

1. Plaintiff FICSA is a Swiss private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.
2. Plaintiff Ferring Pharma is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.
3. Plaintiff Ferring B.V. is a Dutch private limited liability company having its offices at Polaris Avenue 144, Hoofddorp, 2132 JX, Netherlands.

4. On information and belief, Defendant Novel is a domestic Delaware corporation having a principal place of business at 400 Campus Drive, Somerset, New Jersey 08873.

5. On information and belief, Defendant Gavis is a domestic Delaware limited liability company having a principal place of business at 400 Campus Drive, Somerset, New Jersey 08873.

### **JURISDICTION AND VENUE**

6. This action arises under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively.

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. This Court has personal jurisdiction over Novel.

9. On information and belief, Novel is in the business of, *inter alia*, developing, manufacturing, packaging, and obtaining regulatory approval for numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including this District.

10. On information and belief, Novel has extensive contacts with the State of Delaware. Novel is a domestic Delaware corporation, has appointed an agent in Delaware to receive service of process, has previously submitted to jurisdiction in this District, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g., Pfizer Inc. et al. v. Novel Laboratories, Inc.*, No. 11-cv-27 (D. Del.); *CIMA Labs, Inc. et al. v. Novel Laboratories, Inc.*, No. 08-cv-886 (D. Del.); *Salix Pharmaceuticals, Inc. et al. v. Novel Laboratories, Inc.*, No. 14-cv-213 (D. Del.) (now *Salix Pharmaceuticals, Inc. et al. v. G&W Laboratories, Inc.*).

11. This Court has personal jurisdiction over Gavis.

12. On information and belief, Gavis is in the business of, *inter alia*, marketing, distributing, and wholesaling pharmaceutical products for sale and use throughout the United States, including this District.

13. On information and belief, Gavis has extensive contacts with the State of Delaware. Gavis is a domestic Delaware limited liability company, has appointed an agent in Delaware to receive service of process, maintains an active Pharmacy-Wholesale license in Delaware (license number A4-0002387), and maintains an active Distributor/Manufacturer CSR (controlled substances) license in Delaware (license number DM-0012065),

14. On information and belief, Novel and Gavis were and are affiliates and operate as a coordinated entity. For example, the “ABOUT GAVIS” portion of the Gavis website includes a subheading for “NOVEL LABS” and states that “Together Novel Laboratories and GAVIS® Pharmaceuticals offer the complete package: formulation, development, manufacturing, packaging, sales, marketing, and distribution.” A true and correct copy of the referenced portion of the Gavis website is attached as Exhibit A. For further example, the “About Us” portion of the Novel website includes a subheading “Affiliates” and lists Gavis as an affiliated company. A true and correct copy of the referenced portion of the Novel website is attached as Exhibit B.

15. On information and belief, the management of Novel and Gavis are the same or substantially similar. The Gavis website lists the following individuals and titles on the “MANAGEMENT” subpage:

- a. Scott Talbot, Vice President, Quality Assurance and Regulatory Compliance
- b. Bala Nayar, Ph.D., Vice President, Specialty Product Development
- c. Prasad Uppalapati, Vice President, Operations

- d. James Geregnani, Director, Product Development
- e. Aman Trehan, Ph.D., Director, Intellectual Property

A true and correct copy of the referenced portion of the Gavis website is attached as Exhibit C.

16. The Novel website lists the same five individuals as part of the Novel management team. With the exception of James Geregnani, who is listed as “Senior Director, Product Development” on the Novel website, the titles of the individuals are the same. A true and correct copy of the “Leadership Team” subpage of the Novel website is attached as Exhibit D.

17. On information and belief, and based on the representations on their respective websites, Gavis is the marketing and distribution arm for the drug products developed and manufactured by Novel.

18. Venue is proper in this District under 28 U.S.C. § 1400(b) as both Novel and Gavis are domestic Delaware business entities and thus reside in Delaware.

### **NATURE OF THE ACTION**

19. This is an action for infringement of United States Patent Numbers 8,450,338 (“the ’338 patent”), 8,481,083 (“the ’083 patent”), and 9,669,110 (“the ’110 patent”) (collectively, the “patents in suit”) under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. This action involves Ferring’s drug product Prepopik<sup>®</sup>, indicated for cleansing of the colon as a preparation for colonoscopy in adults.

### **FERRING’S PREPOPIK<sup>®</sup> NDA**

20. Ferring Pharma is the holder of approved New Drug Application (“NDA”) No. 202535 for Prepopik<sup>®</sup> (sodium picosulfate, magnesium oxide and citric acid) for Oral Solution.

21. On July 16, 2012, the United States Food and Drug Administration (“FDA”) approved NDA No. 202535 for the manufacture, marketing, and sale of Prepopik<sup>®</sup> for cleansing of the colon as a preparation for colonoscopy in adults.

22. Ferring has sold Prepopik<sup>®</sup> under NDA No. 202535 since its approval.

### **THE PATENTS IN SUIT**

23. On May 28, 2013, the United States Patent and Trademark Office (“USPTO”) duly and legally issued the ’338 patent, which bears the title “Granular Compositions of Sodium Picosulfate and Potassium Bicarbonate and Uses Thereof” naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the ’338 patent is attached as Exhibit E.

24. Plaintiff FICSA is the owner by assignment of the ’338 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the ’338 patent.

25. On July 9, 2013, the USPTO duly and legally issued the ’083 patent, which bears the title “Granular Compositions of Magnesium Oxide and Citric Acid and Uses Thereof” naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the ’083 patent is attached as Exhibit F.

26. Plaintiff FICSA is the owner by assignment of the ’083 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the ’083 patent.

27. On June 6, 2017, the USPTO duly and legally issued the ’110 patent, which bears the title “Method for Timing a Colonoscopy” naming Raymond E. Joseph as inventor. A true and correct copy of the ’110 patent is attached as Exhibit G.

28. Plaintiff Ferring B.V. is the owner by assignment of the ’110 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the ’110 patent.

29. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '338 patent and the '083 patent are listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering Prepopik®.

**NOVEL'S PARAGRAPH IV NOTICE LETTER AND THE CURRENT CONTROVERSY**

30. Novel caused to be sent a letter from Alston & Bird LLP on behalf of Novel dated May 19, 2017 to Ferring Pharma, FICSA, and Ferring Pharms AS (the "Notice Letter") notifying Ferring that Novel had filed ANDA No. 210306 ("Novel's ANDA") seeking approval to commercially manufacture, use, or sell a generic version of Ferring's Prepopik® ("Novel's ANDA Product") prior to the expiration of the '338 patent and the '083 patent ("the Orange Book Listed patents"). The Notice Letter stated that Novel was providing information to Ferring "pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act ('the Act') and 21 C.F.R. §§ 314.94 and 314.95." Ferring Pharma and FICSA received the Notice Letter on May 22, 2017. Ferring Pharms AS does not exist.

31. As stated in the Notice Letter, Novel's ANDA contains certifications under 21 U.S.C. § 355(j)(2) indicating that, in Novel's opinion, the Orange Book Listed patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Novel's ANDA Product ("Paragraph IV Certifications").

32. Novel attached its "Detailed Factual and Legal Bases for Novel Laboratories, Inc.'s Paragraph IV Certifications that U.S. Patent Nos. 8,450,338 and 8,481,083 Are Invalid, Unenforceable, and/or Will Not Be Infringed" to the Notice Letter (the "Detailed Statement"). The Detailed Statement alleges that Novel's ANDA Product will not infringe the claims of the Orange Book Listed patents.

33. Ferring commenced this action within forty-five (45) days of receiving the Notice Letter.

34. There is an actual, real, immediate, and justiciable controversy between Ferring and Novel regarding whether Novel's ANDA Product will infringe the patents in suit.

### **COUNT I**

#### **Infringement of the '338 patent**

35. Ferring realleges paragraphs 1 to 34 and incorporates them by reference.

36. Novel's submission of Novel's ANDA to the FDA under § 505(j) of the Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Novel's ANDA Product before the expiration of the '338 patent was an act of infringement of the '338 patent under 35 U.S.C. § 271(e)(2).

37. Defendants' manufacture, use, sale, offer for sale in, or importation into the United States of Novel's ANDA Product prior to the expiration of the '338 patent, including any applicable exclusivities or extensions, will infringe, either literally or under the doctrine of equivalents, one or more claims of the '338 patent under 35 U.S.C. § 271(a).

38. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Novel's ANDA No. 210306 be a date that is not earlier than the expiration of the term of the '338 patent, including any extension(s) granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '338 patent to which Ferring is or becomes entitled.

39. There is an actual case or controversy between Ferring and Defendants regarding whether the process used to make Novel's ANDA Product infringes, either literally or under the doctrine of equivalents, claims 8 to 19 of the '338 patent.

40. Defendants have made, and will continue to make, substantial preparation to import into the United States, and/or to use, offer to sell, and/or sell within the United States Novel's ANDA Product, which is made by a process claimed in one more of claims 8 to 19 of the '338 patent, prior to the expiration of the '338 patent.

41. Defendants' importation into the United States, and/or use, offer to sell, and/or sale of Novel's ANDA Product within the United States will constitute infringement, either literally or under the doctrine of equivalents, of one or more of claims 8 to 19 of the '338 patent under 35 U.S.C. § 271(g).

42. Ferring is entitled to a declaratory judgment that Defendants' importation into the United States, and/or use, offer to sell, and/or sale of Novel's ANDA Product within the United States will constitute infringement, either literally or under the doctrine of equivalents, of one or more of claims 8 to 19 of the '338 patent under 35 U.S.C. § 271(g).

43. Ferring will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

## **COUNT II**

### **Infringement of the '083 patent**

44. Ferring realleges paragraphs 1 to 34 and incorporates them by reference.

45. Novel's submission of Novel's ANDA to the FDA under § 505(j) of the FDCA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Novel's ANDA Product before the expiration of the '083 patent was an act of infringement of the '083 patent under 35 U.S.C. § 271(e)(2).

46. Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Novel's ANDA Product, prior to the expiration of the '083 patent, including any



applicable exclusivities or extensions, will infringe, either literally or under the doctrine of equivalents, one or more claims of the '083 patent under 35 U.S.C. § 271(a).

47. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Novel's ANDA No. 210306 be a date that is not earlier than the expiration of the term of the '083 patent, including any extension(s) granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '083 patent to which Ferring is or becomes entitled.

48. Ferring will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

### **COUNT III**

#### **Declaratory Judgment of Infringement of the '110 patent**

49. Ferring realleges paragraphs 1 to 34 and incorporates them by reference.

50. Defendants have made, and will continue to make, substantial preparation to import into the United States, and/or to use, offer to sell, and/or sell within the United States Novel's ANDA Product.

51. Upon FDA approval of Novel's ANDA Product, Novel and/or Gavis will infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

52. On information and belief, after the FDA has approved Novel's ANDA No. 210306, Novel and/or Gavis intends to manufacture, market, sell, and offer to sell Novel's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Novel's ANDA Product.

53. There is an actual case or controversy between Ferring and Defendants regarding whether the use of Novel's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent and whether Novel and/or Gavis will induce others to infringe one or more claims of the '110 patent.

54. On information and belief, Novel and/or Gavis will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Novel and/or Gavis knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent by marketing Novel's ANDA Product with the FDA-approved product insert.

55. On information and belief, Novel and/or Gavis has knowledge of the '110 patent and knows that the use of Novel's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent.

56. Ferring will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, Ferring respectfully requests the following judgment and relief:

a. A declaration that the claims of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 are valid and enforceable;

b. A declaration that Novel's submission to the FDA of Novel's ANDA No. 210302 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Novel's ANDA Product before the expiration of United States Patent

Number 8,450,338 and United States Patent Number 8,481,083 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

c. A declaration that Defendants' manufacture, use, offer to sell, sale in, and/or importation into the United States of Novel's ANDA Product prior to the expiration of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 will infringe one or more claims of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 under 35 U.S.C. § 271;

d. An order that the effective date of the approval of Novel's ANDA No. 210306 be a date that is not earlier than the expiration of the term of United States Patent Number 8,450,338 and United States Patent Number 8,481,083, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Ferring is or becomes entitled;

e. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 prior to the expiration date of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110, and any additional dates of exclusivity;

f. A permanent injunction enjoining Defendants and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 210306 until the expiration date of

United States Patent Number 8,450,338 and United States Patent Number 8,481,083 and any additional dates of exclusivity;

g. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Novel's ANDA Product before the expiration of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110, and any additional dates of exclusivity;

h. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Ferring its reasonable attorneys' fees, costs, and expenses; and

i. Any and all other and further relief as this Court deems just and proper.

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