IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., ASTELLAS PHARMA US, INC., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	C.A. No. 23-629-JFB-CJB
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
EVITALIN LLC, d/b/a menMD, PHARMALABS LLC, and PHARMALABS HOLDCO, INC.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., Astellas Pharma US, Inc., and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

THE PARTIES

A. Astellas Pharma Inc., Astellas Ireland Co., Ltd., Astellas Pharma US, Inc., and Astellas Pharma Global Development, Inc. (Collectively, "Astellas," or "Plaintiffs")

1. Plaintiff Astellas Pharma Inc. ("APInc") is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. APInc was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff APInc.

3. Astellas Pharma US, Inc. ("APUI") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062. APUI is a subsidiary of Plaintiff APInc.

4. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062. APGD is a subsidiary of Plaintiff APInc.

B. Evitalin LLC, d/b/a menMD

5. On information and belief, Defendant Evitalin LLC does business, *inter alia*, under the name "menMD" and/or "menMD, Inc." (hereinafter "Evitalin" or "menMD").

6. On information and belief, Defendant Evitalin LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 14440 Myerlake Circle, Clearwater, FL 33760.

7. On information and belief, Defendant menMD is registered to do business as Evitalin LLC in the State of Delaware and is organized as a "domestic" limited liability company under File Number 4932400, and thus has purposely availed itself to the privileges of conducting business in this Judicial District.

8. On information and belief, in the State of Florida, where Defendant menMD has its principal place of business, it is registered to do business as Evitalin LLC as a "foreign" limited liability company, identifying the State of Delaware as the jurisdiction under the laws of which it is organized.

9. On information and belief, Defendant menMD is in the business of providing sales, marketing, and consulting services to the medical community.

C. PharmaLabs LLC and PharmaLabs HoldCo, Inc. (together, "PharmaLabs")

10. On information and belief, Defendant PharmaLabs LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10901 Roosevelt Blvd N, Suite 1200C, St. Petersburg, FL 33716.

11. On information and belief, Defendant PharmaLabs LLC is a compounding pharmacy that is in the business of making and selling, *inter alia*, pharmaceutical products. On information and belief, Defendant PharmaLabs LLC is in the business of providing medications as a compounding pharmacy at least 2012.

12. On information and belief, the manager of Defendant PharmaLabs LLC is PharmaLabs HoldCo, Inc.

13. On information and belief, Defendant PharmaLabs HoldCo, Inc. is a corporation that is incorporated under the laws of Delaware, having a principal place of business at 10901 Roosevelt Blvd N, Suite 1200C, St. Petersburg, FL 33716.

14. On information and belief, Defendant PharmaLabs LLC is registered to do business in the State of Delaware and is organized as a "domestic" limited liability company under File Number 5180858, and thus has purposely availed itself to the privileges of conducting business in this Judicial District.

15. On information and belief, in the State of Florida, where Defendant PharmaLabs LLC has its principal place of business, it is registered to do business as a "foreign" limited liability company, identifying the State of Delaware as the jurisdiction under the laws of which it is organized.

16. On information and belief, Defendant PharmaLabs Holdco, Inc. is incorporated in the State of Delaware under File Number 6810333, and thus has purposely availed itself to the privileges of conducting business in this Judicial District.

17. On information and belief, Defendant PharmaLabs HoldCo, Inc. is a management company that is, *inter alia*, the manager of Defendant PharmaLabs LLC.

18. On information and belief, Defendants menMD and PharmaLabs share at least some common officers.

19. On information and belief, Defendants PharmaLabs operate as the pharmacy partner of Defendant menMD.

NATURE OF ACTION

20. This is an action for patent infringement arising under the United States patent laws, Title 35, United States Code, seeking monetary damages and other relief against Defendants (menMD and PharmaLabs, collectively, "Defendants") for infringement of United States Patent Nos. 6,346,532 ("the '532 Patent"), 7,342,117 ("the '117 Patent"), 7,982,049 ("the '049 Patent"), and 8,835,474 ("the '474 Patent") (collectively "the Patents-in-suit").

21. This action relates to Defendants' importation, manufacturing, use, selling and/or offering to sell in the United States immediate release capsules containing 20 mg and 40 mg of mirabegron to patients seeking treatment of overactive bladder ("Defendants' Mirabegron Products").

JURISDICTION AND VENUE

22. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

23. This Court has personal jurisdiction over Defendant menMD at least because, on information and belief, Defendant menMD is a limited liability company organized and existing under the laws of Delaware.

24. On information and belief, Defendant menMD conducts business throughout the United States, including in this Judicial District, and has committed acts of infringement in this Judicial District and elsewhere.

25. On information and belief, Defendant menMD partners with affiliates, partners, and/or agents such as pharmacies that engage in compounding medications, including those imported, sold, offered for sale, and/or used in the pharmaceutical industry throughout the United States, including in this Judicial District.

26. On information and belief, Defendant menMD regularly solicits business throughout the United States, including in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

27. On information and belief, Defendant menMD conducts marketing and sales activities throughout the United States, including in the State of Delaware, including but not limited to distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

28. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendant menMD.

29. This Court has personal jurisdiction over Defendant PharmaLabs LLC at least because, on information and belief, Defendant PharmaLabs LLC is a limited liability company organized and existing under the laws of Delaware. On information and belief, Defendant PharmaLabs LLC is registered with the Delaware Department of State, Division of Professional Regulation as a Pharmacy (license number A9-0001227) and further has a controlled substances

license in Delaware under license number PH-0011109. On information and belief, Defendant PharmaLabs LLC had a retail pharmacy drug wholesale distributor license in Florida. On information and belief, Defendant PharmaLabs LLC is registered with the Florida Department of Health as a Community Pharmacy (license number PH26495).

30. On information and belief, Defendant PharmaLabs LLC conducts business throughout the United States, including in this Judicial District, and has committed acts of infringement in this Judicial District and elsewhere.

31. On information and belief, Defendant PharmaLabs LLC, together with its affiliates, partners, and/or agents, engages in compounding and selling medications, including those imported, sold, offered for sale, and/or used in the pharmaceutical industry throughout the United States, including in this Judicial District.

32. On information and belief, Defendant PharmaLabs LLC, directly or indirectly through its subsidiaries, affiliates, partners, and agents, regularly solicits business throughout the United States, including in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

33. On information and belief, Defendant PharmaLabs LLC, directly or indirectly through its subsidiaries, affiliates, partners, and agents, conducts marketing and sales activities throughout the United States, including in the State of Delaware, including but not limited to distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

34. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendant PharmaLabs LLC.

35. This Court has personal jurisdiction over Defendant PharmaLabs HoldCo, Inc. at least because, on information and belief, Defendant PharmaLabs HoldCo, Inc. is a corporation that is incorporated under the laws of Delaware.

36. On information and belief, Defendant PharmaLabs HoldCo, Inc. conducts business throughout the United States, including in this Judicial District, and has committed acts of infringement in this Judicial District and elsewhere.

37. On information and belief, Defendant PharmaLabs HoldCo, Inc. together with its affiliates, partners, and/or agents, engages in compounding and selling medications, including those imported, sold, offered for sale, and/or used in the pharmaceutical industry throughout the United States, including in this Judicial District.

38. On information and belief, Defendant PharmaLabs HoldCo, Inc. directly or indirectly through its subsidiaries, affiliates, partners, and agents, regularly solicits business throughout the United States, including in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

39. On information and belief, Defendant PharmaLabs HoldCo, Inc. directly or indirectly through its subsidiaries, affiliates, partners, and agents, conducts marketing and sales activities throughout the United States, including in the State of Delaware, including but not limited to distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

40. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendant PharmaLabs HoldCo, Inc.

41. For at least these reasons, venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

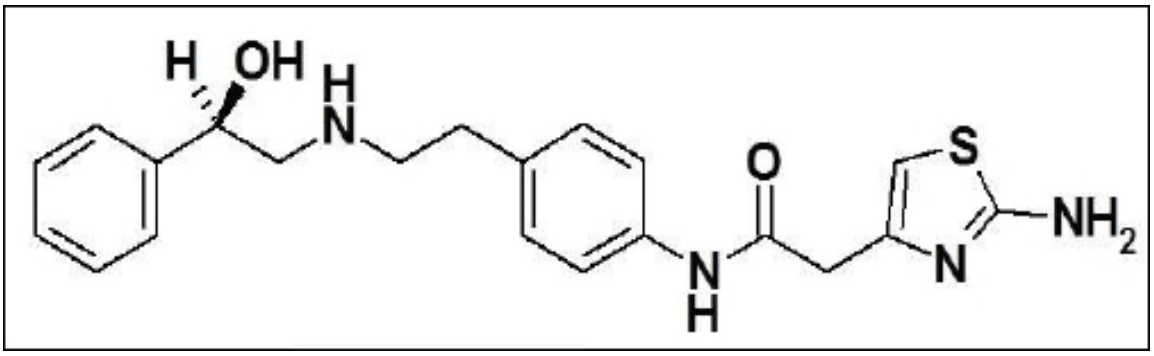
FACTUAL BACKGROUND

A. MYRBETRIQ®

42. APGD holds approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron ("Myrbetriq® Tablets"). The United States Food and Drug Administration ("FDA") approved NDA No. 202611 on June 28, 2012 for Myrbetriq® Tablets.

43. The FDA granted Myrbetriq® Tablets regulatory exclusivities, including on the Patents-in-suit. These regulatory exclusivities that are associated with the Patents-in-suit do not all expire until May 4, 2024.

44. Mirabegron is a synthetic, man-made chemical compound with the following chemical structure:



45. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, (R)-2-(2-aminothiazol-4-

yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, 2-(2-aminothiazol-4-yl)-N-[4- (2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide, 2-amino-N-[4-[2-[[(2R)-2-hydroxy-2-phenylethyl]amino]ethyl]phenyl]-4-thiazoleacetamide, 2-(2-Amino-1,3-thiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl] acetamide, 2-(2-Aminothiazol-4-yl)-N-(4-(2-(2R)-hydroxy-2-phenylethylamino)ethyl)phenyl) acetamide, and (R)-2-(2-aminothiazol-4-yl)-N-(4-(2-((2-hydroxy-2-phenylethyl)amino)ethyl) phenyl)acetamide.

46. The FDA determined that Myrbetriq® Tablets, both 25 and 50 mg strengths, are safe and effective oral treatments for overactive bladder ("OAB"). The FDA has not approved any pharmaceutical product containing mirabegron as the active ingredient for any other indication.

47. Myrbetriq® Tablets comprise extended-release formulations for mirabegron because immediate-release formulations for mirabegron were associated with an undesirable food effect that could cause harmful cardiovascular side effects.

48. The active pharmaceutical ingredient in Myrbetriq® Tablets comprises α-Form crystals of mirabegron. Myrbetriq® Tablets further include the excipients butylated hydroxytoluene, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, and ferric oxide, which comprise a pharmaceutically acceptable carrier.

49. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

50. AICL has contracted with APUI to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

B. PATENTS-IN-SUIT

1. THE ’532 PATENT

51. The United States Patent & Trademark Office (“PTO”) duly and legally issued the ’532 Patent, entitled “Amide Derivatives or Salts Thereof,” on February 12, 2002. On February 24, 2015, after an *ex parte* reexamination proceeding, the PTO duly and legally issued a reexamination certificate confirming the validity and patentability of the ’532 Patent. A true and correct copy of the ’532 Patent is attached as **Exhibit A**.

52. The ’532 Patent claims, *inter alia*, the novel, synthetic chemical compound mirabegron.

53. APInc is the assignee of the ’532 Patent.

54. AICL is the exclusive licensee of the ’532 Patent, with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

55. The ’532 Patent was in full force until it expired on March 27, 2022, and the FDA pediatric exclusivity associated with the ’532 Patent expired on September 27, 2022.

56. The ’532 Patent was listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for Myrbetriq® Tablets by July 30, 2012, and remained listed until expiry of the FDA pediatric exclusivity associated with the ’532 Patent.

57. Astellas has complied with the applicable marking requirements of 35 U.S.C. § 287 with respect to the ’532 Patent.

2. THE ’117 PATENT

58. The PTO duly and legally issued the ’117 Patent entitled “α-Form or β-Form Crystal of Acetanilide Derivative,” on March 11, 2008. A true and correct copy of the ’117 Patent is attached as **Exhibit B**.

59. The ’117 Patent claims, *inter alia*, novel crystal forms of the synthetic chemical compound mirabegron, including α-Form and β-Form crystals of mirabegron.

60. Claim 1 of the ’117 Patent covers, *inter alia*, α-Form crystals of mirabegron.

61. As shown in Figure 4 of the ’117 Patent, α-Form crystals of mirabegron exhibit multiple peaks when analyzed using powder X-ray diffraction (“XRPD”). For example, XRPD peaks are typically observed at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34º 2θ when measured using Cu x-rays. *See* **Exhibit B** at Fig. 4.

62. As shown in Figure 5 of the ’117 Patent, α-Form crystals of mirabegron exhibit a heat absorption peak at about 142 to 146º C when measured by differential scanning colorimetry (“DSC”) analysis. *See* **Exhibit B** at Fig. 5.

63. This Court previously construed the claim term “main peaks,” which appears in the claims of the ’117 Patent. *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-905-JFB-CJB, 2018 WL 4776372, at *11-*15 (D.Del. June 18, 2018). In particular, this Court opined that “main peaks,” as it appears in the claims of the ’117 Patent, means “peaks that are characteristic of the particular crystal form as distinguished from other crystal forms.” *Id.* at *16. This Court rejected a construction of this term that included relative peak intensity. *Id.* at *15. (“[I]n the Court’s view… relative intensity is *not* what allows a POSA to distinguish crystalline forms from one another. Rather, it is a set of distinguishing peaks that allows a POSA to do so.”).

64. The ’117 Patent expires no earlier than November 4, 2023, and the FDA pediatric exclusivity associated with the ’117 Patent expires no earlier than May 4, 2024.

65. APInc is the assignee of the ’117 Patent.

66. AICL is the exclusive licensee of the '117 Patent, with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

67. The '117 Patent has been listed in the Orange Book as covering Astellas' Myrbetriq® Tablets since July 30, 2012.

68. Astellas has complied with the applicable marking requirements of 35 U.S.C. § 287 with respect to the '117 Patent.

3. THE '049 PATENT

69. The PTO duly and legally issued the '049 Patent entitled "α-Form or β-Form Crystal of Acetanilide Derivative," on July 19, 2011. A true and correct copy of the '049 Patent is attached as **Exhibit C**.

70. The '049 Patent claims, *inter alia*, pharmaceutical compositions comprising α-Form or β-Form crystal mirabegron and a pharmaceutically acceptable carrier.

71. Claim 1 of the '049 Patent covers, *inter alia*, pharmaceutical compositions containing the α-Form crystals of mirabegron.

72. This Court previously construed the claim term "α-form crystal," which appears in the claims of the '049 Patent. *Astellas Pharma Inc.*, 2018 WL 4776372 at *5-*11. In particular, this Court opined that term "α-form crystal" means "a term of reference for a polymorphic crystal form of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide that can be distinguished from other forms by its characteristic peak(s) and DSC analysis as identified in the specification." *Id.* at *11.

73. Claim 13 of the '049 Patent covers, *inter alia*, capsules containing the α-Form crystals of mirabegron.

74. The ’049 Patent expires no earlier than November 4, 2023, and the FDA pediatric exclusivity associated with the ’049 Patent expires no earlier than May 4, 2024.

75. The ’049 Patent has been listed in the Orange Book as covering Astellas’ Myrbetriq® Tablets since July 30, 2012.

76. APInc is the assignee of the ’049 Patent.

77. AICL is the exclusive licensee of the ’049 Patent, with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

78. Astellas has complied with the applicable marking requirements of 35 U.S.C. § 287 with respect to the ’049 Patent.

4. THE ’474 PATENT

79. The PTO duly and legally issued the ’474 Patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on September 16, 2014. A true and correct copy of the ’474 patent is attached as **Exhibit D**.

80. The ’474 Patent claims, *inter alia*, novel methods of treating overactive bladder by administering mirabegron, which is a synthetic chemical compound, to a patient.

81. The ’474 Patent expires no earlier than November 4, 2023, and the FDA pediatric exclusivity associated with the ’474 Patent expires no earlier than May 4, 2024.

82. The ’474 Patent has been listed in the Orange Book as covering Astellas’ Myrbetriq® Tablets since October 14, 2014.

83. APInc is the assignee of the ’474 Patent.

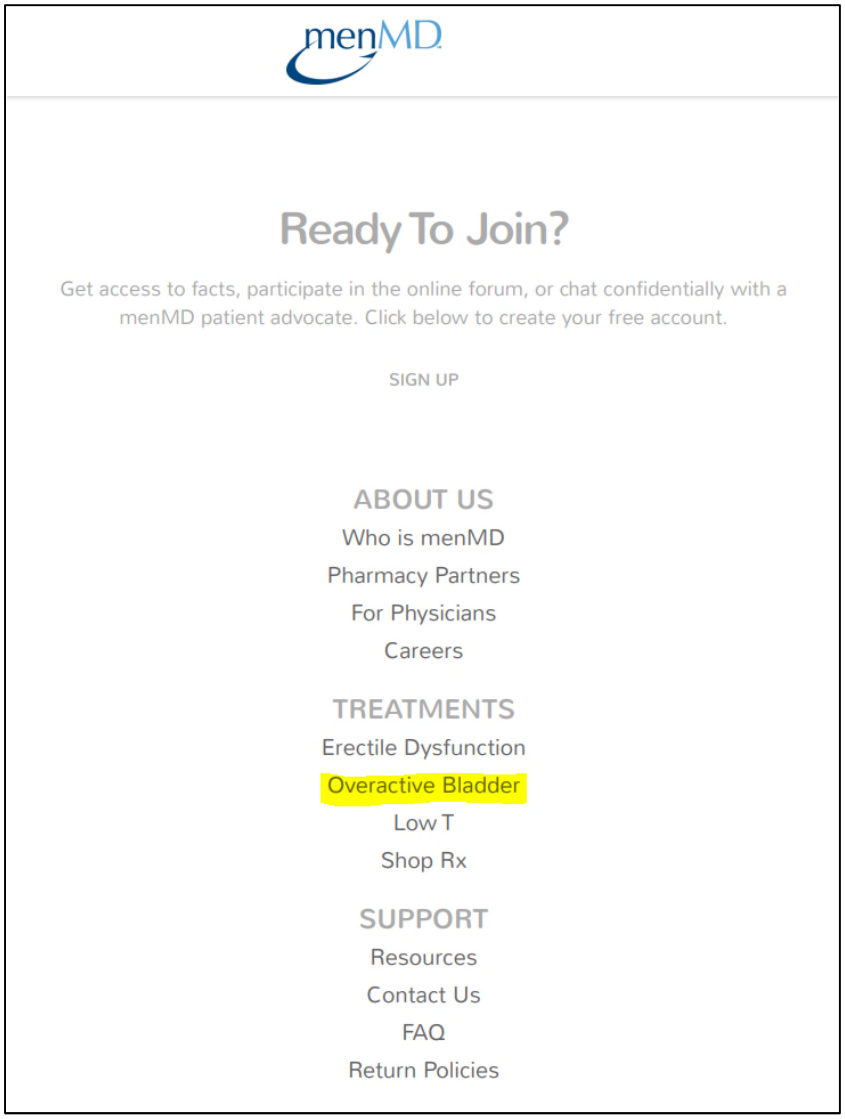
84. AICL is the exclusive licensee of the '474 Patent, with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

85. Astellas has complied with the applicable marking requirements of 35 U.S.C. § 287 with respect to the '474 Patent.

C. DEFENDANTS' INFRINGING ACTIVITIES AND PRODUCTS

86. On information and belief, since at least 2013, Defendant menMD has provided an online platform that, *inter alia*, helps fill various treatment orders from healthcare providers through partnering pharmacies. On information and belief, Defendant menMD has been in the business, *inter alia*, of providing sales, marketing, and consulting services to the medical community. On information and belief, Defendant menMD "has a background in various specialties and [its] providers are industry leaders from the top university and private hospital systems in the country." *See, e.g.*, https://menmd.com/about/. On information and belief, Defendant menMD has a nationwide network of physicians and healthcare providers who trust menMD to offer medication through accredited pharmacies. A true and correct copy of Defendant menMD's webpage at https://menmd.com/about/ as of May 16, 2023 is attached as **Exhibit F**.

87. On information and belief, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, manufactures, distributes, imports, markets, sells and/or offers for sale various treatments for bladder control conditions, including Defendants' Mirabegron Products to treat overactive bladder, through its website and has done so since at least May 2019. For example, Defendants' Mirabegron Products were listed under its website tab titled "Overactive Bladder." A true and correct copy of the archived webpage at http://menmd.com, archived on 05-31-2019, available via the "Internet Archive, the WayBack Machine," accessed at https://archive.org/web/ is attached as **Exhibit G**, as excerpted and highlighted below:



88. On information and belief, Defendants PharmaLabs are pharmacy partners of Defendant menMD. On information and belief, Defendants PharmaLabs make, *inter alia*, Defendants' Mirabegron Products, and/or provide those products to patients in need thereof in concert with Defendant menMD and have done so since at least May 2019.

89. On information and belief, upon receiving orders from customers, Defendants will provide Defendants' Mirabegron Products, with instructions to use them to treat overactive bladder and has done so since at least May 2019.

90. On information and belief, customers, healthcare providers, and/or patients administer Defendants' Mirabegron Products for the treatment of overactive bladder. On information and belief, Defendants have known and encouraged since at least 2019 that customers, healthcare providers, and/or patients would administer Defendants' Mirabegron Products for the treatment of overactive bladder.

91. On information and belief, Defendants PharmaLabs make, use, or import mirabegron active pharmaceutical ingredient ("API") to make Defendants' Mirabegron Products and have done so since at least May 2019.

92. On information and belief, the mirabegron API used to make Defendants' Mirabegron Products contains the α-Form crystals of mirabegron and has done so since at least May 2019.

93. On information and belief, the Defendants' Mirabegron Products contain the α-Form crystals of mirabegron and have done so since at least May 2019.

94. On information and belief, Defendants PharmaLabs provide customers, healthcare providers, and/or patients instructions on how to use Defendants' Mirabegron Products for the treatment of overactive bladder and have done so since at least May 2019. For example, on information and belief, Defendants PharmaLabs direct customers, healthcare providers, and/or patients to menMD for instructions on how to use Defendants' Mirabegron Products for the treatment of overactive bladder.

95. On information and belief, Defendants PhamaLabs directly or indirectly through their affiliates, partners, and agents, manufacture, distribute, import, market, sell and/or offer for sale Defendants' Mirabegron Products and have done so since at least May 2019. On information and belief, Defendants PhamaLabs encouraged patients to visit Defendant menMD's website by

providing a direct link to Defendant menMD's website and have done so since at least May 2019. A true and correct copy of the archived webpage at http://www.plabrx.com/products, archived on 05-07-2019, available via the "Internet Archive, the WayBack Machine," accessed at https://archive.org/web/ is attached as **Exhibit T**, as excerpted and highlighted below:

96. On information and belief, Defendants PharmaLabs and menMD participate in the sale of Defendants' Mirabegron Products and has done so since at least May 2019.

97. On information and belief, Defendant menMD provided instructions to customers, healthcare providers, and/or patients in need on how to use Defendants' Mirabegron Products to treat overactive bladder.

98. On information and belief, when patients filled prescriptions of Defendants' Mirabegron Products, Defendants PharmaLabs provided instructions to patients in need on how to use those products for the treatment of overactive bladder.

99. On information and belief, Defendants' Mirabegron Products have not been the subject of any marketing approval applications to the FDA, nor have Defendants' Mirabegron Products been approved by the FDA as a sufficiently safe and effective treatment for any indication, including for the treatment of overactive bladder.

100. On June 14, 2019, Plaintiffs sent a cease-and-desist letter to Defendant menMD's CEO Carey Frasca, at 10901 Roosevelt Blvd. N., St. 100B, St. Petersburg, FL 33716 via overnight

courier (the "June 14, 2019 Letter"). A true and correct copy of this letter is attached as **Exhibit H**.

101. The June 14, 2019 Letter informed Defendants that, *inter alia*, that the FDA's Orange Book contained a listing of the patents that covered Myrbetriq® Tablets and that Defendants' marketing, selling and importation of mirabegron and Defendants' Mirabegron Products infringed at least the '532 Patent. The June 14, 2019 Letter put Defendants on notice that Astellas marked Myrbetriq® Tablets in the United States, the Myrbetriq® Tablets were listed in the FDA's Orange Book which contains patent and exclusivity information for FDA-approved drugs, and that each of the Patents-in-suit covered Myrbetriq® Tablets. Accordingly, no later than June 14, 2019, Defendants were all on notice of the Patents-in-suit and that they covered Defendants' Mirabegron Products.

102. On or about June 21, 2019, outside counsel for Defendants, Mr. Gregory A. Krauss, responded to the June 14, 2019 Letter on behalf of Defendants. A true and correct copy of this letter is attached as **Exhibit I**. This response from outside counsel establishes that, no later than June 21, 2019, Defendant menMD had actual notice of the '532 Patent and the Orange Book listing for Myrbetriq® Tablets, including the Patents-in-suit. Furthermore, because Plaintiffs' June 14, 2019 Letter was addressed and sent to the principal place of business for Defendants PharmaLabs, Defendants PharmaLabs also had actual notice of the Patents-in-suit and that they covered the Defendants' Mirabegron Products.

103. On or about June 28, 2019, outside counsel for Defendants responded further to the June 14, 2019 Letter, indicating that Defendants had allegedly ceased marketing, offering to sell and selling Defendants' Mirabegron Products. A true and correct copy of this letter is attached as **Exhibit J**.

104. On information and belief, on or before September 2022, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, continued offering for sale and selling Defendants' Mirabegron Products, to treat the incontinence symptom of overactive bladder, at least featured as packaged bottles, through its website. A true and correct copy of the archived webpage titled "Treatment Options for Male Incontinence" at https://menmd.com/condition/male-incontinence/, archived on 09-29-2022, available via the "Internet Archive, the WayBack Machine," accessed at https://archive.org/web/ is attached as **Exhibit K**, and as excerpted below:

105. On information and belief, on or before September 2022, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, offered further details about

Defendants' Mirabegron Products, featured at least as packaged bottles and Defendants' Mirabegron Products used to treat the urinary incontinence symptom of overactive bladder, through its website as reproduced below. A true and correct copy of the archived webpage titled "Mirabegron" available at https://menmd.com/product/mirabegron/, archived on 09-29-2022, available via the "Internet Archive, the WayBack Machine," accessed at https://archive.org/web/ is attached as **Exhibit L**, and as excerpted below:

106. On information and belief, on or about September 2022, Defendants PharmaLabs continued supplying Defendants' Mirabegron Products to patients at the request, and with the assistance of, Defendant menMD, to treat overactive bladder.

107. On information and belief, on or about February 2023, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, listed Defendants' Mirabegron Products on its "Patient-specific price list" dated February 15, 2023, available for download at https://cdn.menmd.com/wp-content/uploads/2023/02/16101511/Price-List-All-States-UPDATED_-02.15.23.pdf; a true and correct copy is also attached as **Exhibit M**.

108. On February 15, 2023, Plaintiffs sent another cease-and-desist letter to outside counsel for Defendants, informing him that Defendants' continued sales of Defendants' Mirabegron Products were unlawful because, *inter alia*, they infringed at least the '117, '049, and '474 Patents (the "February 15, 2023 Letter"). A true and correct copy of this letter is attached as **Exhibit N**.

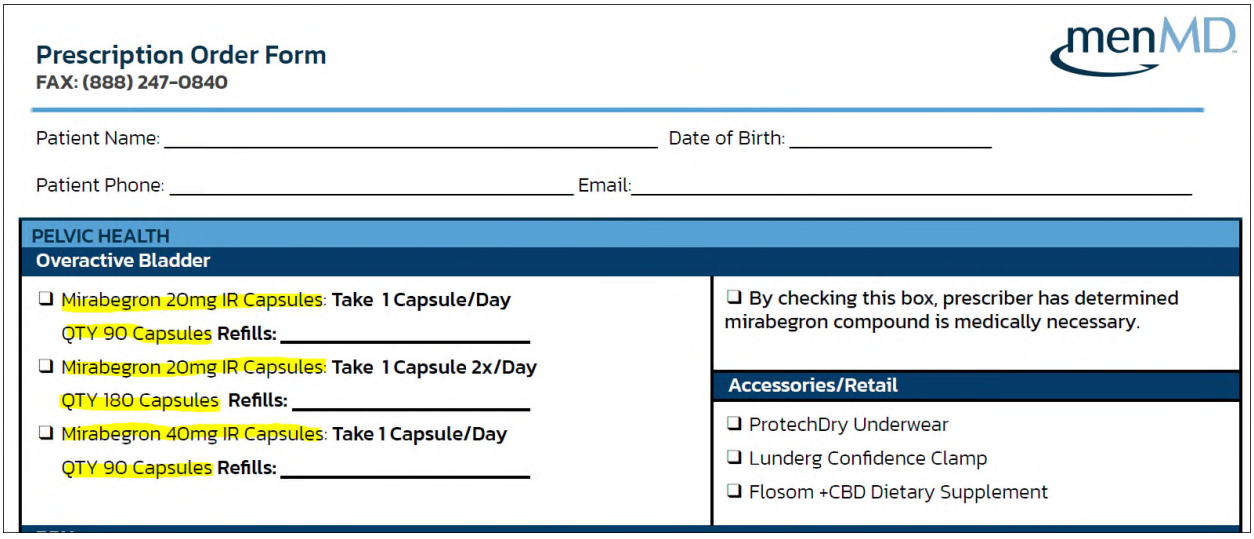
109. On or about February 24, 2023, outside counsel for Defendants responded to Plaintiffs' February 15, 2023 Letter (the "February 24, 2023 Letter"). A true and correct copy of this letter is attached as **Exhibit O**. In that letter, outside counsel represented that Defendants have "stopped printing any marketing materials concerning mirabegron and has taken down all statements about mirabegron from its website." *See* **Exhibit O** at 1.

110. Despite representations Defendants had stopped marketing Defendants' Mirabegron Products, on information and belief, on or about March 2023, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, continued to list Defendants' Mirabegron Products on its "Patient-specific price list" dated March 28, 2023; a true and correct copy is also attached as **Exhibit P**. This price list offered the Defendants' Mirabegron Products

for "Overactive Bladder" listing them as "Mirabegron Compounded Immediate Release Capsules" in strengths of "20 mg IR Capsules" and "40 mg IR Capsules", each of which offered as 30-capsule and 90-capsule units, as reproduced below:

Overactive Bladder			
Mirabegron Compounded Immediate Release Capsules	20mg IR Capsules	30 Capsules 90 Capsules	$69 $186
	40mg IR Capsules	30 Capsules 90 Capsules	$79.50 $214

111. On information and belief, on or about March 2023, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, continued to list Defendants' Mirabegron Products on the menMD Prescription Order Form, updated March 28, 2023; a true and correct copy is also attached as **Exhibit Q**. MenMD's Prescription Order Form lists Defendant' Mirabegron Products as "Mirabegron 20 mg IR Capsules" in 90-capsule quantity size, "Mirabegron 20 mg IR Capsules" in 180-capsule quantity size, and "Mirabegron 40 mg IR Capsules" in 90-capsule quantity, as reproduced below:



Prescription Order Form
FAX: (888) 247-0840

menMD

Patient Name: _____ Date of Birth: _____

Patient Phone: _____ Email: _____

PELVIC HEALTH
Overactive Bladder

❑ Mirabegron 20mg IR Capsules: **Take 1 Capsule/Day**
QTY 90 Capsules **Refills:** _____

❑ Mirabegron 20mg IR Capsules: **Take 1 Capsule 2x/Day**
QTY 180 Capsules **Refills:** _____

❑ Mirabegron 40mg IR Capsules: **Take 1 Capsule/Day**
QTY 90 Capsules **Refills:** _____

❑ By checking this box, prescriber has determined mirabegron compound is medically necessary.

Accessories/Retail

❑ ProtechDry Underwear
❑ Lunderg Confidence Clamp
❑ Flosom +CBD Dietary Supplement

112. On information and belief, on or about March 2023, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, continued to target healthcare professionals and provided them with marketing and promotional information for Defendants' Mirabegron

Products, and price lists and Prescription Order Form listing those products. On information and belief, on or about March 2023, Defendant menMD, directly or indirectly through its affiliates, partners, and agents, continued to encourage healthcare professionals to prescribe the Defendants' Mirabegron Products to patients in need. On information and belief, Defendant menMD encouraged healthcare professionals to order Defendants' Mirabegron Products through Defendants PharmaLabs, located at 10901 Roosevelt Boulevard N, Suite #1200C, St. Petersburg, FL 33716.

113. On or about April 7, 2023, outside counsel for Defendants sent Plaintiffs a follow-up letter to its February 24, 2023 Letter (the "April 7, 2023 Letter"). In the April 7, 2023 Letter, outside counsel for Defendants denied infringement of the '117, '049, and '474 Patents after an apparent investigation into Defendants' Mirabegron Products. A true and correct copy of this letter is attached **Exhibit R**.

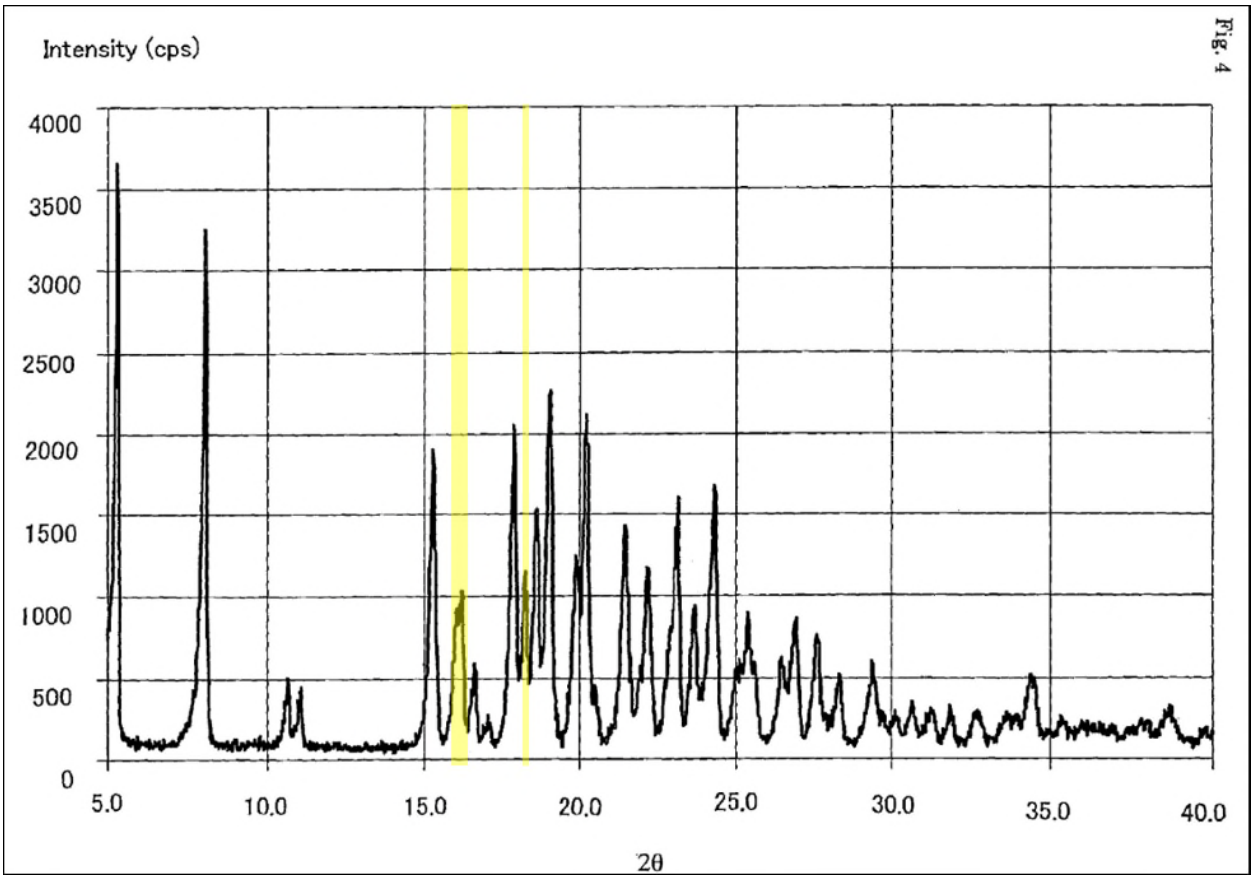
114. On information and belief, Defendants' denial of infringement is erroneous and without merit.

115. With respect to the '117 Patent, Defendants' outside counsel premised noninfringement on "powder X-ray diffraction test results on the [mirabegron API] [its] pharmacy partner used for [Defendants' Mirabegron Products]." **Exhibit R** at 1. In his assessment, these XRPD results "reveal different polymorphs of mirabegron than those disclosed and specifically claimed in the '117 and '049 Patents." *See* **Exhibit R** at 2. In particular, his assessment was purportedly based upon XRPD peaks appearing at approximately 16.3 and 18.6° 2θ, which he asserts is not a "main peak" as required by the claims of the '117 Patent. *See* **Exhibit R** at 2.

116. In his April 7, 2023 Letter, outside counsel for Defendants admitted that the mirabegron API used in Defendants' Mirabegron Products: (1) contains mirabegron, (2) is

crystalline, and (3) contains "peaks" as measured by XRPD. These admissions all support the presence of the claimed crystalline forms in the '117 and '049 Patents.

117. Outside counsel for Defendants' contention that XRPD peaks appearing at approximately 16.3 and 18.6° 2θ demonstrate noninfringement is incorrect. For example, Figure 4 of the '117 Patent includes both of these peaks for the α-Form crystals of mirabegron:

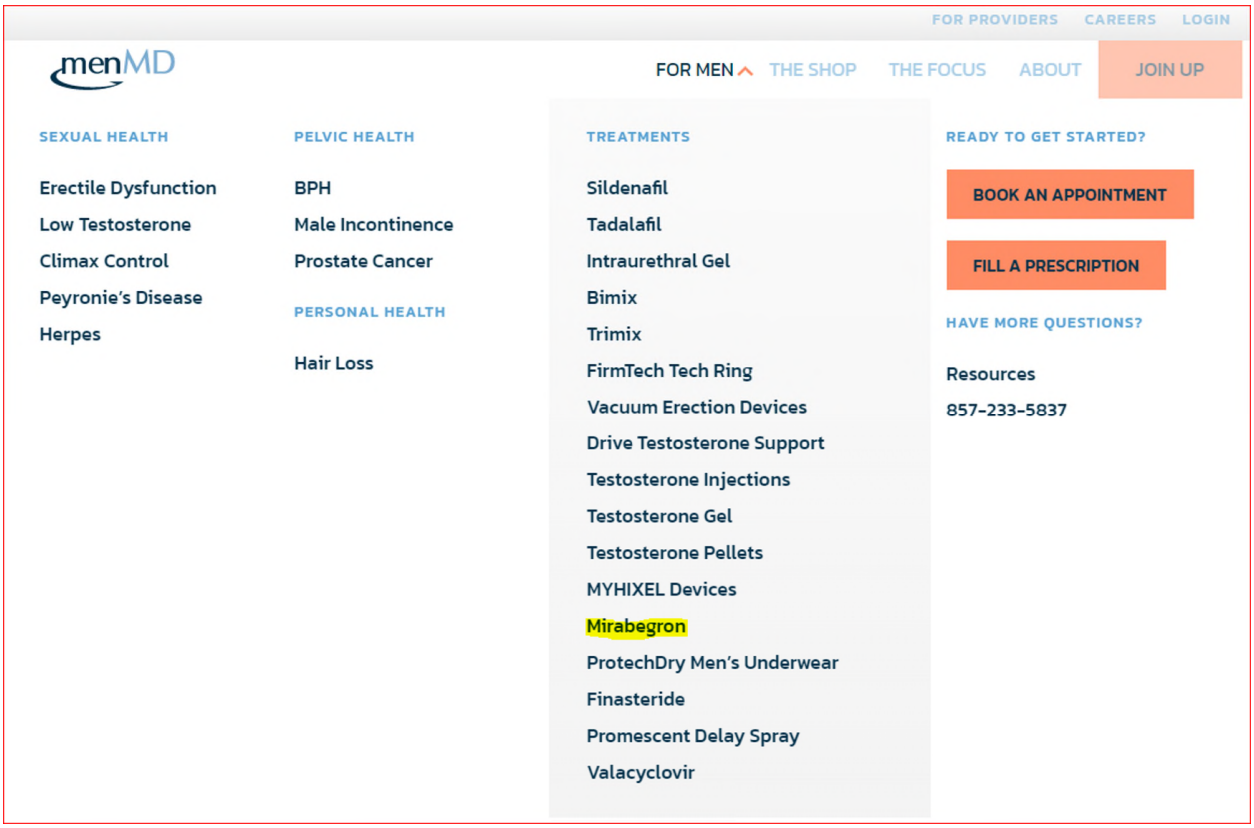


118. As part of his noninfringement contention, outside counsel for Defendants argues that these two XRPD peaks at approximately 16.3 and 18.6° 2θ are not "main peaks" as required by the claims of the '117 Patent by reading relative intensity of the XRPD peaks into the claim. **Exhibit R** at 2. However, this Court previously rejected such a construction of the term, rendering his contention objectively baseless. *Astellas Pharma Inc.*, 2018 WL 4776372, at *15 ("[I]n the

Court's view… relative intensity is *not* what allows a POSA to distinguish crystalline forms from one another. Rather, it is a set of distinguishing peaks that allows a POSA to do so.").

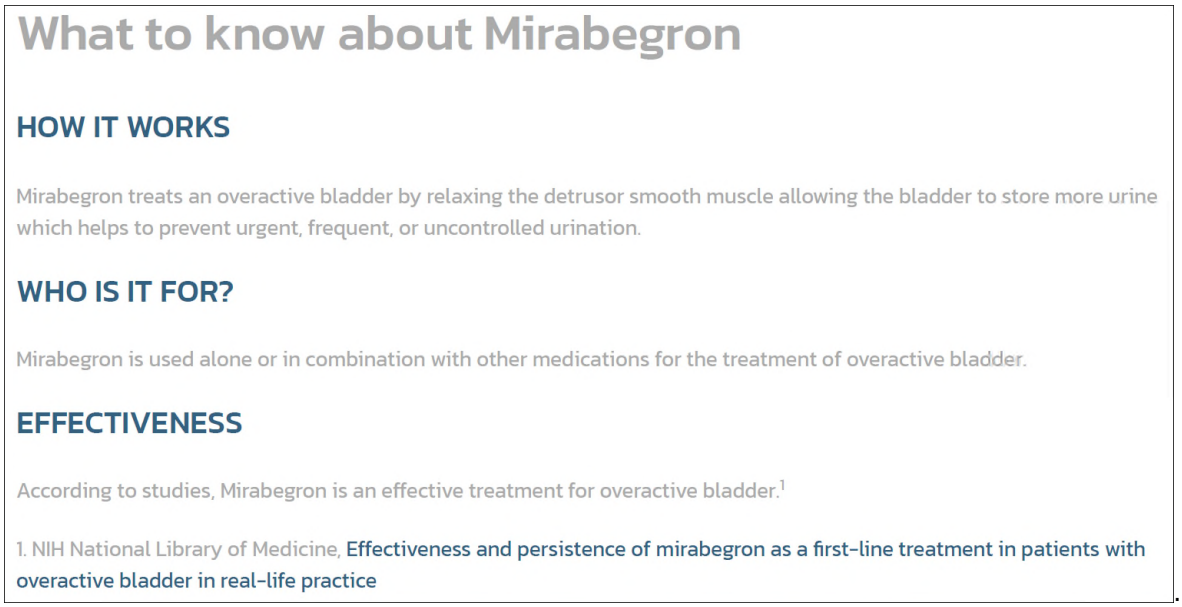
119. In his April 7, 2023 Letter, outside counsel for Defendants also argues that the claims of the '117 and '049 Patents are indefinite because the patent specifications state that XRPD results "should not be strictly interpreted" "since a relative intensity can vary a little depending on the direction of crystal growth." **Exhibit R** at 2. However, this Court previously rejected an invalidity defense of indefiniteness for the claim term "main peaks" based, *inter alia*, upon the presence of additional peaks. *Astellas Pharma Inc.*, 2018 WL 4776372, at *11-14. More importantly, the Court opined "that a POSA 'would easily be able to ascertain whether a mirabegron crystal form conforms to the claims of the '117 patent by, for example, testing it by XRPD and then determining whether peaks are present at the recited locations.'" *Id*. at *14. Outside counsel for Defendants did not provide all XRPD data to allow Plaintiffs to perform this analysis as further evidence of Defendants infringement of the '117 Patent.

120. On information and belief, despite Defendants' representations in their February 24, 2023 Letter that they have taken down all statements about mirabegron from Defendant menMD's website, Defendants continued to sell and offer to sell Defendants' Mirabegron Products, for example, through the website https://menmd.com/, as excerpted and highlighted below:



121. Despite representations in their February 24, 2023 Letter, Defendants continue to sell Defendants' Mirabegron Products featured as packaged bottles through the website https://menmd.com/product/mirabegron/ as reproduced below. Defendant menMD continues to offer incentives to its customers to purchase Defendants' Mirabegron Products by stating that patients may "[t]ransfer [their] existing prescription to menMD and get [their] first month [of mirabegron] free!" On its website, Defendant menMD promotes Defendants' Mirabegron Products stating that they are "immediate release capsules" and that they are "used to treat urinary incontinence" and help "prevent urgent, frequent, or uncontrolled urination," *i.e.*, the symptoms of overactive bladder. In order to promote the efficacy of Defendants' Mirabegron Products, Defendant menMD, on its website, continues to provide a link to the Korean Study titled "Effectiveness and persistence of mirabegron as a first-line treatment in patients with overactive bladder in real-life practice". A true and correct copy of menMD's mirabegron webpage at

https://menmd.com/product/mirabegron/, accessed April 27, 2023, is attached as **Exhibit S**, as excerpted below:



What to know about Mirabegron

HOW IT WORKS

Mirabegron treats an overactive bladder by relaxing the detrusor smooth muscle allowing the bladder to store more urine which helps to prevent urgent, frequent, or uncontrolled urination.

WHO IS IT FOR?

Mirabegron is used alone or in combination with other medications for the treatment of overactive bladder.

EFFECTIVENESS

According to studies, Mirabegron is an effective treatment for overactive bladder.[1]

1. NIH National Library of Medicine, Effectiveness and persistence of mirabegron as a first-line treatment in patients with overactive bladder in real-life practice

122. On information and belief, at least as of March 28, 2023, Defendant menMD continued to sell and offer to sell mirabegron by listing it in its patient-specific price list. *See* **Exhibit P**. Defendant menMD's patient-specific price list offers Defendants' Mirabegron Product for "Overactive Bladder" listing them as "Mirabegron Compounded Immediate Release Capsules" in strengths of "20 mg IR Capsules" and "40 mg IR Capsules", each of which offered as 30-capsule and 90-capsule units, as reproduced below.

Overactive Bladder			
Mirabegron Compounded Immediate Release Capsules	20mg IR Capsules	30 Capsules	$69
		90 Capsules	$186
	40mg IR Capsules	30 Capsules	$79.50
		90 Capsules	$214

123. Defendants were additionally put on actual notice of the Patents-in-suit by way of the June 9, 2023 complaint filed against Defendants. D.I. 1.

D. DEFENDANTS' WILLFUL AND EXCEPTIONAL BEHAVIOR

124. On information and belief, despite being put on notice by Plaintiffs of infringement, Defendants continue to willfully infringe the Patents-in-suit.

125. On information and belief, despite several letters signed by its outside counsel indicating that Defendant's had ceased infringing activities, Defendants nonetheless continued to willfully infringe the Patents-in-suit. *See e.g.*, **Exhibits J**, **M**, **O**, **S**.

126. On information and belief, despite being served with a complaint filed on June 9, 2023 alleging infringement (D.I. 1), Defendants nonetheless continued to willfully infringe the '117, '049, and '474 Patents.

127. On information and belief, in response to Plaintiffs' June 9, 2023 lawsuit, Defendants filed an objectively baseless Motion to Dismiss by erroneously asserting that the complaint failed to state a claim under Fed. R. Civ. P. 12(b)(6), and alternatively, for collateral estoppel based on this Court's determination of invalidity of an unrelated patent under 35 U.S.C. § 101 (D.I. 16).

128. Defendants' willful infringement and continued litigation misconduct warrants a finding by the Court of exceptional case and attorney's fees to Plaintiffs.

CLAIMS FOR RELIEF

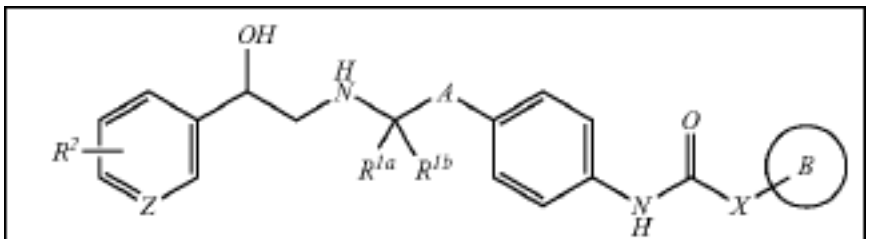
COUNT I: DIRECT INFRINGEMENT OF THE '532 PATENT BY DEFENDANT MENMD

129. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

130. Defendant menMD has directly infringed one or more claims of the '532 Patent, including at least exemplary Claims 1 and 5, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell and/or selling mirabegron, and/or products containing mirabegron prior to the expiration of the '532 Patent.[1]

[1] Plaintiffs will identify all asserted claims of the patents in suit in accordance with the Court's Local Rules and/or scheduling order.

131. For example, on information and belief, Defendants' Mirabegron Products comprise compounds of formula (I):



in the formula, each of the symbols means as follows:

ring B is a nitrogen-containing heteroaryl group which is unsubstituted or substituted and is optionally fused with a benzene ring;

X is a lower alkylene or an alkenylene, both of which are unsubstituted or substituted with hydroxy or a lower alkyl group, or X is a carbonyl or a group represented by —NH—, and when X is a lower alkylene which is substituted with a lower alkyl group, a carbon atom of the ring B optionally bonds with the lower alkyl group so that a ring is formed;

A is methylene, ethylene, or a group represented by -CH_2O—;

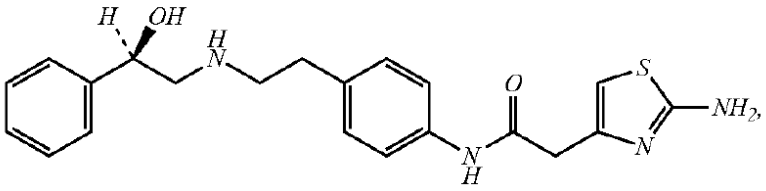
R^{1a}, R^{1b} are the same or different and each is a hydrogen atom or a lower alkyl group;

R^2 is a hydrogen atom or a halogen atom; and

Z is a group represented by ═CH—; or a salt thereof. Thus, Defendants' Mirabegron Products fall within the scope of at least Claim 1 of the '532 Patent.

132. For example, on information and belief, Defendants' Mirabegron Products comprise compounds of formula (Ia):

(Ia)



or a salt thereof. Thus, Defendants' Mirabegron Products fall within the scope of at least Claim 5 of the '532 Patent.

133. Defendant menMD has admitted that Defendants' Mirabegron Products contain mirabegron, a compound that infringes at least exemplary Claims 1 and 5 of the '532 Patent. *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1.

134. Defendant menMD had actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '532 Patent, no later than June 14, 2019.

135. Defendant menMD's acts of infringement have caused damage to Plaintiffs.

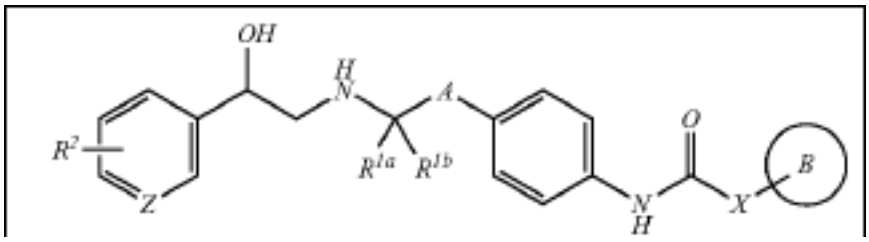
136. Defendant menMD's infringement of the '532 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

COUNT II: DIRECT INFRINGEMENT OF THE '532 PATENT BY PHARMALABS

137. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

138. Defendants PharmaLabs have directly infringed one or more claims of the '532 Patent, including at least exemplary Claims 1 and 5, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell, and/or selling mirabegron, and/or products containing mirabegron prior to the expiration of the '532 Patent.

139. For example, on information and belief, Defendants' Mirabegron Products comprise compounds of formula (I):



in the formula, each of the symbols means as follows:

ring B is a nitrogen-containing heteroaryl group which is unsubstituted or substituted and is optionally fused with a benzene ring;

X is a lower alkylene or an alkenylene, both of which are unsubstituted or substituted with hydroxy or a lower alkyl group, or X is a carbonyl or a group represented by —NH—, and when X is a lower alkylene which is substituted with a lower alkyl group, a carbon atom of the ring B optionally bonds with the lower alkyl group so that a ring is formed;

A is methylene, ethylene, or a group represented by -CH_2O—;

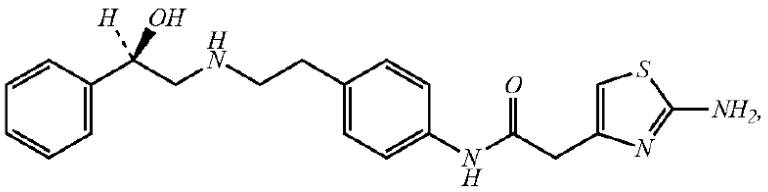
R^{1a}, R^{1b} are the same or different and each is a hydrogen atom or a lower alkyl group;

R^2 is a hydrogen atom or a halogen atom; and

Z is a group represented by =CH—; or a salt thereof. Thus, Defendants' Mirabegron Products fall within the scope of at least Claim 1 of the '532 Patent.

140. For example, on information and belief, Defendants' Mirabegron Products comprise compounds of formula (Ia):

(Ia)



or a salt thereof. Thus, Defendants' Mirabegron Products fall within the scope of at least Claim 5 of the '532 Patent.

141. Defendants PharmaLabs have admitted that Defendants' Mirabegron Products contain mirabegron, a compound that infringes at least exemplary Claims 1 and 5 of the '532 Patent. *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1.

142. Defendants PharmaLabs have actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '532 Patent, no later than June 14, 2019.

143. Defendants PharmaLabs' acts of infringement have caused damage to Plaintiffs.

144. Defendants PharmaLabs' infringement of the '532 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

COUNT III: DIRECT INFRINGEMENT OF THE '117 PATENT BY DEFENDANT MENMD

145. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

146. Defendant menMD has directly infringed one or more claims of the '117 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell and/or selling Defendants' Mirabegron Products.

147. Claim 1 of the '117 Patent recites: "A crystal of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide having a heat absorption peak at 142 to 146° C. in the DSC analysis and having main peaks at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34 in the terms of 2θ(°) in the powder X-ray diffraction."

148. Defendant menMD admitted that Defendants' Mirabegron Products contain mirabegron, a synthetic chemical compound that is also known as "(R)-2-(2-aminothiazol-4-yl)-

4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide". *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1.

149. Defendant menMD also admitted that Defendants' Mirabegron Products contain crystalline mirabegron that exhibits XRPD peaks, including those at about 16.3 and 18.6° 2θ. α-Form crystals of mirabegron exhibit these two peaks, as well as main peaks at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34 in the terms of 2θ(°) in the powder X-ray diffraction. *See, e.g.*, Figure 4 of the '117 Patent. α-Form crystals of mirabegron also exhibit a heat absorption peak at 142 to 146° by DSC as shown in Figure 5 of the '117 Patent. Thus, on information and belief, Defendants' Mirabegron Products fall within the scope of at least Claim 1 of the '117 Patent.

150. Defendant menMD had actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '117 Patent, no later than June 14, 2019.

151. Defendant menMD's acts of infringement have caused damage to Plaintiffs.

152. Defendant menMD's infringement of the '117 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

153. Plaintiffs have no adequate remedy at law to redress the infringement by Defendant menMD.

COUNT IV: DIRECT INFRINGEMENT OF THE '117 PATENT BY DEFENDANT PHARMALABS

154. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

155. Defendants PharmaLabs have directly infringed one or more claims of the '117 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell, and/or selling Defendants' Mirabegron Products.

156. Claim 1 of the ’117 Patent recites: “A crystal of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide having a heat absorption peak at 142 to 146° C. in the DSC analysis and having main peaks at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34 in the terms of 2θ(°) in the powder X-ray diffraction.”

157. Defendants PharmaLabs admitted that Defendants’ Mirabegron Products contain mirabegron, a synthetic chemical compound that is also known as “(R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide”. *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1.

158. Defendants PharmaLabs also admitted that Defendants’ Mirabegron Products contain crystalline mirabegron that exhibits XRPD peaks, including those at about 16.3 and 18.6° 2θ. α-Form crystals of mirabegron exhibit these two peaks, as well as main peaks at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34 in the terms of 2θ(°) in the powder X-ray diffraction. *See, e.g.*, Figure 4 of the ’117 Patent. α-Form crystals of mirabegron also exhibit a heat absorption peak at 142 to 146° by DSC as shown in Figure 5 of the ’117 Patent. Thus, on information and belief, Defendants’ Mirabegron Products fall within the scope of at least Claim 1 of the ’117 Patent.

159. Defendants PharmaLabs had actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the ’117 Patent, no later than June 14, 2019.

160. Defendants PharmaLabs’ acts of infringement have caused damage to Plaintiffs.

161. Defendants PharmaLabs’ infringement of the ’117 Patent have been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

162. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants PharmaLabs.

COUNT V: DIRECT INFRINGEMENT OF THE '049 PATENT BY DEFENDANT MENMD

163. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

164. Defendant menMD has directly infringed one or more claims of the '049 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell and/or selling Defendants' Mirabegron Products.

165. Claim 1 of the '049 Patent recites: "A solid pharmaceutical composition comprising the α-form crystal of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide and a pharmaceutically acceptable carrier."

166. Defendant menMD admitted that Defendants' Mirabegron Products contain mirabegron, a synthetic chemical compound that is also known as "(R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide". *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1. Defendants' Mirabegron Products are provided as capsules, which comprise a pharmaceutically acceptable carrier.

167. Defendant menMD also admitted that Defendants' Mirabegron Products contain crystalline mirabegron that exhibits XRPD peaks, including those at about 16.3 and 18.6° 2θ. **Exhibit R** at 2. α-Form crystals of mirabegron exhibit at least these two peaks in the terms of 2θ(°) in the powder X-ray diffraction. *See, e.g.*, Figure 4 of the '117 Patent. Thus, on information and belief, Defendants' Mirabegron Products fall within the scope of at least Claim 1 of the '049 Patent.

168. Defendant menMD had actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '049 Patent, no later than June 14, 2019.

169. Defendant menMD's acts of infringement have caused damage to Plaintiffs.

170. Defendant menMD's infringement of the '049 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

171. Plaintiffs have no adequate remedy at law to redress the infringement by Defendant menMD.

COUNT VI: DIRECT INFRINGEMENT OF THE '049 PATENT BY DEFENDANT PHARMALABS

172. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

173. Defendants PharmaLabs have directly infringed one or more claims of the '049 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(a), by using, manufacturing, importing, offering to sell, and/or selling Defendants' Mirabegron Products.

174. Claim 1 of the '049 Patent recites: "A solid pharmaceutical composition comprising the α-form crystal of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide and a pharmaceutically acceptable carrier."

175. Defendants PharmaLabs admitted that Defendants' Mirabegron Products contain mirabegron, a synthetic chemical compound that is also known as "(R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide". *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1. Defendants' Mirabegron Products are provided as capsules, which comprise a pharmaceutically acceptable carrier.

176. Defendants PharmaLabs also admitted that Defendants' Mirabegron Products contain crystalline mirabegron that exhibits XRPD peaks, including those at about 16.3 and 18.6° 2θ. α-Form crystals of mirabegron exhibit at least these two peaks in the terms of 2θ(°) in the powder X-ray diffraction. *See, e.g.*, Figure 4 of the '117 Patent. Thus, on information and belief, Defendants' Mirabegron Products fall within the scope of at least Claim 1 of the '049 Patent.

177. Defendants PharmaLabs had actual knowledge, or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the ’049 Patent, no later than June 14, 2019.

178. Defendants PharmaLabs’ acts of infringement have caused damage to Plaintiffs.

179. Defendant PharmaLabs’ infringement of the ’049 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

180. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants PharmaLabs.

COUNT VII: INDUCEMENT OF THE ’474 PATENT BY DEFENDANTS

181. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

182. Defendants have induced infringement of one or more claims of the ’474 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(b), by offering to sell and/or selling Defendants’ Mirabegron Products for treating overactive bladder.

183. Claim 1 of the ’474 Patent recites: “A method for treating overactive bladder comprising administering an effective amount of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a salt thereof as an active ingredient to a subject in need thereof.”

184. Defendants admitted that Defendants’ Mirabegron Products contain the active ingredient mirabegron, a synthetic chemical compound that is also known as “(R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide.” *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1. On information and belief, Defendants’ Mirabegron Products are sold as capsules comprising an effective amount of mirabegron, 20 or 40 mg, for treating overactive bladder in a patient in need thereof. *See e.g.*, **Exhibit P** at 4, **Exhibit Q** at 4, **Exhibit R** at 3.

185. On information and belief, Defendants actively encourage and encouraged its customers, including healthcare providers and/or patients in need thereof to use the Defendants' Mirabegron Products to treat overactive bladder knowing that the aforementioned use would constitute direct infringement of at least exemplary Claim 1 of the '474 Patent.

186. Defendants had actual knowledge or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '474 Patent, and of their infringement of those patents, at least as of June 14, 2019.

187. Defendants actively encourage use of the Defendants' Mirabegron Products specifically for the treatment of overactive bladder on its website, price lists, and prescription order forms. *See e.g.*, **Exhibit P** at 4, **Exhibit Q** at 4, **Exhibit S** at 1. Thus, by offering Defendants' Mirabegron Products on menMD's website, price lists, and prescription order forms for the patented use, Defendants knowingly took steps to induce direct infringement of exemplary Claim 1 by their customers, including healthcare providers and/or patients in need thereof to use the Defendants' Mirabegron Products.

188. Defendants' acts of infringement have caused damage to Plaintiffs.

189. Defendants' infringement of the '474 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

190. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants.

COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT BY DEFENDANTS

191. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

192. Defendants have contributed to the infringement of one or more claims of the '474 Patent, including at least exemplary Claim 1, in violation of 35 U.S.C. § 271(c), by importing, offering to sell and/or selling Defendants' Mirabegron Products.

193. Claim 1 of the '474 Patent recites: "A method for treating overactive bladder comprising administering an effective amount of (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a salt thereof as an active ingredient to a subject in need thereof."

194. Defendants admitted that Defendants' Mirabegron Products contain the active ingredient mirabegron, a synthetic chemical compound that is also known as "(R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide." *See e.g.*, **Exhibit J** at 1, **Exhibit R** at 1. On information and belief, Defendants' Mirabegron Products are sold as capsules comprising an effective amount of mirabegron, 20 or 40 mg, for treating overactive bladder in a subject in need thereof. *See e.g.*, **Exhibit P** at 4, **Exhibit Q** at 4, **Exhibit R** at 3. Thus, Defendants' Mirabegron Products are a material part of the invention, knowing the same to be especially made for use as claimed by at least exemplary Claim 1 of the '474 Patent.

195. Defendants admitted that it had started offering to sell and selling Defendants' Mirabegron Products. *See* **Exhibit J** at 1.

196. The FDA has not approved any mirabegron containing product for use other than to treat overactive bladder. The only reasonable use for Defendants' Mirabegron Products is to practice the method of treating overactive bladder in accordance with exemplary Claim 1 of the '474 Patent and there is no substantial noninfringing use. Defendants' Mirabegron Products are not staple articles or commodities of commerce and Defendants had reason to believe that their customers, including healthcare providers and/or patients in need thereof would use the

Defendants' Mirabegron Products to treat overactive bladder knowing that the aforementioned use would constitute direct infringement of at least exemplary Claim 1 of the '474 Patent. The menMD website states that the Defendants' Mirabegron Products are for use to treat overactive bladder, including the urinary incontinence symptom of overactive bladder. On information and belief, Defendants' Mirabegron Products are accompanied by instructions instructing the use of the Defendants' Mirabegron Products to treat overactive bladder knowing that the aforementioned use would constitute direct infringement of at least exemplary Claim 1 of the '474 Patent.

197. On information and belief, when Defendants receive an order for Defendants' Mirabegron Products, they will contribute to the direct infringement of others by providing to their customers, including healthcare providers and/or patients, a mirabegron capsule formulation comprising an effective amount of the mirabegron to treat overactive bladder. On information and belief, Defendants' customers, including healthcare providers and/or patients administer an effective amount of mirabegron in a manner that infringes one or more claims of the '474 Patent, including at least exemplary Claim 1.

198. Defendants had actual knowledge or at the very least constructive knowledge, of Myrbetriq® Tablets and its Orange Book listed patents, including the '474 Patent, and of Defendants' Mirabegron Products being especially made for a use that infringes the '474 Patent, at least as of June 14, 2019.

199. On information and belief, mirabegron is the only active ingredient in Defendants' Mirabegron Products. Thus, Defendants' Mirabegron Products constitute a material part of the invention of the '474 Patent.

200. Defendant menMD's website, price lists, and prescription order forms lists Defendants' Mirabegron Products specifically and only for the treatment of overactive bladder as

claimed in the ’474 Patent. *See e.g.*, **Exhibit P** at 4, **Exhibit Q** at 4, **Exhibit S** at 1. Thus, Defendants’ Mirabegron Products have no substantial non-infringing uses.

201. Defendants’ acts of infringement have caused damage to Plaintiffs.

202. Defendants’ infringement of the ’474 Patent has been willful and deliberate. Plaintiffs have been damaged and otherwise harmed by such willful infringement.

203. Plaintiffs have no adequate remedy at law to redress the infringement by Defendants.

JURY DEMAND

204. Plaintiffs demand a trial by jury of all issues triable of right by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs APInc, AICL, APUI, and APGD, pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment that each Defendant has infringed the ’532, ’117, ’049, and ’474 Patents;

B. An order preliminarily and permanently enjoining each Defendant and its officers, agents, servants, attorneys, employees, all parent and subsidiary corporations, its assigns and successors in interest, and those acting in privity or concert therewith, from continuing and/or future acts of infringements of the ’117, ’049, and ’474 Patents;

C. An award of damages or other monetary relief in an amount sufficient to compensate Plaintiffs for Defendants’ wrongful infringing acts of the ’532, ’117, ’049, and ’474 Patents, together with pre- and post-judgment interest and costs under 35 U.S.C. § 284;

D. A finding that each Defendant’s infringement has been willful trebling the damages awarded to Plaintiffs under 35 U.S.C. § 284;

E. A declaration that this case is exceptional under 35 U.S.C. § 285 and awarding Plaintiffs their costs, expenses, and reasonable attorneys' fees;

F. An accounting of each Defendant's infringing activities through trial and judgment; and

G. Such further and other relief as this Court deems just and proper.

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Dated: October 5, 2023

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
405 N. King St., 8th Floor
Wilmington, DE 19801
(302) 984-6331
dsilver@mccarter.com
ajoyce@mccarter.com

Simon D. Roberts
Jason A. Leonard
Vincent Li
Jayita Guhaniyogi
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852

Attorneys for Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., Astellas Pharma US, Inc., and Astellas Pharma Global Development, Inc.