part of an ongoing and continuous effort to misappropriate Rigshospitalet’s inventions, to prosecute the GLP-2 SBS Applications and Patents, to profit on royalty-free sales of Gattex, and to conceal all of these actions from Drs. Mortensen and Jeppesen and Rigshospitalet.

76. Shire-NPS’s breaches have damaged Rigshospitalet in an amount to be proven at trial. Rigshospitalet seeks monetary damages and equitable relief for these breaches of the Clinical Study Agreement.

COUNT II
(Breach of the Implied Covenant of Good Faith and Fair Dealing – Against Shire-NPS)

77. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–76 of this Complaint.

78. The Clinical Study Agreement is a valid and enforceable agreement by and among Rigshospitalet, Dr. Mortensen, and Shire-NPS (and its affiliates).

79. Rigshospitalet and Dr. Mortensen performed all of their obligations under the Clinical Study Agreement.

80. The implied covenant of good faith and fair dealing inherent in the Clinical Study Agreement required that Shire-NPS notify Rigshospitalet if Shire-NPS believed that any proposed publications relating to the Teduglutide Study disclosed inventions for which a patent application should be filed.

81. The implied covenant of good faith and fair dealing inherent in the Clinical Study Agreement further required that Shire-NPS not secretly prosecute patent applications claiming inventions that resulted from the Teduglutide Study, including inventions by Drs. Mortensen and Jeppesen (or other Rigshospitalet employees).

82. These implied obligations are implicit in the requirements of Sections 7 and 8 of the Clinical Study Agreement and the breach of those obligations would deny Rigshospitalet the benefit of the bargain that it struck in the Clinical Study Agreement and, in particular, in Sections 7 and 8 of the Clinical Study Agreement.

83. Shire-NPS breached the implied covenant of good faith and fair dealing by not telling Rigshospitalet that Shire-NPS believed that the GLP-2 SBS Article disclosed inventions for which a patent application should be filed, and by secretly prosecuting the '233 Application and the GLP-2 SBS Applications and Patents.

84. Shire-NPS's breaches of the implied covenant of good faith and fair dealing were part of an ongoing and continuous effort to misappropriate Rigshospitalet's inventions, to prosecute the GLP-2 SBS Applications and Patents, to profit on royalty-free sales of Gattex, and to conceal all of these actions from Drs. Mortensen and Jeppesen and Rigshospitalet.

85. Shire-NPS's breaches of the implied covenant of good faith and fair dealing have damaged Rigshospitalet in an amount to be proven at trial. Rigshospitalet seeks monetary damages and equitable relief for these breaches of the implied covenant of good faith and fair dealing.

COUNT III

(Transfer of Ownership/Quiet Title – Against Shire NPS and Takeda USA)

86. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–85 of this Complaint.

87. Rigshospitalet seeks to quiet title to the GLP-2 SBS Applications and Patents.

88. Pursuant to the Clinical Study Agreement, Rigshospitalet owns and holds title to “any intellectual property resulting from the [Teduglutide] Study.” (Section 8, Clinical Study Agreement.)

89. The GLP-2 SBS Applications and Patents are intellectual property resulting from the Teduglutide Study and claim inventions resulting from the Teduglutide Study.

90. Rigshospitalet is the rightful owner of title to the GLP-2 SBS Applications and Patents.

91. Rigshospitalet seeks a declaration that Rigshospitalet holds sole and exclusive title to the GLP-2 SBS Applications and Patents, and an order transferring ownership of such intellectual property to Rigshospitalet.

COUNT IV

(Correction of Inventorship – Against Shire-NPS)

92. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–91 of this Complaint.

93. Drs. Mortensen and Jeppesen are the sole and exclusive inventors of the inventions claimed in the '061 Patent. Drs. Mortensen and Jeppesen are, at a minimum, co-inventors on inventions claimed in the other GLP-2 SBS Applications and Patents.

94. The GLP-2 SBS Applications and Patents all disclose and claim methods of treating SBS patients with colon-in-continuity using dosing regimens of GLP-2 receptor agonists. The GLP-2 SBS Applications and Patents disclose and claim such treatment of patients with at least a certain percentage (*e.g.*, 50% or 75%) of colon-in-continuity with remnant small intestine. The GLP-2 SBS Applications and Patents disclose and claim that such treatments increase wet weight and energy absorption and decrease fecal wet weight in SBS patients with colon-in-continuity.

95. Drs. Mortensen and Jeppesen conceived of those inventions. Drs. Mortensen and Jeppesen formed a definite and permanent idea that the treatment of such patients using GLP-2 receptor agonists would be effective and that the benefits would include increased wet weight and energy absorption and decreased fecal wet weight.

96. Drs. Mortensen and Jeppesen then reduced their inventions to practice by recruiting and testing SBS patients with colon-in-continuity as part of the Teduglutide Study, and then reporting the results (including the benefits) in their GLP-2 SBS Article – a draft of which Shire-NPS misappropriated and filed as the '233 Application.

97. Accordingly, Drs. Mortensen and Jeppesen should be named as sole and exclusive inventors on the '061 Patent and at least as co-inventors on all of the other GLP-2 SBS Applications and Patents.

98. Rigshospitalet seeks a declaration and order that Drs. Mortensen and Jeppesen are the sole and exclusive inventors of the '061 Patent and at least joint inventors of each of the other GLP-2 SBS Patents pursuant to 35 U.S.C. § 256.

COUNT V
(Infringement of '061 Patent – Against Shire-NPS and Takeda USA)

99. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–98 of this Complaint.

100. The '061 Patent is titled “Treatment Of Short Bowel Syndrome Patients With Colon-In-Continuity” and was issued by the Patent Office on December 7, 2010.

101. Rigshospitalet owns all rights, title, and interests in the '061 Patent.

102. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '061 Patent.

103. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '061 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '061 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

104. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '061 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '061 Patent.

105. Such administration of Gattex is “[a] method for enhancing intestinal absorption in a patient with short bowel syndrome presenting with colon in continuity with remnant small

intestine.” Gattex is used to treat SBS patients presenting with colon-in-continuity with remnant small intestine and will enhance intestinal absorption in such patients.

106. Such administration of Gattex also includes the step of “selecting for treatment a short bowel syndrome patient presenting with colon-in-continuity with remnant small intestine.” The SBS patient, or caregiver, is choosing to administer Gattex to an SBS patient presenting with colon-in-continuity with remnant small intestine.

107. Such administration of Gattex also includes “treating said patient with a GLP-2 receptor agonist using a dosing regimen effective to enhance intestinal absorption, wherein said GLP-2 receptor agonist is selected from the group consisting of a GLP-2 peptide, a GLP-2 analog, a derivative GLP-2 peptide or a derivatized GLP-2 analog.” Gattex includes teduglutide which is a GLP-2 receptor agonist and, in particular, a GLP-2 analog. The dosages described in the package insert are a dosing regimen effective to enhance intestinal absorption in SBS patients presenting with colon-in-continuity with remnant small intestine.

108. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '061 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS

emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

109. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '061 Patent. Shire-NPS has known about the '061 Patent since it issued on December 7, 2010. Shire-NPS filed the application leading to issuance of the '061 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '061 Patent issued. Takeda USA, on information and belief, has known about the '061 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

110. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '061 Patent and have acted with the specific intent that their customers infringe claim 1 of the '061 Patent. Shire-NPS listed the '061 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and then, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '061 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '061 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of

the '061 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '061 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

111. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '061 Patent.

112. As a result of Shire-NPS's and Takeda USA's infringement of the '061 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT VI
(Infringement of '992 Patent – Against Shire-NPS and Takeda USA)

113. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–112 of this Complaint.

114. United States Patent No. 9,060,992 (“'992 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on June 23, 2015.

115. Rigshospitalet owns all rights, title, and interests in the '992 Patent.

116. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '992 Patent.

117. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '992 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '992 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

118. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '992 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '992 Patent.

119. Such administration of Gattex is "[a] method for enhancing intestinal absorption in a patient with short bowel syndrome with colon-in-continuity with remnant small intestine, wherein the patient retains colon sufficient to produce at least about 10% of endogenous GLP-2 levels produced by a healthy individual in a fed state." Gattex is used to treat SBS patients with colon-in-continuity with remnant small intestine who retain colon sufficient to produce at least about 10% of endogenous GLP-2 levels produced by a healthy individual in a fed state and will enhance intestinal absorption in such patients.

120. Such administration of Gattex also includes the "step of administering to said patient a GLP-2 receptor agonist using a dosing regimen effective to enhance intestinal absorption, wherein said GLP-2 receptor agonist is selected from the group consisting of a GLP-2 peptide, a GLP-2 analog, a derivatized GLP-2 peptide or a derivatized GLP-2 analog." Gattex includes teduglutide which is a GLP-2 receptor agonist and, in particular, a GLP-2 analog. The dosages described in the package insert are a dosing regimen effective to enhance intestinal absorption in SBS patients with colon-in-continuity with remnant small intestine who retain colon sufficient to produce at least about 10% of endogenous GLP-2 levels produced by a healthy individual in a fed state.

121. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '992 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including

patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

122. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '992 Patent. Shire-NPS has known about the '992 Patent since it issued on June 23, 2015. Shire-NPS filed the application leading to issuance of the '992 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '992 Patent issued. Takeda USA, on information and belief, has known about the '992 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

123. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '992 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '992 Patent. Shire-NPS listed the '992 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '992 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and

approval of Takeda USA, identifies the '992 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '992 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '992 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

124. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '992 Patent.

125. As a result of Shire-NPS’s and Takeda USA’s infringement of the '992 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT VII
(Infringement of '434 Patent – Against Shire-NPS and Takeda USA)

126. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–125 of this Complaint.

127. United States Patent No. 9,545,434 (“’434 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on January 17, 2017.

128. Rigshospitalet owns all rights, title, and interests in the '434 Patent.

129. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '434 Patent.

130. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '434 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '434 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

131. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '434 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '434 Patent.

132. Such administration of Gattex is “[a] method for treating a patient with short bowel syndrome with colon-in-continuity with remnant small intestine.” Gattex is used to treat SBS patients with colon-in-continuity with remnant small intestine.

133. Such administration of Gattex also includes “administering to the patient an amount of a GLP-2 receptor agonist that is effective to reduce intestinal wet weight excretion in the patient, wherein the GLP-2 receptor agonist is selected from the group consisting of a GLP-2 peptide, a GLP-2 analog, a derivatized GLP-2 peptide, and a derivatized GLP-2 analog.” Gattex includes teduglutide which is a GLP-2 receptor agonist and, in particular, a GLP-2 analog. Gattex also reduces intestinal wet weight excretion in SBS patients with colon-in-continuity with remnant small intestine.

134. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '434 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

135. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '434 Patent. Shire-NPS has known about the '434 Patent since it issued on January 17, 2017. Shire-NPS filed the application leading to issuance of the '434 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '434 Patent issued. Takeda USA, on information and belief, has known about the '434 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

136. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '434 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '434 Patent. Shire-NPS listed the '434 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who

Are Dependent on Parenteral Support”) and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the ’434 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the ’434 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’434 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’434 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

137. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’434 Patent.

138. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’434 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT VIII
(Infringement of ’014 Patent – Against Shire-NPS and Takeda USA)

139. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–138 of this Complaint.

140. United States Patent No. 9,981,014 (“’014 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 29, 2018.

141. Rigshospitalet owns all rights, title, and interests in the '014 Patent.

142. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '014 Patent.

143. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '014 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '014 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

144. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '014 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '014 Patent.

145. Such administration of Gattex is “[a] method for treating an adult human patient with short bowel syndrome presenting with colon-in-continuity with remnant small intestine” Gattex is used to treat SBS patients with colon-in-continuity with remnant small intestine.

146. Such administration of Gattex also includes “said method comprising administering to the patient [Gly2]hGLP-2 using a dosing regimen effective to enhance intestinal absorption by the patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. Gattex also enhances intestinal absorption in SBS patients presenting with colon-in-continuity with remnant small intestine.

147. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '014 Patent. For example, Shire-NPS and Takeda USA distribute Gattex

with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

148. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '014 Patent. Shire-NPS has known about the '014 Patent since it issued on May 29, 2018. Shire-NPS filed the application leading to issuance of the '014 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '014 Patent issued. Takeda USA, on information and belief, has known about the '014 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

149. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '014 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '014 Patent. Shire-NPS listed the '014 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '014 Patent and pediatric

extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '014 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '014 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '014 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

150. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '014 Patent.

151. As a result of Shire-NPS’s and Takeda USA’s infringement of the '014 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT IX
(Infringement of '334 Patent – Against Shire-NPS and Takeda USA)

152. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–151 of this Complaint.

153. United States Patent No. 9,987,334 (“’334 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on June 5, 2018.

154. Rigshospitalet owns all rights, title, and interests in the '334 Patent.

155. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '334 Patent.

156. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '334 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '334 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

157. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '334 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '334 Patent.

158. Such administration of Gattex is “[a] method of treating an adult human patient having short bowel syndrome secondary to a non-malignant disease, who receives an amount of parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat adult patients with colon-in-continuity with remnant small intestine who have SBS secondary to a non-malignant disease and receive weekly parenteral nutrition.

159. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly amount of parenteral nutrition received by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex will reduce or eliminate the need for parenteral infusions in patients

with colon-in-continuity with remnant small intestine who have SBS secondary to a non-malignant disease and receive weekly parenteral nutrition.

160. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '334 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

161. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '334 Patent. Shire-NPS has known about the '334 Patent since it issued on June 5, 2018. Shire-NPS filed the application leading to issuance of the '334 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '334 Patent issued. Takeda USA, on information and belief, has known about the '334 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

162. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '334 Patent and have acted with the specific intent to cause their

customers to infringe claim 1 of the '334 Patent. Shire-NPS listed the '334 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '334 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '334 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '334 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '334 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

163. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '334 Patent.

164. As a result of Shire-NPS's and Takeda USA's infringement of the '334 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT X
(Infringement of '528 Patent – Against Shire-NPS and Takeda USA)

165. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–164 of this Complaint.

166. United States Patent No. 9,993,528 (“’528 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on June 12, 2018.

167. Rigshospitalet owns all rights, title, and interests in the ’528 Patent.

168. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’528 Patent.

169. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’528 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the ’528 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

170. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the ’528 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the ’528 Patent.

171. Such administration of Gattex is “[a] method of increasing the villus height of an adult human patient having short bowel syndrome, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat SBS patients with colon-in-continuity with remnant small intestine who receive weekly parenteral nutrition and can increase villus height in such patients.

172. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to increase the villus height of said patient.” Gattex

includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosing regimen provided in the package insert is effective to increase the villus height in SBS patients with colon-in-continuity with remnant small intestine who receive weekly parenteral nutrition.

173. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '528 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

174. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '528 Patent. Shire-NPS has known about the '528 Patent since it issued on June 12, 2018. Shire-NPS filed the application leading to issuance of the '528 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '528 Patent issued. Takeda USA, on information and belief, has known about the '528 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

175. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '528 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '528 Patent. Shire-NPS listed the '528 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '528 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '528 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '528 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '528 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

176. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '528 Patent.

177. As a result of Shire-NPS's and Takeda USA's infringement of the '528 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XI
(Infringement of '835 Patent – Against Shire-NPS and Takeda USA)

178. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–177 of this Complaint.

179. United States Patent No. 9,974,835 (“’835 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 22, 2018.

180. Rigshospitalet owns all rights, title, and interests in the ’835 Patent.

181. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’835 Patent.

182. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’835 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the ’835 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

183. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the ’835 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the ’835 Patent.

184. Such administration of Gattex is “[a] method of treating an adult human patient having short bowel syndrome secondary to Crohn’s disease, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is

used to treat SBS patients with colon-in-continuity with remnant small intestine who may have SBS secondary to Crohn's disease and who receive parenteral support each week.

185. Such administration of Gattex also includes "said method comprising administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly parenteral nutrition received by said patient." Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert is effective to reduce or eliminate the weekly parenteral nutrition received by SBS patients with colon-in-continuity with remnant small intestine, who may have SBS secondary to Crohn's disease.

186. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '835 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

187. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '835 Patent. Shire-NPS has known about the '835 Patent since

it issued on May 22, 2018. Shire-NPS filed the application leading to issuance of the '835 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '835 Patent issued. Takeda USA, on information and belief, has known about the '835 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

188. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '835 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '835 Patent. Shire-NPS listed the '835 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '835 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '835 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '835 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '835 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

189. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '835 Patent.

190. As a result of Shire-NPS's and Takeda USA's infringement of the '835 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XII
(Infringement of '435 Patent – Against Shire-NPS and Takeda USA)

191. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–190 of this Complaint.

192. United States Patent No. 9,545,435 (“'435 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on January 17, 2017.

193. Rigshospitalet owns all rights, title, and interests in the '435 Patent.

194. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '435 Patent.

195. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '435 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '435 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

196. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '435 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '435 Patent.

197. Such administration of Gattex is “[a] method of treating a patient having short bowel syndrome with congenital intestinal abnormalities, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat SBS patients with congenital intestinal abnormalities, presenting with colon-in-continuity with remnant small intestine, who receive parenteral nutrition each week.

198. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly parenteral nutrition received by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert can reduce or eliminate the weekly parenteral nutrition received by SBS patients with congenital intestinal abnormalities, presenting with colon-in-continuity with remnant small intestine, who receive parenteral nutrition each week.

199. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '435 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS

emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

200. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '435 Patent. Shire-NPS has known about the '435 Patent since it issued on January 17, 2017. Shire-NPS filed the application leading to issuance of the '435 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '435 Patent issued. Takeda USA, on information and belief, has known about the '435 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

201. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '435 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '435 Patent. Shire-NPS listed the '435 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '435 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '435 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of

the '435 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '435 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

202. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '435 Patent.

203. As a result of Shire-NPS's and Takeda USA's infringement of the '435 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XIII
(Infringement of '655 Patent – Against Shire-NPS and Takeda USA)

204. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–203 of this Complaint.

205. United States Patent No. 9,968,655 (“'655 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 15, 2018.

206. Rigshospitalet owns all rights, title, and interests in the '655 Patent.

207. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '655 Patent.

208. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '655 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '655 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

209. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '655 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '655 Patent.

210. Such administration of Gattex is "[a] method of treating an adult human patient having short bowel syndrome secondary to volvulus, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine." Gattex is used to treat adult patients with SBS secondary to volvulus presenting with colon-in-continuity with remnant small intestine and who receive parenteral nutrition each week.

211. Such administration of Gattex also includes "administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly amount of parenteral nutrition received by said patient." Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce or eliminate the weekly amount of parenteral nutrition received by patients with SBS secondary to volvulus presenting with colon-in-continuity with remnant small intestine and who receive parenteral nutrition each week.

212. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '655 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that

includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

213. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '655 Patent. Shire-NPS has known about the '655 Patent since it issued on May 15, 2018. Shire-NPS filed the application leading to issuance of the '655 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '655 Patent issued. Takeda USA, on information and belief, has known about the '655 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

214. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '655 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '655 Patent. Shire-NPS listed the '655 Patent in the Orange Book with Use Code U-2308 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '655 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '655 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-

NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '655 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '655 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

215. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '655 Patent.

216. As a result of Shire-NPS's and Takeda USA's infringement of the '655 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XIV
(Infringement of '310 Patent – Against Shire-NPS and Takeda USA)

217. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–216 of this Complaint.

218. United States Patent No. 9,539,310 ("'310 Patent") is titled "Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity" and was issued by the Patent Office on January 10, 2017.

219. Rigshospitalet owns all rights, title, and interests in the '310 Patent.

220. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '310 Patent.

221. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '310 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '310 Patent are infringed by the administration of Gattex to "treat[] adult patients with short bowel syndrome who are

dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

222. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the ’310 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the ’310 Patent.

223. Such administration of Gattex is “[a] method of decreasing fecal wet weight of a patient having short bowel syndrome, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat and decrease fecal weight of SBS patients presenting with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

224. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to decrease the fecal wet weight of said patient compared to fecal wet weight of said patient before said dosing regimen.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimens in the package insert may decrease the fecal weight of SBS patients presenting with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

225. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the ’310 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity.

Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

226. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '310 Patent. Shire-NPS has known about the '310 Patent since it issued on January 10, 2017. Shire-NPS filed the application leading to issuance of the '310 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '310 Patent issued. Takeda USA, on information and belief, has known about the '310 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

227. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '310 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '310 Patent. Shire-NPS listed the '310 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '310 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '310 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of

using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’310 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’310 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

228. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’310 Patent.

229. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’310 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XV

(Infringement of ’867 Patent – Against Shire-NPS and Takeda USA)

230. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–229 of this Complaint.

231. United States Patent No. 9,572,867 (“’867 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on February 21, 2017.

232. Rigshospitalet owns all rights, title, and interests in the ’867 Patent.

233. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’867 Patent.

234. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’867 Patent, including at least claim 1, in violation of 35 U.S.C.

§ 271(b). Shire-NPS and Takeda USA concede that claims of the '867 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

235. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the '867 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '867 Patent.

236. Such administration of Gattex is “[a] method of reducing recurrence of kidney stones in a patient having short bowel syndrome, who has previously suffered from at least one kidney stone, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat and reduce kidney stones in SBS patients presenting with colon-in-continuity with remnant small intestine who previously suffered from at least one kidney stone.

237. Such administration of Gattex also includes “comprising administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce the likelihood of kidney stone recurrence in said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce the likelihood of kidney stone recurrence in SBS patients presenting with colon-in-continuity with remnant small intestine who previously suffered from at least one kidney stone.

238. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '867 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including

step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that a majority of the patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

239. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '867 Patent. Shire-NPS has known about the '867 Patent since it issued on February 21, 2017. Shire-NPS filed the application leading to issuance of the '867 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '867 Patent issued. Takeda USA, on information and belief, has known about the '867 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

240. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '867 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '867 Patent. Shire-NPS listed the '867 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '867 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '867 Patent as "a patent for which a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’867 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’867 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

241. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’867 Patent.

242. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’867 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XVI
(Infringement of ’273 Patent – Against Shire-NPS and Takeda USA)

243. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–242 of this Complaint.

244. United States Patent No. 9,592,273 (“’273 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on March 14, 2017.

245. Rigshospitalet owns all rights, title, and interests in the ’273 Patent.

246. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’273 Patent.

247. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '273 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b).

248. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '273 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '273 Patent.

249. Such administration of Gattex is "[a] method of inducing small intestine growth of a patient having short bowel syndrome, who receives parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine." Gattex is used to treat and induce small intestine growth in SBS patients presenting with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

250. Such administration of Gattex also includes "administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to induce small intestine growth." Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may induce small intestine growth in SBS patients presenting with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

251. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '273 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many presenting with colon-in-continuity. Takeda

USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS also emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

252. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '273 Patent. Shire-NPS has known about the '273 Patent since it issued on March 14, 2017. Shire-NPS filed the application leading to issuance of the '273 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '273 Patent issued. Takeda USA, on information and belief, has known about the '273 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

253. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '273 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '273 Patent. Shire-NPS listed the '273 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '273 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '273 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of

using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’273 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’273 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

254. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’273 Patent.

255. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’273 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XVII

(Infringement of ’274 Patent – Against Shire-NPS and Takeda USA)

256. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–255 of this Complaint.

257. United States Patent No. 9,592,274 (“’274 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on March 14, 2017.

258. Rigshospitalet owns all rights, title, and interests in the ’274 Patent.

259. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’274 Patent.

260. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’274 Patent, including at least claim 1, in violation of 35 U.S.C.

§ 271(b). Shire-NPS and Takeda USA concede that claims of the '274 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

261. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the '274 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '274 Patent.

262. Such administration of Gattex is “[a] method of reducing recurrence of dehydration of a patient having short bowel syndrome, who has previously suffered from dehydration, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat and prevent dehydration in SBS patients with colon-in-continuity with remnant small intestine who have previously suffered from dehydration.

263. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce the likelihood of dehydration recurrence in said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce the likelihood of dehydration in SBS patients with colon-in-continuity with remnant small intestine who have previously suffered from dehydration.

264. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '274 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including

step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

265. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '274 Patent. Shire-NPS has known about the '274 Patent since it issued on March 14, 2017. Shire-NPS filed the application leading to issuance of the '274 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '274 Patent issued. Takeda USA, on information and belief, has known about the '274 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

266. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '274 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '274 Patent. Shire-NPS listed the '274 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and support of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '274 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '274 Patent as "a patent for which a claim of patent infringement could reasonably

be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’274 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’274 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

267. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’274 Patent.

268. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’274 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XVIII
(Infringement of ’079 Patent – Against Shire-NPS and Takeda USA)

269. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–268 of this Complaint.

270. United States Patent No. 9,555,079 (“’079 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on January 31, 2017.

271. Rigshospitalet owns all rights, title, and interests in the ’079 Patent.

272. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’079 Patent.

273. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '079 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '079 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

274. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '079 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '079 Patent.

275. Such administration of Gattex is “[a] method of reducing or suppressing gastric secretion of a patient having short bowel syndrome, who receives an amount of parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat and reduce or suppress gastric secretion in SBS patients with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

276. Such administration of Gattex also includes “said method comprising administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or suppress gastric secretion.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce or suppress gastric secretion in SBS patients with colon-in-continuity with remnant small intestine who receive parenteral nutrition each week.

277. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '079 Patent. For example, Shire-NPS and Takeda USA distribute Gattex

with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

278. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '079 Patent. Shire-NPS has known about the '079 Patent since it issued on January 31, 2017. Shire-NPS filed the application leading to issuance of the '079 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '079 Patent issued. Takeda USA, on information and belief, has known about the '079 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

279. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '079 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '079 Patent. Shire-NPS listed the '079 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '079

Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '079 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '079 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '079 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

280. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '079 Patent.

281. As a result of Shire-NPS’s and Takeda USA’s infringement of the '079 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XIX
(Infringement of '656 Patent – Against Shire-NPS and Takeda USA)

282. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–281 of this Complaint.

283. United States Patent No. 9,968,656 (“’656 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 15, 2018.

284. Rigshospitalet owns all rights, title, and interests in the '656 Patent.

285. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '656 Patent.

286. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '656 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '656 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

287. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '656 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '656 Patent.

288. Such administration of Gattex is “[a] method of treating an adult human patient having short bowel syndrome with colon-in-continuity and at least about 50 cm of remnant small intestine and who receives an amount of parenteral nutrition each week.” Gattex is used to treat SBS patients with colon-in-continuity and at least 50 cm of remnant small intestine who receive parenteral nutrition each week.

289. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly amount of parenteral nutrition received by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce or eliminate the weekly amount of parenteral nutrition received by SBS patients with colon-in-continuity and at least 50 cm of remnant small intestine.

290. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '656 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patient, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

291. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '656 Patent. Shire-NPS has known about the '656 Patent since it issued on May 15, 2018. Shire-NPS filed the application leading to issuance of the '656 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '656 Patent issued. Takeda USA, on information and belief, has known about the '656 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

292. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '656 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '656 Patent. Shire-NPS listed the '656 Patent in the Orange Book with Use Code U-2308 ("Treatment of Adult Patients with Short Bowel Syndrome Who

Are Dependent on Parenteral Support”) and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the ’656 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the ’656 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the ’656 Patent. Takeda USA, in coordination with Shire-NPS, also lists the ’656 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

293. Shire-NPS’s and Takeda USA’s infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the ’656 Patent.

294. As a result of Shire-NPS’s and Takeda USA’s infringement of the ’656 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XX
(Infringement of ’837 Patent – Against Shire-NPS and Takeda USA)

295. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–294 of this Complaint.

296. United States Patent No. 9,974,837 (“’837 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 22, 2018.

297. Rigshospitalet owns all rights, title, and interests in the '837 Patent.

298. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '837 Patent.

299. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '837 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '837 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

300. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 1 of the '837 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the '837 Patent.

301. Such administration of Gattex is “[a] method of treating an adult human patient having short bowel syndrome without inflammatory bowel disease, who receives an amount of parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat SBS patients with colon-in-continuity with remnant small intestine without inflammatory bowel disease and who receive parenteral nutrition each week.

302. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly amount of parenteral nutrition received by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce or eliminate the amount of parenteral nutrition received by SBS patients with

colon-in-continuity with remnant small intestine without inflammatory bowel disease and who receive parenteral nutrition each week.

303. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '837 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

304. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '837 Patent. Shire-NPS has known about the '837 Patent since it issued on May 22, 2018. Shire-NPS filed the application leading to issuance of the '837 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '837 Patent issued. Takeda USA, on information and belief, has known about the '837 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

305. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '837 Patent and have acted with the specific intent to cause their

customers to infringe claim 1 of the '837 Patent. Shire-NPS listed the '837 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '837 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '837 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '837 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '837 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

306. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '837 Patent.

307. As a result of Shire-NPS's and Takeda USA's infringement of the '837 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XXI
(Infringement of '335 Patent – Against Shire-NPS and Takeda USA)

308. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–307 of this Complaint.

309. United States Patent No. 9,987,335 (“’335 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on June 5, 2018.

310. Rigshospitalet owns all rights, title, and interests in the ’335 Patent.

311. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’335 Patent.

312. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’335 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the ’335 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

313. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the ’335 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the ’335 Patent.

314. Such administration of Gattex is “[a] method of increasing the crypt depth of an adult human patient having short bowel syndrome and reduced crypt depth as compared to a normal healthy individual, who receives an amount of parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat and increase the crypt depth in SBS patients who present with colon-in-continuity with remnant small intestine and who receive parenteral nutrition each week.

315. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to increase the crypt depth of said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. By listing the ’335 Patent and pediatric extension in the Orange Book, Shire-NPS and Takeda USA conceded that the administration of Gattex according to the dosage regimen in the package insert may increase the crypt depth of SBS patients.

316. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the ’335 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

317. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the ’335 Patent. Shire-NPS has known about the ’335 Patent since it issued on June 5, 2018. Shire-NPS filed the application leading to issuance of the ’335 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the ’335 Patent issued. Takeda USA, on information and belief, has known about

the '335 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

318. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '335 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '335 Patent. Shire-NPS listed the '335 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '335 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '335 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '335 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '335 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

319. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '335 Patent.

320. As a result of Shire-NPS's and Takeda USA's infringement of the '335 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XXII
(Infringement of '016 Patent – Against Shire-NPS and Takeda USA)

321. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–320 of this Complaint.

322. United States Patent No. 9,981,016 (“’016 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 29, 2018.

323. Rigshospitalet owns all rights, title, and interests in the ’016 Patent.

324. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the ’016 Patent.

325. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the ’016 Patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the ’016 Patent are infringed by the administration of Gattex to “treat[] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

326. Shire-NPS’s and Takeda USA’s customers have directly infringed, and continue to directly infringe, at least claim 1 of the ’016 Patent. The administration of Gattex by an SBS patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 1 of the ’016 Patent.

327. Such administration of Gattex is “[a] method of treating an adult human patient having short bowel syndrome secondary to multiple strictures due to adhesions or radiation, who receives an amount of parenteral nutrition each week, and who presents with colon-in-continuity with remnant small intestine.” Gattex is used to treat patients with SBS secondary to

multiple strictures due to adhesion of radiation who present with colon-in-continuity with remnant small intestine, and who receive parenteral nutrition each week.

328. Such administration of Gattex also includes “administering [Gly2]hGLP-2 to said patient using a dosing regimen effective to reduce or eliminate said weekly amount of parenteral nutrition received by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. The administration of Gattex according to the dosage regimen in the package insert may reduce or eliminate the weekly amount of parenteral nutrition received by patients with SBS secondary to multiple strictures due to adhesion of radiation, who present with colon-in-continuity with remnant small intestine.

329. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 1 of the '016 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

330. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '016 Patent. Shire-NPS has known about the '016 Patent since

it issued on May 29, 2018. Shire-NPS filed the application leading to issuance of the '016 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '016 Patent issued. Takeda USA, on information and belief, has known about the '016 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

331. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 1 of the '016 Patent and have acted with the specific intent to cause their customers to infringe claim 1 of the '016 Patent. Shire-NPS listed the '016 Patent in the Orange Book with Use Code U-1320 (“Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support”) and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '016 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '016 Patent as “a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted . . .” 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals’ manufacture, distribution, marketing, and sale of generic Gattex would induce infringement of the '016 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '016 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

332. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '016 Patent.

333. As a result of Shire-NPS's and Takeda USA's infringement of the '016 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XXIII
(Infringement of '658 Patent – Against Shire-NPS and Takeda USA)

334. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–333 of this Complaint.

335. United States Patent No. 9,968,658 (“'658 Patent”) is titled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” and was issued by the Patent Office on May 15, 2018.

336. Rigshospitalet owns all rights, title, and interests in the '658 Patent.

337. Shire-NPS and Takeda USA know and have known that Rigshospitalet owns all rights, title, and interests in the '658 Patent.

338. Shire-NPS and Takeda USA have in the past induced, and continue to induce, the infringement of claims of the '658 Patent, including at least claim 11, in violation of 35 U.S.C. § 271(b). Shire-NPS and Takeda USA concede that claims of the '658 Patent are infringed by the administration of Gattex to “treat [] adult patients with short bowel syndrome who are dependent on parenteral support” because they have identified such treatment as an infringing use of Gattex in the Orange Book.

339. Shire-NPS's and Takeda USA's customers have directly infringed, and continue to directly infringe, at least claim 11 of the '658 Patent. The administration of Gattex by an SBS

patient with colon-in-continuity, or by a caregiver to an SBS patient with colon-in-continuity, infringes claim 11 of the '658 Patent.

340. Such administration of Gattex is “[a] method for treating an adult human patient having short bowel syndrome with elevated basal levels of endogenous GLP-2 (as compared to a normal healthy individual) and who is dependent on parenteral nutrition.” Gattex is used to treat SBS patients with elevated basal levels of endogenous GLP-2 who are dependent on parenteral nutrition.

341. Such administration of Gattex also includes “administering to said patient [Gly2]hGLP-2 using a dosing regimen effective to enhance intestinal absorption by said patient.” Gattex includes [Gly2]hGLP-2, known as teduglutide. Gattex is effective to enhance intestinal absorption in SBS patients with elevated basal levels of endogenous GLP-2 who are dependent on parenteral nutrition.

342. Shire-NPS and Takeda USA encouraged, instructed, and directed customers to infringe claim 11 of the '658 Patent. For example, Shire-NPS and Takeda USA distribute Gattex with a package insert indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. The package insert also reports that in clinical studies of Gattex, many patients presenting with colon-in-continuity. Takeda USA and Shire-NPS also jointly market Gattex on a website (www.gattexhcp.com) that includes information indicating that Gattex is intended for use in SBS patients including patients with colon-in-continuity, providing dosage information for such patients, and including step-by-step instructions for the administration of Gattex for such patients. Takeda USA and Shire-NPS

emphasize on the website that the majority of patients weaned off parenteral support were SBS patients presenting with colon-in-continuity.

343. Shire-NPS and Takeda USA encouraged, instructed, and directed this infringing use with full knowledge of the '658 Patent. Shire-NPS has known about the '658 Patent since it issued on May 15, 2018. Shire-NPS filed the application leading to issuance of the '658 Patent, prosecuted the application leading to the issuance of the patent, and was notified by the Patent Office when the '658 Patent issued. Takeda USA, on information and belief, has known about the '658 Patent since no later than January 8, 2019, by which time Takeda USA had completed diligence and closed on its acquisition of Shire plc.

344. Shire-NPS and Takeda USA have known that the administration of Gattex infringes claim 11 of the '658 Patent and have acted with the specific intent to cause their customers to infringe claim 11 of the '658 Patent. Shire-NPS listed the '658 Patent in the Orange Book with Use Code U-1320 ("Treatment of Adult Patients with Short Bowel Syndrome Who Are Dependent on Parenteral Support") and, with the knowledge and approval of Takeda USA, listed the pediatric extension in the Orange Book. By so listing the '658 Patent and pediatric extension in the Orange Book, Shire-NPS, with the knowledge and approval of Takeda USA, identifies the '658 Patent as "a patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug [Gattex] and that . . . claims a method of using such drug for which approval . . . has been granted" 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 U.S.C. § 355(c)(2). Shire-NPS also filed suit against Par Pharmaceuticals and alleged that Par Pharmaceuticals' manufacture, distribution, marketing, and sale of generic Gattex would induce

infringement of the '658 Patent. Takeda USA, in coordination with Shire-NPS, also lists the '658 Patent for Gattex on the Takeda USA website: www.takeda.com/en-us/patents.

345. Shire-NPS's and Takeda USA's infringement has been willful, deliberate, and intentional. Shire-NPS and Takeda USA have taken the above actions with full knowledge that Rigshospitalet owns all rights, title, and interests in the '658 Patent.

346. As a result of Shire-NPS's and Takeda USA's infringement of the '658 Patent, Rigshospitalet has suffered substantial damages, and will continue to suffer substantial damages, in an amount to be proven at trial.

COUNT XXIV
(Unjust Enrichment – Against Shire-NPS)

347. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–346 of this Complaint.

348. Rigshospitalet conferred a benefit on Shire-NPS by performing the Teduglutide Study, conceiving of the inventions described in the GLP-2 SBS Article, and sharing the GLP-2 SBS Article with Shire-NPS on a confidential basis and solely for publication in *Gut*.

349. Rigshospitalet devoted substantial time, money, and resources to performing the Teduglutide Study. For example, and without limitation, Rigshospitalet provided access to SBS patients, including SBS patients with colon-in-continuity; use of Rigshospitalet's facilities and equipment to perform the Teduglutide Study, expand the subjects to include SBS patients with colon-in-continuity, and analyze the clinical data; and access to and collaboration with Rigshospitalet doctors with expertise treating SBS patients including Drs. Mortensen and Jeppesen to perform the Teduglutide Study, analyze the data, and describe the results of the Teduglutide Study and analysis. Rigshospitalet provided clinical data resulting from the

Teduglutide Study to Shire-NPS and Shire-NPS used that clinical data to obtain FDA approval for Gattex.

350. Rigshospitalet, by and through Drs. Mortensen and Jeppesen, also conceived of treating SBS patients with colon-in-continuity with GLP-2 receptor agonists. This discovery was made by Drs. Mortensen and Jeppesen in the course of their employment by Rigshospitalet, using Rigshospitalet resources, and at Rigshospitalet's expense.

351. Rigshospitalet, by and through Drs. Mortensen and Jeppesen, also drafted and provided to Shire-NPS the draft GLP-2 SBS Article describing the treatment of SBS patients with colon-in-continuity with GLP-2 receptor agonists and including clinical data supporting that treatment. The GLP-2 SBS Article was drafted by Drs. Mortensen and Jeppesen in the course of their employment by Rigshospitalet, using Rigshospitalet resources, and at Rigshospitalet's expense. Rigshospitalet, by and through Drs. Mortensen and Jeppesen, provided the draft GLP-2 SBS Article to Shire-NPS on a confidential basis and solely for publication in the publicly available journal *Gut*. The GLP-2 SBS Article included clinical data supporting the treatment of SBS patients with colon-in-continuity and Shire-NPS used that clinical data to obtain FDA approval for Gattex and to substantially expand the treatments for which Gattex could be indicated and approved (*e.g.*, SBS patients with colon-in-continuity). Shire-NPS also misused the GLP-2 SBS Article to prosecute the GLP-2 Applications and Patents.

352. Shire-NPS recognized and appreciated the benefit conferred upon it by Rigshospitalet. For example, and without limitation, Shire-NPS used the clinical trial data provided by Rigshospitalet to obtain FDA approval for Gattex. The clinical data used by Shire-NPS included clinical data relating to the treatment of SBS patients with colon-in-continuity,

e.g., as disclosed in the draft GLP-2 SBS Article. The clinical data relating to the treatment of SBS patients with colon-in-continuity allowed Shire-NPS to expand the indication for Gattex to include SBS patients with colon-in-continuity.

353. Shire-NPS, recognizing the surprising invention made by Drs. Mortensen and Jeppesen, also filed the draft GLP-2 SBS Article with the Patent Office as a provisional patent application and has since obtained numerous GLP-2 Patents claiming priority to that provisional application — patents that it has listed in the Orange Book and on its website, and asserted in litigation to exclude generic competition.

354. Shire-NPS willfully, deliberately, in bad faith, and with an intent to deceive Rigshospitalet, Dr. Mortensen, and Dr. Jeppesen, withheld from them the fact that it had filed the GLP-2 SBS Article as a provisional patent application and continued to withhold that information from them. On information and belief, Shire-NPS did this because it recognized the massive potential financial gains associated with the inventions and did not want to share any of those gains with Rigshospitalet, Dr. Mortensen, or Dr. Jeppesen.

355. Shire-NPS willfully, deliberately, in bad faith, and with an intent to deceive the Patent Office, misrepresented both the ownership and the inventors of the inventions claimed in the '233 Application and the GLP-2 SBS Applications and Patents. On information and belief, Shire-NPS did this because it recognized the massive potential financial gains associated with the inventions and did not want to share any of those gains with Rigshospitalet, Dr. Mortensen, or Dr. Jeppesen.

356. Shire-NPS and its affiliates have earned more than \$2 billion in revenues on United States sales of Gattex while using the GLP-2 SBS Applications and Patents to block generics from entering the market. This revenue stream includes, without limitation, the

incremental benefit that Shire-NPS obtained by having the GLP-2 Patents and being able to continue to exclude generics as the alleged sole and exclusive owner of the GLP-2 Patents. For example, Shire-NPS has listed the GLP-2 SBS Patents in the Orange Book, filed suit against a generic manufacturer for infringing the GLP-2 SBS Patents, and used those patents to deter other generic manufacturers from developing generic teduglutide products and entering the market. All of these actions have allowed Shire-NPS to maintain monopoly pricing and earn substantial profits that it could not otherwise have earned.

357. It would be inequitable for Shire-NPS to retain this benefit under the circumstances and without compensating Rigshospitalet for the benefit conferred on Shire-NPS.

358. Rigshospitalet is entitled to compensation for the benefit conferred by it on Shire-NPS in an amount to be proven at trial and equitable relief.

COUNT XXIV
(Fraudulent Nondisclosure – Against Shire-NPS)

359. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–358 of this Complaint.

360. Shire-NPS was obligated to exercise reasonable care to disclose, and in fact had a legal duty to disclose, to Rigshospitalet — including employees Drs. Mortensen and Jeppesen — that Shire-NPS intended that patent protection be sought for the inventions described in the GLP-2 SBS Article and that it would not secretly file that article as the '233 Application with the Patent Office.

361. Shire-NPS had such a duty to disclose its intention that patent protection be sought based on, for example, the fact that Rigshospitalet employees Drs. Mortensen and Jeppesen were the inventors of the inventions described in the GLP-2 SBS Article, drafted the GLP-2 SBS Article, and provided the GLP-2 SBS Article to Shire-NPS on a confidential basis

and for the sole purpose of publishing the article in *Gut*. In addition, Shire-NPS also had such a duty to disclose its intention to Rigshospitalet and Dr. Mortenson because the Clinical Study Agreement provided that Rigshospitalet “shall own” the inventions; required that Shire-NPS notify Rigshospitalet if it believed that any proposed publications relating to the Teduglutide Study included inventions for which a patent application should be filed; and required that Shire-NPS “shall notify [Rigshospitalet] in writing if it wishes to file a patent application” claiming an invention disclosed to it by Rigshospitalet; and obligated Shire-NPS to give notice to Rigshospitalet if Shire-NPS “reasonably believes a patent application claiming an Invention (as such term i[s] defined in Section 8[] below) should be filed prior to” the publication of the GLP-2 SBS Article. (Sections 7, 8, Clinical Study Agreement.)

362. Shire-NPS deliberately and knowingly did not disclose, and affirmatively concealed, that it secretly filed the GLP-2 SBS Article with the Patent Office as the ’233 Application, and secretly continued to prosecute the GLP-2 SBS Applications and Patents.

363. Shire-NPS’s failure to disclose, and affirmative concealment of, its secret filing of the GLP-2 SBS Article with the Patent Office as the ’233 Application, and secret continuing prosecution of the GLP-2 SBS Applications and Patents, was material and significant.

364. Rigshospitalet relied on Shire-NPS’s non-disclosure of this information to its substantial detriment. For example, and without limitation, Rigshospitalet was not afforded recognition as the owner of the GLP-2 SBS patents, Rigshospitalet employees Drs. Mortensen and Jeppesen did not receive recognition as the true inventors of the GLP-2 SBS Applications and Patents, and Rigshospitalet was not paid any royalties by Shire-NPS for its use of the GLP-2 SBS Patents and Applications — including at a minimum the monies that Shire-NPS would have paid Rigshospitalet for the assignments and/or licenses necessary to ensure that Shire-NPS

had exclusive rights to the inventions and could exclude generics from competing against it in the market.

365. Rigshospitalet is entitled to monetary damages in an amount to be proven at trial and equitable relief.

COUNT XXVI
(Conversion – Against Shire-NPS)

366. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–365 of this Complaint.

367. Shire-NPS intentionally and wrongfully exercised dominion and control over the draft GLP-2 SBS Article (and the discoveries described therein) by taking it from Rigshospitalet, and Drs. Mortensen and Jeppesen, and secretly submitting it to Patent Office despite the fact that the article was provided to Shire-NPS on a confidential basis and solely for submission to *Gut* for purposes of publication to the medical community at large.

368. Rigshospitalet had an ownership interest in the draft GLP-2 SBS Article (and the discoveries described therein) because the article was drafted by Rigshospitalet employees Drs. Mortensen and Jeppesen in their capacity as Rigshospitalet employees, reported on data obtained in connection with the Teduglutide Study, and described the inventions of Rigshospitalet employees therein.

369. Rigshospitalet was damaged by Shire-NPS's conversion of the draft GLP-2 SBS Article and its submission to the Patent Office. Rigshospitalet's damages include, without limitation, revenues that it should have earned from Shire-NPS's licensing of the inventions described therein from Rigshospitalet.

370. Rigshospitalet is entitled to monetary damages in an amount to be proven at trial and equitable relief.

COUNT XXVII

(Unfair and Deceptive Trade Practices – Against Shire-NPS and Takeda USA)

371. Rigshospitalet incorporates by reference herein the allegations stated above in Paragraphs 1–370 of this Complaint.

372. Rigshospitalet, Shire-NPS, and Takeda USA engage in trade or commerce.

373. Shire-NPS and Takeda USA engaged in an unfair method of competition, *i.e.*, their conduct was unfair; was immoral, unethical, oppressive, and unscrupulous; and falls within established traditional, statutory, and common law concepts of unfairness.

374. For example, and without limitation, Shire-NPS and Takeda USA did not disclose and continued to not disclose that they had filed the '233 Application, had prosecuted GLP-2 SBS Applications and Patents, and were continuing to prosecute GLP-2 SBS Applications and Patents. All of the GLP-2 SBS Applications filed after 2018 identified Lexington, Massachusetts as the mailing address of applicant and assignee — Shire-NPS. Shire-NPS and Takeda USA's wrongful conduct therefore has primarily and substantially taken place within Massachusetts at least since at least 2018.

375. Shire-NPS and Takeda USA held the GLP-2 SBS Patents out as their own in the Orange Book and on their website, despite knowing that they do not own the patents, in order to keep generics out of the market and to continue to earn monopoly profits on Gattex. Shire-NPS and Takeda USA took, directed, and oversaw such wrongful acts from their Massachusetts headquarters.

376. Shire-NPS filed and maintained a patent infringement suit against Par Pharmaceuticals in 2018 from its Massachusetts headquarters, asserting the GLP-2 SBS Applications and Patents, in order to keep Par Pharmaceuticals out of the market. *Shire-NPS Pharmaceuticals, Inc. v. Par Pharmaceutical Companies, Inc. et al.*, Civil Action No. 1-18-cv-

01115, ECF No. 1 (Complaint) ¶ 2 (D. Del. July 28, 2018) (identifying “principal place of business [] located at 300 Shire Way, Lexington, Massachusetts 02421).

377. Shire-NPS and Takeda USA have for several years willfully and knowingly orchestrated this scheme and engaged in this misconduct from their Massachusetts headquarters. Since 2016, Shire-NPS has engaged in this misconduct primarily from its Massachusetts headquarters and reaped the benefits of the scheme at that headquarters. Since 2020, Takeda USA has engaged in this misconduct primarily from its Massachusetts headquarters and reaped the benefits of the scheme at that headquarters.

378. Shire-NPS’s and Takeda USA’s unfair and deceptive trade practices and competition have directly and proximately caused Rigshospitalet to suffer loss of money or property, including, without limitation, royalties that Rigshospitalet should have been earning on sales of Gattex.

379. Accordingly, Shire-NPS and Takeda USA have engaged in, and are continuing to engage in, unfair and deceptive trade practices in violation of Massachusetts General Law, c. 93A, §§ 1 *et seq.*

380. Rigshospitalet is entitled to monetary damages in an amount to be proven at trial, treble damages, attorneys’ fees and costs, and equitable relief.

PRAYER FOR RELIEF

WHEREFORE, Rigshospitalet respectfully prays that judgment be entered for Rigshospitalet and against Defendants, as follows:

- (a) Entry of judgment in Rigshospitalet’s favor on all claims;

(b) Entry of judgment declaring that Dr. Mortensen and Dr. Jeppesen are the sole and exclusive inventors of the '061 Patent and at least co-inventors of the inventions claimed in the other GLP-2 SBS Patents;

(c) Order the Patent Office to correct inventorship of the GLP-2 SBS Patents;

(d) Entry of judgment declaring that Rigshospitalet is the sole, exclusive, and rightful owner of all rights, title, and interests in the GLP-2 SBS Applications and Patents;

(e) Order Defendants to execute a confirmatory assignment transferring all rights, title, and interests in the GLP-2 SBS Applications and Patents to Rigshospitalet;

(f) Entry of judgment that Defendants have infringed, and are continuing to infringe, the GLP-2 SBS Patents and that their infringement has been, and continues to be, willful;

(g) Award Rigshospitalet monetary damages, including, without limitation, treble damages for Defendants' willful infringement, and knowing and willful violation of Mass. Gen. Laws. C. 93A §§ 1 *et seq.*;

(h) Entry of judgment that this case is exceptional under 35 U.S.C. § 285;

(i) Entry of an order awarding to Rigshospitalet its attorneys' fees, costs, and expenses incurred in prosecuting this action;

(j) Entry of a permanent injunction against Shire-NPS's and Takeda USA's manufacture, advertising, distribution, and sale of Gattex; and

(k) Such other and further relief, including equitable relief, as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Rigshospitalet requests a trial by jury of any issues so triable by right.

Dated: September 29, 2021

Respectfully submitted,

/s/ Anthony S. Fiotto

Anthony S. Fiotto (BBO# 558089)
MORRISON & FOERSTER LLP
John Hancock Tower
200 Clarendon Street, Floor 20
Boston, Massachusetts 02116
Telephone: 617.648.4700
Facsimile: 617.830.0142
Email: AFiotto@mofo.com

Counsel for Plaintiff Rigshospitalet

OF COUNSEL:

Michael A. Jacobs (*pro hac application to be filed*)
Richard S.J. Hung (*pro hac application to be filed*)
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105
Telephone: 415.268.7000
Facsimile: 415.268.7522
Email: MJacobs@mofo.com
RHung@mofo.com

Counsel for Plaintiff Rigshospitalet