William P. Deni, Jr.
J. Brugh Lower
**GIBBONS P.C.**
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

*Attorneys for Plaintiffs*
*Bausch Health Ireland Limited*
*and Salix Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN LABORATORIES LTD.; AGILA SPECIALTIES INC.; MYLAN API US LLC; MYLAN INC.; VIATRIS INC.; and MYLAN PHARMACEUTICALS INC. — A VIATRIS COMPANY,<br><br>Defendants. | Civil Action No. 21-10403<br><br>*Document Electronically Filed* |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Plaintiffs") by way of Complaint against Defendants Mylan Laboratories Ltd., Agila Specialties Inc., Mylan API US LLC, Mylan Inc., Viatris Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company (collectively, "Defendants") allege as follows:

**THE PARTIES**

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business

Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principal place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 208745, which covers Trulance®.

3. Upon information and belief, Defendant Mylan Laboratories Ltd. is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Mylan Laboratories Ltd. is an agent and/or affiliate of Defendants Agila Specialties Inc., Mylan API US LLC, Mylan Inc., Viatris Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company.

4. Upon information and belief, Defendant Agila Specialties Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 201 South Main Street, Lambertville New Jersey 08530. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Agila Specialties Inc. is an agent and/or affiliate of Defendants Mylan Laboratories Ltd., Mylan API US LLC, Mylan Inc., Viatris Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company.

5. Upon information and belief, Defendant Mylan API US LLC is a corporation organized and existing under the laws of Delaware, having its principal place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Mylan API US LLC is an agent and/or affiliate of Defendants Mylan Laboratories Ltd., Agila Specialties, Inc., Mylan Inc., Viatris Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company.

6. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg Pennsylvania 15317. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Mylan Inc. is an agent and/or affiliate of Defendants Mylan Laboratories Ltd., Agila Specialties Inc, Mylan API US LLC, Viatris Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company.

7. Upon information and belief, Defendant Viatris Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg Pennsylvania 15317. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Viatris Inc. is an agent and/or affiliate of Defendants Mylan Laboratories Ltd., Agila Specialties Inc, Mylan API US LLC, Mylan Inc., and Mylan Pharmaceuticals Inc. — a Viatris Company.

8. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. — a Viatris Company is a corporation organized and existing under the laws of Delaware, having a place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg Pennsylvania 15317. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available SEC 10-K filings, Defendant Mylan Pharmaceuticals Inc. — a Viatris Company is an agent and/or affiliate of Defendants Mylan Laboratories Ltd., Agila Specialties Inc, Mylan API US LLC, Mylan Inc., and Viatris Inc.

## NATURE OF THE ACTION

9. This is an action for infringement of United States Patent Nos. 7,041,786 ("the '786 patent"), 7,799,897 ("the '897 patent"), 8,637,451 ("the '451 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231

patent") and 10,011,637 ("the '637 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market their generic plecanatide oral tablets, 3 mg ("Defendants' generic plecanatide oral tablets").

## JURISDICTION AND VENUE

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

11. Upon information and belief, this Court has jurisdiction over Defendant Mylan Laboratories Ltd. Upon information and belief, Mylan Laboratories Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Laboratories Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, Mylan Laboratories Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Laboratories Ltd. is registered to do business in this judicial district. Upon information and belief, Mylan Laboratories Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Mylan Laboratories Ltd. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and

belief, Mylan Laboratories Ltd. has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan Laboratories Ltd. has a place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Mylan Laboratories Ltd. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan Laboratories Ltd. has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

12. Upon information and belief, this Court has jurisdiction over Defendant Agila Specialties Inc. Upon information and belief, Agila Specialties Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Agila Specialties Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available press releases, Agila Specialties Inc. has prepared, has manufactured, has marketed, prepares, manufactures, markets, will prepare, will manufacture and/or will market peptide products for Defendants, including Defendants' generic plecanatide oral tablets. Upon information and belief, Agila Specialties Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Agila Specialties Inc. is incorporated in this judicial district and registered to do business in this judicial district. Upon information and belief, Agila Specialties Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Agila Specialties Inc. has its principal place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief,

Agila Specialties Ltd. has a place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Agila Specialties Ltd. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Agila Specialties Inc. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Agila Specialties Inc. has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

13. Upon information and belief, this Court has jurisdiction over Defendant Mylan API US LLC. Upon information and belief, Mylan API US LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan API US LLC directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available press releases, Mylan API US LLC has prepared, has manufactured, has marketed, prepares, manufactures, markets, will prepare, will manufacture and/or will market drug products for Defendants, including Defendants' generic plecanatide oral tablets. Upon information and belief, Mylan API US LLC purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan API US LLC is registered to do business in this judicial district. Upon information and belief, Mylan API US LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Mylan API US LLC has its principal place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Mylan API US LLC has a place of business at 201 South

Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan API US LLC has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Mylan API US LLC has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan API US LLC has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

14. Upon information and belief, this Court has jurisdiction over Defendant Mylan Inc. Upon information and belief, Mylan Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Inc. is registered to do business in this judicial district. Upon information and belief, Mylan Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Mylan Inc. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Mylan Inc. has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan Inc. has a place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Mylan Inc. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan Inc. has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

15. Upon information and belief, this Court has jurisdiction over Defendant Viatris Inc.

Upon information and belief, Viatris Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Viatris Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic plecanatide oral tablets. Upon information and belief, Viatris Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Viatris Inc. is registered to do business in this judicial district. Upon information and belief, Viatris Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Viatris Inc. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Viatris Inc. has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Viatris Inc. has a place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Viatris Inc. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Viatris Inc. has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

16. Upon information and belief, this Court has jurisdiction over Defendant Mylan Pharmaceuticals Inc. — a Viatris Company. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic

plecanatide oral tablets. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company is registered to do business in this judicial district. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other Cases initiated in this jurisdiction. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 45 Napoleon Court, Somerset, New Jersey 08873. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey.

17. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of their generic drugs—that will be purposefully directed at, upon information and belief, New Jersey and elsewhere. Defendants' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of their proposed generic drugs. Upon information and belief, Defendants intend to direct sales of their drugs into New Jersey, among other places, once they have the requested FDA approval to market them. Upon information and belief, Defendants will engage in marketing of Defendants' generic plecanatide oral tablets in New Jersey upon approval of their ANDA.

18. One or more of Defendants availed themselves of the rights, benefits, and privileges of this Court by filing at least the following civil actions in the District of New Jersey: *Mylan Specialty L.P. v. Aurobindo Pharma USA Inc.*, Case No. 3:18-cv-15190; *Mylan Technologies Inc. et al. v. Novartis Pharmaceuticals Corporation*, Case No. 2:18-cv-12022; *Mylan Technologies Inc. et al. v. Novartis Pharmaceuticals Corporation*, Case No. 2:18-cv-09140; *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*, Case No. 2:14-cv-02094; *Mylan Inc. et al. v. Apotex Inc. et al.*, Case No. 3:14-cv-04560; *Mylan Inc. et al. v. SmithKline Beecham Corporation et al.*, Case No. 3:10-cv-04809.

19. One or more of Defendants availed themselves of the rights, benefits, and privileges of this Court by filing a motion to intervene in at least the following case in the District of New Jersey: *AstraZeneca Pharmaceuticals LP et al. v. Sagent Pharmaceuticals Inc. et al.*, Case No. 1:14-cv-03547.

20. One or more of Defendants availed themselves of the rights, benefits, and privileges of this Court by filing an *amicus curiae* motion in at least the following case in the District of New Jersey: *Pfizer Inc. et al. v. Teva Pharmaceuticals USA Inc.*, Case No. 2:08-cv-01331.

21. One or more of Defendants consented to or did not contest the jurisdiction of this Court by way of motion in at least the following District of New Jersey actions: *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:20-cv-13103; *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 2:19-cv-16484; *Vifor (International) AG et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:19-cv-13955; *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:17-cv-06714; *Otsuka Pharmaceutical Co., Ltd. v. Mylan NV et al.*, Case No. 1:17-cv-00392; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:16-cv-04921; *AstraZeneca*

*Pharmaceuticals LP et al. v. Mylan Institutional LLC et al.*, Case No. 1:16-cv-04612; *Senju Pharmaceutical Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.*, Case No. 1:16-cv-01361; *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-00035; *Valeant Pharmaceuticals International, Inc., et al. v. Mylan Pharmaceuticals, Inc. et al.*, Case No. 2:15-cv-8180; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:15-cv-07009; *AstraZeneca Pharmaceuticals LP et al. v. Agila Specialties, Inc. et al.*, Case No. 1:15-cv-06039; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:15-cv-03327; *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 3:14-cv-07811; *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-07094; *Cadence Pharmaceuticals, Inc. et al. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-08000; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:13-cv-06560; *Aptalis Pharma US Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-04158; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals et al.*, Case No. 2:13-cv-04022; *Insite Vision Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-03720; *In re Certain Consolidated Zoledronic Acid Cases*, Case No. 2:12-cv-03967; *Janssen Products L.P. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:12-cv-03569; *Shire LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:12-cv-03234; *AstraZeneca AB et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:12-cv-01378; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:11-cv-06844; *Alkermes Pharma Ireland Limited et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04967; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04966; *Tibotec Inc. et al. v. Lupin Limited et al.*, Case No. 2:11-cv-04437; *Orexo AB v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:11-cv-03788; *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Case No. 2:11-cv-03781; *Warner*

*Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:11-cv-03262; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals, Inc., et al.*, Case No. 3:11-cv-02483; *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-06018; *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Case No. 2:10-cv-05954; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:10-cv-05519; *Teva Neuroscience, Inc. et al. v. Watson Pharma, Inc. et al.*, Case No. 2:10-cv-05078; *Pfizer Inc. et al. v. Mylan Inc. et al.*, Case No. 2:10-cv-03246; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-02073; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:10-cv-01235; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-01234; *Novartis AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:09-cv-03604; *Warner Chilcott Laboratories Ireland Ltd. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:09-cv-02073; *Sunovion Pharmaceuticals Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:09-cv-01302; *Warner Chilcott Laboratories Ireland Ltd. et al. v. Impax Laboratories, Inc. et al.*, Case No. 2:08-cv-06304; *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:08-cv-05042; *Daiichi Sankyo Company, Ltd. et al. v. Matrix Laboratories, Ltd. et al.*, Case No. 2:08-cv-02752; *Aventis Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 2:07-cv-05054; *Sepracor Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 3:07-cv-05017; *Novartis Corporation et al. v. Mylan Laboratories Inc. et al.*, Case No. 2:07-cv-04918; *Hoffmann-La Roche Inc. et al. v. GenPharm Inc. et al.*, Case No. 2:07-cv-04661; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:07-cv-03039; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-05166; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:06-cv-03462; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-

00757; *Aventis Pharmaceuticals Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:05-cv-04255; *Eisai Co. Ltd. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:05-cv-01112; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-02305; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:04-cv-01689; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-01077; *Janssen Pharmaceutica N.V. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-06220; *Cephalon Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-01394; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:03-cv-01179; and *Schering Corporation v. Mylan Pharmaceuticals Inc.*, Case No. 2:00-cv-01657.

22. One or more of Defendants availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:20-cv-13103; *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 2:19-cv-16484; *Vifor (International) AG et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:19-cv-13955; *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105; *Horizon Pharma Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-04921; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Institutional LLC* Case No. 1:16-cv-04612; *Senju Pharmaceutical Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.*, Case No. 1:16-cv-01361; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:15-cv-07009; *AstraZeneca Pharmaceuticals LP et al. v. Agila Specialties, Inc. et al.*, Case No. 1:15-cv-06039; *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm. Co., Ltd. et al.*, Case No. 3:15-cv-05982; *BTG International Limited v. Amneal Pharmaceuticals LLC et al.*, Case No. 2:15-cv-5909; *AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:15-cv-03384; *Horizon*

*Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:15-cv-03327; *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA Inc.. et al.*, Case No. 3:14-cv-07811; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-07094; *Janssen Products L.P. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:14-cv-04550; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:13-cv-06560; *Aptalis Pharma US Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-04158; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:13-cv-04022; *Insite Vision Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-03720; *In re Certain Consolidated Zoledronic Acid Cases*, Case No. 2:12-cv-03967; *Janssen Products L.P. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:12-cv-03569; *Shire LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:12-cv-03234; *AstraZeneca AB et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:12-cv-01378; *Shire LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:12-cv-00638; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:11-cv-06844; *Alkermes Pharma Ireland Limited et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04967; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04966; *Tibotec Inc et al. v. Lupin Limited et al.*, Case No. 2:11-cv-04437; *Orexo AB v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:11-cv-03788; *Shire LLC et al. v. Amneal Pharmaceuticals, LLC*, Case No. 2:11-cv-03781; *Warner Chilcott Company v. Mylan Inc. et al.*, Case No. 3:11-cv-03262; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:11-cv-02483; *Ortho-McNeil-Janssen Pharmaceuticals Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-06018; *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Case No. 2:10-cv-05954; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:10-cv-05519; *Teva Neuroscience, Inc. v. Watson Pharma, Inc. et al.*, Case No. 2:10-cv-05078; *Pfizer*

*Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-03246; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-02073; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:10-cv-01235; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-01234; *Novartis AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:09-cv-03604; *Warner Chilcott Laboratories Ireland Ltd. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:09-cv-02073; *Hoffmann-La Roche Inc. v. Mylan Inc. et al.*, Case No. 2:09-cv-01692; *Sunovion Pharmaceuticals Inc v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:09-cv-01302; *Warner Chilcott Laboratories Ireland Ltd. v. Impax Laboratories, Inc. et al.*, Case No. 2:08-cv-06304; *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:08-cv-05042; *Daiichi Sankyo Company, Ltd. et al. v. Matrix Laboratories, Ltd. et al.*, Case No. 2:08-cv-02752; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:07-cv-05054; *Sepracor Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 3:07-cv-05017; *Novartis Corporation et al. v. Mylan Laboratories Inc. et al.*, Case No. 2:07-cv-04918; *Hoffmann-La Roche Inc. v. GenPharm Inc. et al.*, Case No. 2:07-cv-04661; *Teva Pharmaceutical Industries Ltd. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:07-cv-04214; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:07-cv-03039; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-05166; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:06-cv-03462; *Novartis Pharmaceuticals Corp. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:06-cv-02885; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-00757; *Aventis Pharmaceuticals Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:05-cv-04255; *Eisai Co. Ltd. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:05-cv-01112; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-02305; *Ortho-*

*McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:04-cv-01689; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-01077; *Janssen Pharmaceutica N.V. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-06220; *Cephalon Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-01394; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:03-cv-01179; *Organon Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:01-cv-02171; and *Schering Corporation v. Mylan Pharmaceuticals Inc.*, Case No. 2:00-cv-01657.

23. Upon information and belief, including, based on, *inter alia*, Defendants' website, Defendants' publicly-available SEC 10-K filings and Defendants' publicly-available press releases, Defendants operate as a single integrated business. Upon information and belief, each Defendant acts as an agent of each other, and Defendants work together to, inter alia, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

24. Defendants know or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, New Jersey 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

25. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

26. Venue is proper against Defendant Mylan Laboratories Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

27. Venue is proper against Defendant Agila Specialties Inc. because it operates a principal place of business in this judicial district.

28. Venue is proper against Defendant Mylan API US LLC because it operates a principal place of business in this judicial district.

29. Venue is proper against Defendant Mylan Inc. because it has committed acts of infringement and has a regular and established place of business in this judicial district. Upon information and belief, Mylan Inc. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Mylan Inc. has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan Inc. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan Inc. has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey. Upon information and belief, Mylan Inc., *inter alia*, developed and/or otherwise contributed to the development and/or filing of Defendants' ANDA for Defendants' generic plecanatide oral tablets in this judicial district. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available press releases, Defendants have prepared, have developed, have manufactured, have marketed, prepare, develop, manufacture, market, will prepare, will develop, will manufacture and/or will market peptide products, including Defendants' generic plecanatide oral tablets, in this judicial district.

30. Venue is proper against Defendant Viatris Inc. because it has committed acts of infringement and has a regular and established place of business in this judicial district. Upon information and belief, Viatris Inc. has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Viatris Inc. has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Viatris Inc. has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Viatris Inc. has publicly touted its New Jersey presence at

https://mylanbetterhealth.com/en/us/new-jersey. Upon information and belief, Defendant Viatris Inc., *inter alia*, developed and/or otherwise contributed to the development and/or filing of Defendants' ANDA for Defendants' generic plecanatide oral tablets in this judicial district. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available press releases, Defendants have prepared, have developed, have manufactured, have marketed, prepare, develop, manufacture, market, will prepare, will develop, will manufacture and/or will market peptide products, including Defendants' generic plecanatide oral tablets, in this judicial district.

31. Venue is proper against Defendant Mylan Pharmaceuticals Inc. — a Viatris Company because it has committed acts of infringement and has a regular and established place of business in this judicial district. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 100 Route 206 N, Peapack, New Jersey 07977. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 201 South Main Street, Lambertville, New Jersey 08530. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has a place of business at 110 Allen Rd., Basking Ridge, New Jersey 07920. Upon information and belief, Mylan Pharmaceuticals Inc. — a Viatris Company has publicly touted its New Jersey presence at https://mylanbetterhealth.com/en/us/new-jersey. Upon information and belief, including, based on, *inter alia*, Defendants' website, Defendants' reference to "Mylan Pharmaceuticals Inc." as "a Viatris Company," and Defendants' publicly-available prior press releases stating that Defendants are terminating operations in West Virginia, Mylan Pharmaceuticals Inc. — a Viatris Company has no legally cognizable incorporation status and/or place of business in West Virginia. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. — a Viatris Company, *inter alia*, developed and/or otherwise contributed to the development and/or filing of Defendants' ANDA for Defendants'

generic plecanatide oral tablets in this judicial district. Upon information and belief, including, based on, *inter alia*, Defendants' publicly-available press releases, Defendants have prepared, have developed, have manufactured, have marketed, prepare, develop, manufacture, market, will prepare, will develop, will manufacture and/or will market peptide products, including Defendants' generic plecanatide oral tablets, in this judicial district.

32. One or more Defendants invoked the venue of this Court by filing at least the following civil actions in the District of New Jersey: *Mylan Specialty L.P. v. Aurobindo Pharma USA Inc.*, Case No. 3:18-cv-15190; *Mylan Pharmaceuticals, Inc., et al. v. Novartis Pharmaceuticals Corporation*, Case No. 2:18-cv-12022; *Mylan Technologies Inc. et al. v. Novartis Pharmaceuticals Corporation*, Case No. 2:18-cv-09140; *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*, Case No. 2:14-cv-02094; *Mylan Inc. et al. v. Apotex Inc. et al.*, Case No. 3:14-cv-04560; *Mylan Inc. et al. v. SmithKline Beecham Corporation et al.*, Case No. 3:10-cv-04809.

33. One or more Defendants invoked the venue of this Court by filing a motion to intervene in at least the following case in the District of New Jersey: *AstraZeneca Pharmaceuticals L.P. et al. v. Sagent Pharmaceuticals Inc. et al.*, Case No. 1:14-cv-03547.

34. One or more Defendants invoked the venue of this Court by filing an *amicus curiae* motion in at least the following case in the District of New Jersey: *Pfizer Inc. et al. v. Teva Pharmaceuticals USA Inc. et al.*, Case No. 2:08-cv-01331.

35. One or more Defendants consented to or did not contest venue in this Court by way of motion in at least the following District of New Jersey actions: *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:20-cv-13103; *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 2:19-cv-16484; *Vifor (International) AG et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:19-cv-13955; *Valeant Pharmaceuticals International,*

*Inc. et al. v. Mylan Pharmaceuticals Inc. et al*., Case No. 2:17-cv-06714; *Otsuka Pharmaceutical Co., Ltd. v. Mylan NV et al.*, Case No. 1:17-cv-00392; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-04921; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Institutional LLC et al.*, Case No. 1:16-cv-04612; *Senju Pharmaceutical Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.*, Case No. 1:16-cv-01361; *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals Inc. et al*., Case No. 2:16-cv-00035; *Valeant Pharmaceuticals International, Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.*, Case No. 2:15-cv-8180; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:15-cv-07009; *AstraZeneca Pharmaceuticals LP et al. v. Agila Specialties, Inc. et al.*, Case No. 1:15-cv-06039; *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:15-cv-03327; *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA Inc.. et al.*, Case No. 3:14-cv-07811; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-07094; *Cadence Pharmaceuticals Inc. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-08000; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:13-cv-06560; *Aptalis Pharma US Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-04158; *Horizon Pharma, Inc. v. Mylan Pharmaceuticals et al.*, Case No. 2:13-cv-04022; *Insite Vision Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-03720; *In re Certain Consolidated Zoledronic Acid Cases*, Case No. 2:12-cv-03967; *Janssen Products L.P. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:12-cv-03569; *Shire LLC et al. v. Mylan Pharmaceuticals, Inc. et al.*, Case No. 2:12-cv-03234; *AstraZeneca AB et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:12-cv-01378; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:11-cv-06844; *Alkermes Pharma Ireland Limited et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04967; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et*

*al.*, Case No. 2:11-cv-04966; *Tibotec Inc. v. Lupin Limited et al.*, Case No. 2:11-cv-04437; *Orexo AB v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:11-cv-03788; *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Case No. 2:11-cv-03781; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:11-cv-03262; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:11-cv-02483; *Ortho-McNeil-Janssen Pharmaceuticals Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-06018; *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Case No. 2:10-cv-05954; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:10-cv-05519; *Teva Neuroscience, Inc. v. Watson Pharma, Inc. et al.*, Case No. 2:10-cv-05078; *Pfizer Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-03246; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-02073; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:10-cv-01235; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-01234; *Novartis AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:09-cv-03604; *Warner Chilcott Laboratories Ireland Ltd. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:09-cv-02073; *Sunovion Pharmaceuticals Inc v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:09-cv-01302; *Warner Chilcott Laboratories Ireland Ltd. v. Impax Laboratories, Inc. et al.*, Case No. 2:08-cv-06304; *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:08-cv-05042; *Daiichi Sankyo Company, Ltd. et al. v. Matrix Laboratories, Ltd. et al.*, Case No. 2:08-cv-02752; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:07-cv-05054; *Sepracor Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 3:07-cv-05017; *Novartis Corporation et al. v. Mylan Laboratories Inc. et al.*, Case No. 2:07-cv-04918; *Hoffmann-La Roche Inc. v. GenPharm Inc. et al.*, Case No. 2:07-cv-04661; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:07-cv-03039; *Ortho-McNeil Pharmaceutical Inc. v.*

*Mylan Laboratories Inc. et al*, Case No. 2:06-cv-05166; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:06-cv-03462; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-00757; *Aventis Pharmaceuticals Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:05-cv-04255; *Eisai Co. Ltd. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:05-cv-01112; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-02305; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:04-cv-01689; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-01077; *Janssen Pharmaceutica N.V. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-06220; *Cephalon Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-01394; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:03-cv-01179; and *Schering Corporation v. Mylan Pharmaceuticals Inc.*, Case No. 2:00-cv-01657.

36. One or more Defendants invoked the venue of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:20-cv-13103; *Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd. et al.*, Case No. 2:19-cv-16484; *Vifor (International) AG et al. v. Mylan Laboratories Ltd. et al.*, Case No. 3:19-cv-13955; *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105; *Horizon Pharma Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-04921; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Institutional LLC et al.*, Case No. 1:16-cv-04612; *Senju Pharmaceutical Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.*, Case No. 1:16-cv-01361; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 1:15-cv-07009; *AstraZeneca Pharmaceuticals LP et al. v. Agila Specialties, Inc. et al.*, Case No. 1:15-cv-06039; *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC*

*Pharm. Co., Ltd. et al.*, Case No. 3:15-cv-05982; *BTG International Limited v. Amneal Pharmaceuticals LLC et al.*, Case No. 2:15-cv-5909; *AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:15-cv-03384; *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:15-cv-03327; *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA Inc.. et al.*, Case No. 3:14-cv-07811; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Case No. 1:14-cv-07094; *Janssen Products L.P. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:14-cv-04550; *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, Case No. 3:13-cv-06560; *Aptalis Pharma US Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-04158; *Horizon Pharma Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:13-cv-04022; *Insite Vision Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:13-cv-03720; *In re Certain Consolidated Zoledronic Acid Cases*, Case No. 2:12-cv-03967; *Janssen Products L.P. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:12-cv-03569; *Shire LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:12-cv-03234; *AstraZeneca AB v. Mylan Laboratories Ltd. et al.*, Case No. 3:12-cv-01378; *Shire LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:12-cv-00638; *Warner Chilcott Company v. Mylan Inc. et al.*, Case No. 3:11-cv-06844; *Alkermes Pharma Ireland Limited et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04967; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:11-cv-04966; *Tibotec Inc. v. Lupin Limited et al.*, Case No. 2:11-cv-04437; *Orexo AB v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:11-cv-03788; *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Case No. 2:11-cv-03781; *Warner Chilcott Company v. Mylan Inc. et al.*, Case No. 3:11-cv-03262; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:11-cv-02483; *Janssen Pharmaceuticals Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-06018; *Janssen Products, L.P., et al. v. Lupin Limited, et al.*,

Case No. 2:10-cv-05954; *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Case No. 3:10-cv-05519; *Teva Neuroscience, Inc. v. Watson Pharma, Inc. et al.*, Case No. 2:10-cv-05078; *Pfizer Inc. v. Mylan Inc. et al.*, Case No. 2:10-cv-03246; *Abbott Laboratories et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-02073; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:10-cv-01235; *Teva Women's Health, Inc. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:10-cv-01234; *Novartis AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:09-cv-03604; *Warner Chilcott Laboratories Ireland Ltd. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:09-cv-02073; *Hoffmann-La Roche Inc. v. Mylan Inc. et al.*, Case No. 2:09-cv-01692; *Sunovion Pharmaceuticals Inc v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:09-cv-01302; *Warner Chilcott Laboratories Ireland Ltd. v. Impax Laboratories, Inc. et al.*, Case No. 2:08-cv-06304; *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:08-cv-05042; *Daiichi Sankyo Company, Ltd. et al. v. Matrix Laboratories, Ltd. et al.*, Case No. 2:08-cv-02752; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:07-cv-05054; *Sepracor Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 3:07-cv-05017; *Novartis Corporation et al. v. Mylan Laboratories Inc. et al.*, Case No. 2:07-cv-04918; *Hoffmann-La Roche Inc. v. GenPharm Inc. et al.*, Case No. 2:07-cv-04661; *Teva Pharmaceutical Industries Ltd. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:07-cv-04214; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:07-cv-03039; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-05166; *Daiichi Sankyo Company, Ltd. et al. v. Mylan Pharmaceuticals Inc.. et al.*, Case No. 2:06-cv-03462; *Novartis Pharmaceuticals Corp. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 3:06-cv-02885; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:06-cv-00757; *Aventis Pharmaceuticals Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:05-cv-04255; *Eisai*

*Co. Ltd. v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 2:05-cv-01112; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-02305; *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. et al*, Case No. 2:04-cv-01689; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:04-cv-01077; *Janssen Pharmaceutica N.V. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-06220; *Cephalon Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 2:03-cv-01394; *Aventis Pharmaceuticals, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 2:03-cv-01179; *Organon Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 2:01-cv-02171; and *Schering Corporation v. Mylan Pharmaceuticals Inc.*, Case No. 2:00-cv-01657.

**THE PATENTS IN SUIT**

37. The U.S. Patent and Trademark Office ("PTO") issued the '786 patent on May 9, 2006. The '786 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the '786 patent and have the right to sue for infringement thereof. A copy of the '786 patent is attached hereto as Exhibit A.

38. The PTO issued the '897 patent on September 21, 2010. The '897 patent claims, *inter alia*, peptides and compositions of peptides. Plaintiffs hold all substantial rights in the '897 patent and have the right to sue for infringement thereof. A copy of the '897 patent is attached hereto as Exhibit B.

39. The PTO issued the '451 patent on January 28, 2014. The '451 patent claims, *inter alia*, methods for stimulating water transport in the gastrointestinal tract. Plaintiffs hold all substantial rights in the '451 patent and have the right to sue for infringement thereof. A copy of the '451 patent is attached hereto as Exhibit C.

40. The PTO issued the '321 patent on April 4, 2017. The '321 patent claims, *inter*

*alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the ’321 patent and have the right to sue for infringement thereof. A copy of the ’321 patent is attached hereto as Exhibit D.

41. The PTO issued the ’097 patent on April 11, 2017. The ’097 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the ’097 patent and have the right to sue for infringement thereof. A copy of the ’097 patent is attached hereto as Exhibit E.

42. The PTO issued the ’024 patent on March 20, 2018. The ’024 patent claims, *inter alia*, methods for treating chronic constipation and methods of treating or alleviating a symptom associated with chronic idiopathic constipation or irritable bowel syndrome. Plaintiffs hold all substantial rights in the ’024 patent and have the right to sue for infringement thereof. A copy of the ’024 patent is attached hereto as Exhibit F.

43. The PTO issued the ’231 patent on March 27, 2018. The ’231 patent claims, *inter alia*, oral dosage formulations of a Guanylate Cyclase-C agonist peptide. Plaintiffs hold all substantial rights in the ’231 patent and have the right to sue for infringement thereof. A copy of the ’231 patent is attached hereto as Exhibit G.

44. The PTO issued the ’637 patent on July 3, 2018. The ’637 patent claims, *inter alia*, purified peptides and processes of purifying peptides. Plaintiffs hold all substantial rights in the ’637 patent and have the right to sue for infringement thereof. A copy of the ’637 patent is attached hereto as Exhibit H.

45. Salix is the holder of NDA No. 208745 for Trulance®, which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the ’786, ’897, ’451, ’321, ’097, ’024,

'231 and '637 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

46. Plecanatide oral tablets, 3mg, are sold in the United States under the trademark Trulance®.

**DEFENDANTS' INFRINGING ANDA SUBMISSION**

47. Upon information and belief, Defendants filed or caused to be filed with the FDA ANDA No. 215686, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

48. Upon information and belief, Defendants' ANDA No. 215686 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Defendants' generic plecanatide oral tablets, intended to be generic versions of Trulance®.

49. Plaintiffs received a letter dated March 18, 2021, purporting to be a Notice of ANDA No. 215686 with Paragraph IV Certifications ("Defendants' Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Defendants' Notice Letter was addressed to Salix and Bausch.

50. Upon information and belief, Defendants acted in concert to prepare and submit Defendants' ANDA No. 215686 and Defendants' Notice Letter.

51. Defendants' Notice Letter alleges that ANDA No. 215686 has been submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Defendants' generic plecanatide oral tablets, intended to be generic versions of Trulance®.

52. Defendants' Notice Letter states that Defendants' ANDA No. 215686 "contains any required bioavailability or bioequivalence data or information," for Defendants' generic plecanatide oral tablets.

53. Defendants' notice letter, which is required by statute and regulation to provide a

full and detailed explanation regarding any non-infringement defense, provides no explanation of any non-infringement defense related to the ’786 patent, the ’897 patent, the ’451 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent or the ’637 patent.

54. Upon information and belief, ANDA No. 215686 seeks approval of Defendants’ generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

**COUNT I FOR PATENT INFRINGEMENT**

**Infringement of the ’786 Patent Under § 271(e)(2)**

55. Paragraphs 1–54 are incorporated herein as set forth above.

56. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’786 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the expiration date of the ’786 patent.

57. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’786 patent.

58. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’786 patent.

59. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’786 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT II FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the ’786 Patent**

60. Paragraphs 1–59 are incorporated herein as set forth above.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

63. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '786 patent, including Defendants' filing of ANDA No. 215686.

64. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '786 patent.

65. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '786 patent.

**COUNT III FOR PATENT INFRINGEMENT**

**Infringement of the '897 Patent Under § 271(e)(2)**

66. Paragraphs 1–65 are incorporated herein as set forth above.

67. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '897 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '897 patent.

68. Upon information and belief, Defendants' generic plecanatide oral tablets will, if

approved and marketed, infringe at least one claim of the ’897 patent.

69. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’897 patent.

70. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’897 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT IV FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the ’897 Patent**

71. Paragraphs 1–70 are incorporated herein as set forth above.

72. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

74. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’897 patent, including Defendants’ filing of ANDA No. 215686.

75. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’897 patent.

76. Plaintiffs are entitled to a declaratory judgment that future commercial

manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '897 patent.

**COUNT V FOR PATENT INFRINGEMENT**

**Infringement of the '451 Patent Under § 271(e)(2)**

77. Paragraphs 1–76 are incorporated herein as set forth above.

78. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '451 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '451 patent.

79. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '451 patent.

80. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '451 patent.

81. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '451 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT VI FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the '451 Patent**

82. Paragraphs 1–81 are incorporated herein as set forth above.

83. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

84. There is an actual case or controversy such that the Court may entertain Plaintiffs'

request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

85. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '451 patent, including Defendants' filing of ANDA No. 215686.

86. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '451 patent.

87. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '451 patent.

## COUNT VII FOR PATENT INFRINGEMENT

### Infringement of the '321 Patent Under § 271(e)(2)

88. Paragraphs 1–87 are incorporated herein as set forth above.

89. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '321 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '321 patent.

90. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '321 patent.

91. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe,

contributorily infringe, and/or induce infringement of at least one claim of the ’321 patent.

92. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’321 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT VIII FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the ’321 Patent**

93. Paragraphs 1–92 are incorporated herein as set forth above.

94. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

95. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

96. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’321 patent, including Defendants’ filing of ANDA No. 215686.

97. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’321 patent.

98. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’321 patent.

**COUNT IX FOR PATENT INFRINGEMENT**

**Infringement of the ’097 Patent Under § 271(e)(2)**

99. Paragraphs 1–98 are incorporated herein as set forth above.

100. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’097 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants’ generic plecanatide oral tablets before the expiration date of the ’097 patent.

101. Upon information and belief, Defendants’ generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the ’097 patent.

102. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’097 patent.

103. If Defendants’ marketing and sale of Defendants’ generic plecanatide oral tablets prior to the expiration of the ’097 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT X FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the ’097 Patent**

104. Paragraphs 1–103 are incorporated herein as set forth above.

105. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

106. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

107. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '097 patent, including Defendants' filing of ANDA No. 215686.

108. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '097 patent.

109. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '097 patent.

**COUNT XI FOR PATENT INFRINGEMENT**

**Infringement of the '024 Patent Under § 271(e)(2)**

110. Paragraphs 1–109 are incorporated herein as set forth above.

111. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '024 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '024 patent.

112. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '024 patent.

113. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '024 patent.

114. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets

prior to the expiration of the ’024 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT XII FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the ’024 Patent**

115. Paragraphs 1–114 are incorporated herein as set forth above.

116. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

117. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

118. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’024 patent, including Defendants’ filing of ANDA No. 215686.

119. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’024 patent.

120. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’024 patent.

**COUNT XIII FOR PATENT INFRINGEMENT**

**Infringement of the ’231 Patent Under § 271(e)(2)**

121. Paragraphs 1–120 are incorporated herein as set forth above.

122. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '231 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '231 patent.

123. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '231 patent.

124. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.

125. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '231 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

**COUNT XIV FOR PATENT INFRINGEMENT**

**Declaratory Judgment of Infringement of the '231 Patent**

126. Paragraphs 1–125 are incorporated herein as set forth above.

127. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

128. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

129. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic plecanatide oral tablets before the expiration date of the '231 patent, including Defendants' filing of ANDA

No. 215686.

130. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '231 patent.

131. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic plecanatide oral tablets will constitute infringement of at least one claim of the '231 patent.

**COUNT XV FOR PATENT INFRINGEMENT**

**Infringement of the '637 Patent Under § 271(e)(2)**

132. Paragraphs 1–131 are incorporated herein as set forth above.

133. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '637 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215686 seeking approval for the commercial marketing of Defendants' generic plecanatide oral tablets before the expiration date of the '637 patent.

134. Upon information and belief, Defendants' generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '637 patent.

135. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '637 patent.

136. If Defendants' marketing and sale of Defendants' generic plecanatide oral tablets prior to the expiration of the '637 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## COUNT XVI FOR PATENT INFRINGEMENT

### Declaratory Judgment of Infringement of the ’637 Patent

137. Paragraphs 1–136 are incorporated herein as set forth above.

138. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

139. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

140. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants’ generic plecanatide oral tablets before the expiration date of the ’637 patent, including Defendants’ filing of ANDA No. 215686.

141. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’637 patent.

142. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants’ generic plecanatide oral tablets will constitute infringement of at least one claim of the ’637 patent.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at

least one claim of the ’786 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’786 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’897 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’897 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’451 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’451 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’321 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’321 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’097 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the

’097 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’024 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’024 patent;

7. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’231 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’231 patent;

8. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’637 patent by submitting or causing to be submitted ANDA No. 215686 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants’ generic plecanatide oral tablets before the expiration of the ’637 patent;

9. Order that the effective date of any approval by the FDA of Defendants’ generic plecanatide oral tablets be a date that is not earlier than the expiration of the ’786 patent, the ’897 patent, the ’451 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent and the ’637 patent, or such later date as the Court may determine;

10. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of Defendants’ generic plecanatide oral tablets until expiration of the ’786 patent, the ’897 patent, the ’451 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent and

the ’637 patent, or such later date as the Court may determine;

11. Enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendants’ ANDA No. 215686 until expiration of the ’786 patent, the ’897 patent, the ’451 patent, the ’321 patent, the ’097 patent, the ’024 patent, the ’231 patent and the ’637 patent;

12. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees; and

13. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: April 28, 2021
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
J. Brugh Lower
**GIBBONS P.C.**
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
jlower@gibbonslaw.com

Bryan C. Diner
Justin J. Hasford
**FINNEGAN HENDERSON FARABOW, GARRETT & DUNNER, LLP**
901 New York Avenue, NW
Washington, DC 20001-4413
Tel: (202) 408-4000

*Attorneys for Plaintiffs*
*Bausch Health Ireland Limited*
*and Salix Pharmaceuticals, Inc.*

**CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: April 28, 2021
Newark, New Jersey

s/ William P. Deni, Jr.

William P. Deni, Jr.
**GIBBONS P.C.**
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com

*Attorneys for Plaintiffs*
*Bausch Health Ireland Limited*
*and Salix Pharmaceuticals, Inc.*