

**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, |) | C.A. No. _____ |
| INC., |) | |
| |) | |
| Plaintiffs, |) | |
| |) | JURY TRIAL DEMANDED |
| v. |) | |
| |) | |
| EVITALIN LLC, d/b/a menMD, |) | |
| PHARMALABS, LLC, and |) | |
| PHARMALABS HOLDCO, INC., |) | |

Defendant.

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. (“API”) 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. API 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 API.

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 API.

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 API.

B. Evitalin LLC, d/b/a menMD (“Evitalin” or “menMD”)

5. On information and belief, Defendant Evitalin LLC does business, *inter alia*, under the name “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, 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”)

8. 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.

9. On information and belief, PharmaLabs, LLC is a compounding pharmacy that is in the business of making and selling, *inter alia*, pharmaceutical products.

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

11. On information and belief, 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.

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

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

NATURE OF ACTION

14. 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 menMD based on menMD's infringement of United States Patent Nos. 6,346,532 ("the '532 Patent"), 7,342,117 ("the '117 Patent"), 7,982,049 ("the '049 Patent"), 8,835,474 ("the '474 Patent"), and RE44,872 ("the '872 Patent").

15. This action relates to menMD's selling and offering to sell mirabegron immediate release capsules in the 20mg and 40mg dosage strengths ("Mirabegron Products").

JURISDICTION AND VENUE

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

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

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

19. On information and belief, 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.

20. On information and belief, 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.

21. On information and belief, 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.

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

23. This Court has personal jurisdiction over PharmaLabs, LLC at least because, on information and belief, PharmaLabs, LLC is a limited liability company organized and existing under the laws of Delaware. On information and belief, 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, PharmaLabs, LLC had a retail pharmacy drug wholesale distributor license in Florida, but that license was withdrawn.

24. On information and belief, 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.

25. On information and belief, PharmaLabs, LLC, together with its affiliates, partners, and/or agents, engage 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.

26. On information and belief, 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.

27. On information and belief, 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.

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 PharmaLabs, LLC.

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

30. On information and belief, 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.

31. On information and belief, PharmaLabs HoldCo, Inc. together with its affiliates, partners, and/or agents, engage 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, 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.

33. On information and belief, 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.

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 PharmaLabs HoldCo, Inc.

35. On information and belief, 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.

36. On information and belief, in the State of Florida, where 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.

37. On information and belief, 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.

38. On information and belief, in the State of Florida, where 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.

39. On information and belief, 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.

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

PATENTS-IN-SUIT

A. The '532 Patent

41. 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.

42. The '532 Patent claims, *inter alia*, the compound mirabegron and compositions containing mirabegron.

43. The '532 Patent also claims, *inter alia*, a pharmaceutical composition containing mirabegron as an active ingredient.

44. The '532 Patent expired on March 27, 2022.

45. The '532 Patent was listed in the United States Food and Drug Administration ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") as covering Astellas' Myrbetriq® products shortly after the Myrbetriq® products were approved in 2012 until the expiry of its patent term and all regulatory exclusivities granted by FDA.

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

B. The '117 Patent

47. 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.

48. The '117 Patent claims, *inter alia*, crystal forms of mirabegron.

49. The '117 Patent expires no earlier than November 4, 2023.

50. The '117 Patent has been listed in the Orange Book as covering Astellas' Myrbetriq® products since shortly after the Myrbetriq® products were approved by FDA in 2012.

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

C. The '049 Patent

52. 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.

53. The '049 Patent claims, *inter alia*, pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier.

54. The '049 Patent expires no earlier than November 4, 2023.

55. The '049 Patent has been listed in the Orange Book as covering Astellas' Myrbetriq® products since shortly after the Myrbetriq® products were approved by FDA in 2012.

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

D. The '474 Patent

57. 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.

58. The '474 Patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron.

59. The '474 Patent expires no earlier than November 4, 2023.

60. The '474 Patent has been listed in the Orange Book as covering Astellas' Myrbetriq® products since shortly after its issuance in 2014.

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

E. The '872 Patent

62. The PTO duly and legally issued the '872 Patent, entitled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," on April 29, 2014. A true and correct copy of the '872 patent is attached as Exhibit E.

63. The '872 Patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to adult subjects.

64. The '872 Patent also claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to non-adult subjects that are not suffering from diabetes.

65. The '872 Patent expires no earlier than November 4, 2023.

66. The '872 Patent has been listed in the Orange Book as covering Astellas' Myrbetriq® products since shortly after its issuance in 2014.

67. Astellas has complied with the applicable marking requirements of 35 U.S.C. § 287 with respect to the '872 Patent.

FACTUAL BACKGROUND

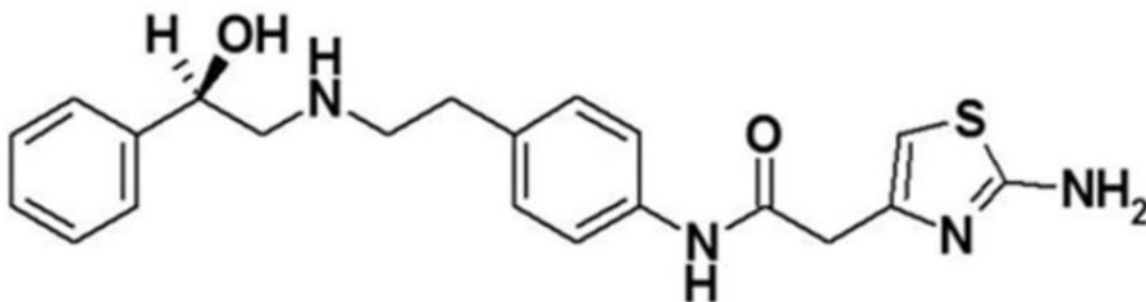
A. Myrbetriq®

68. 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 FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® Tablets.

69. The FDA granted Myrbetriq® regulatory exclusivities, including on the patents-in-suit, that do not expire until at least May 4, 2024.

70. The only FDA-approved formulations containing mirabegron that the FDA has determined to be sufficiently safe and effective for marketing approval are 25 mg and 50 mg extended-release formulations of mirabegron, including Myrbetriq® Tablets.

71. 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, and 2-(2-aminothiazol-4-yl)-N-[4-(2-[[[(2R)-2-hydroxy-2-phenylethyl]amino]ethyl]phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



72. A mirabegron immediate-release formulation was found to be associated with an undesirable food effect that can cause harmful cardiovascular side effects.

73. Myrbetriq® Tablets are indicated for, *inter alia*, the treatment of overactive bladder (“OAB”).

74. API is the assignee of the '532, '117, '049, '474, and '872 Patents.

75. AICL is the exclusive licensee of the '532, '117, '049, '474 and '872 Patents 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.

76. 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.

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

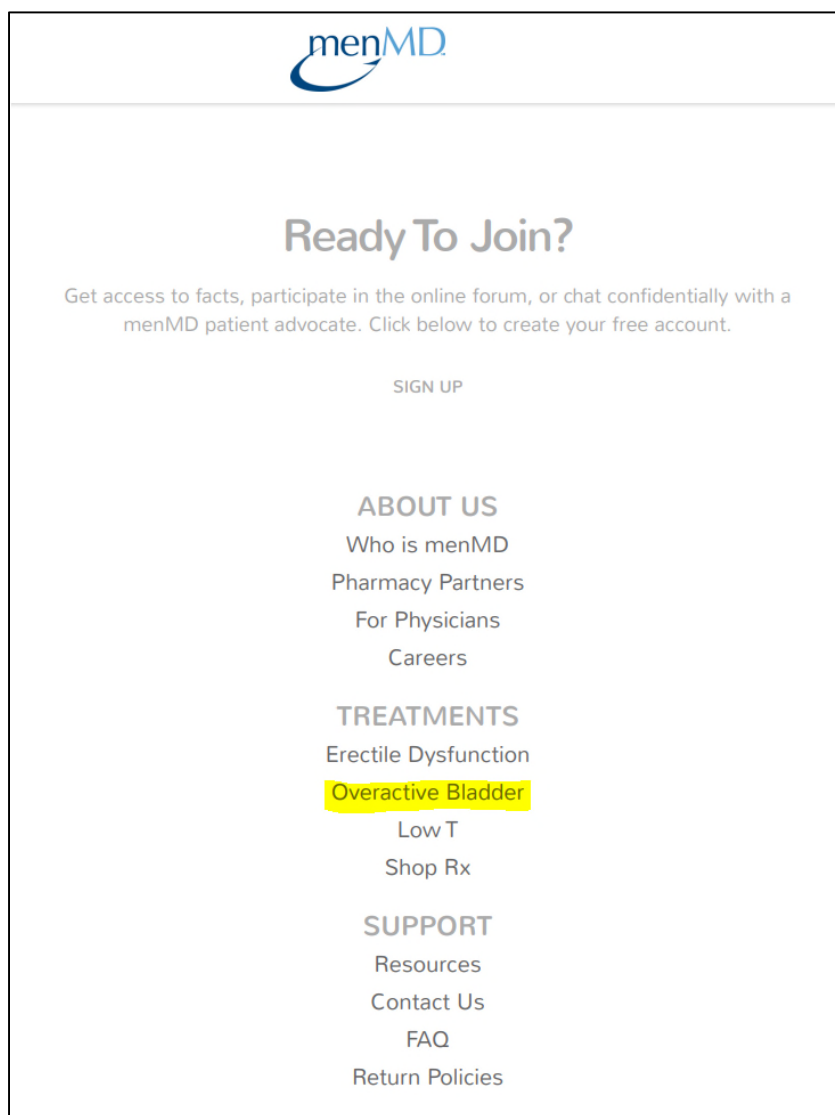
78. Myrbetriq® Tablets are covered by, *inter alia*, the patents listed currently or at any time in the Orange Book associated with Myrbetriq® Tablets, including one or more claims of each of the '532, '117, '049, '474, and '872 Patents.

B. Defendants' Infringing Product and Activities

79. On information and belief, since at least 2013, menMD has provided an online platform that, *inter alia*, helps fill various treatment orders from healthcare providers through partnering pharmacies. On information and belief, menMD has been in the business, *inter alia*, of providing sales, marketing, and consulting services to the medical community. On information and belief, 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, 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 menMD’s webpage at <https://menmd.com/about/> as of May 16, 2023 is attached as Exhibit F.

80. On information and belief, on or before May 2019, menMD, directly or indirectly through its affiliates, partners, and agents, started manufacturing, distributing, importing, marketing, selling and/or offering for sale various treatments for bladder control conditions, including 20 mg and 40 mg immediate release mirabegron formulations (“menMD’s Mirabegron Products”), through its website. On information and belief, menMD’s 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:



81. On information and belief menMD’s Mirabegron Products have not been the subject of any marketing approval applications to the FDA, nor have menMD’s Mirabegron Products been approved by the FDA as a sufficiently safe and effective treatment for OAB.

82. On or about June 14, 2019, Astellas sent a cease and desist letter to menMD informing menMD of, *inter alia*, its unlawful sales and offers for sale of unapproved 40 mg immediate-release version of Myrbetriq®, including menMD’s Mirabegron Products, through its

website at <http://menmd.com/mirabegron>. More specifically, Astellas' June 14, 2019 letter notified menMD that by marketing and selling menMD's Mirabegron Products, menMD had infringed at least U.S. Patent No. 6,346,532 (the "532 Patent"), which was then-unexpired and listed in FDA's Orange Book for Myrbetriq®. A true and correct copy of this letter is attached Exhibit H.

83. On or about June 21, 2019, menMD responded to Astellas' June 14, 2019 letter. A true and correct copy of this letter is attached Exhibit I.


84. On or about June 28, 2019, menMD responded further to Astellas' June 14, 2019 letter, indicating that it had, *inter alia*, ceased marketing, offering to sell and selling its Mirabegron Products. In its June 28, 2019 letter, menMD represented that it "only started offering to sell and selling [its Mirabegron Products] on June 14, 2019, the date of Astellas' cease and desist letter." menMD also represented that it stopped referring patients to its dispensing pharmacy upon receipt of Astellas' June 14, 2019 letter. menMD further represented that any sales of its Mirabegron Products would have occurred between June 14-17, 2019. menMD refused to provide the identities of its suppliers of its compounded Mirabegron Products and mirabegron API used to formulate those products. A true and correct copy of this letter is attached Exhibit J.


85. On information and belief, on or before September 2022, menMD, directly or indirectly through its affiliates, partners, and agents, were offering for sale and selling its Mirabegron Products 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:

The screenshot shows a webpage with the following content:

Treatment Options for Male Incontinence

The good news is – there are plenty of options for treating incontinence. Dive in and learn which ones might work best for you.

Tamsulosin
Alpha Blocker

[LEARN MORE](#) >
 Compare

Mirabegron
Beta-3 Adrenergic Agonist

[LEARN MORE](#) >
 Compare

86. On information and belief, on or before September 2022, menMD, directly or indirectly through its affiliates, partners, and agents, offered further details about its Mirabegron Products through its website. 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:

The Wayback Machine - <https://web.archive.org/web/20220929023536/https://menmd.com/product/mirabegron/>



MALE INCONTINENCE / MIRABEGRON



Mirabegron
Beta-3 Adrenergic Agonist

AT A GLANCE

- Used to treat urinary incontinence
- Used in both men and women

THE DETAILS

Mirabegron is a beta-3 adrenergic receptor agonist that communicates with a specific cell type in the bladder muscle to relax it and reduce symptoms of urinary incontinence.

Rx Required

Starts at \$89 per 30 Capsules

87. On information and belief, on or about February 2023, menMD, directly or indirectly through its affiliates, partners, and agents, listed its 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.

88. On or about February 15, 2023, Astellas sent another cease and desist letter to menMD informing them that their sales of menMD’s Mirabegron Products were unlawful because,

inter alia, they infringed at least the '117, '049, '474, and '872 Patents. A true and correct copy of this letter is attached Exhibit N.

89. On or about February 24, 2023, menMD responded to Astellas' February 15, 2023 letter. A true and correct copy of this letter is attached Exhibit O. menMD's February 24, 2023 letter claimed, *inter alia*, that menMD "has stopped printing any marketing materials concerning mirabegron and has taken down all statements about mirabegron from its website." See Exhibit O at 1.

90. On information and belief, on or about March 2023, menMD, directly or indirectly through its affiliates, partners, and agents, continued to list its Mirabegron Products on its "Patient-specific price list" dated March 28, 2023; a true and correct copy is also attached as Exhibit P.

91. On information and belief, on or about March 2023, menMD, directly or indirectly through its affiliates, partners, and agents, continued to list its Mirabegron Products on the menMD Prescription Order Form, updated March 28, 2023; a true and correct copy is also attached as Exhibit Q.

92. On information and belief, on or about March 2023, menMD, directly or indirectly through its affiliates, partners, and agents, continued to target healthcare professionals and provided them with marketing and promotional information for its Mirabegron Products, and Price List and Prescription Order Form listing those products. On information and belief, on or about March 2023, menMD, directly or indirectly through its affiliates, partners, and agents, continued to encourage healthcare professionals to prescribe its Mirabegron Products to patients in need. On information and belief, menMD encouraged healthcare professionals to order its Mirabegron Products through PharmaLabs, located at 10901 Roosevelt Boulevard N, Suite #1200C, St. Petersburg, FL 33716.

93. On information and belief, PharmaLabs is a compounding pharmacy. On information and belief, PharmaLabs is in the business of providing medications as a compounding pharmacy at least 2012. On information and belief, PharmaLabs is a pharmacy partner of menMD.

94. On information and belief, PharmaLabs and menMD have certain common officers. On information and belief, PharmaLabs is an alter ego of menMD.

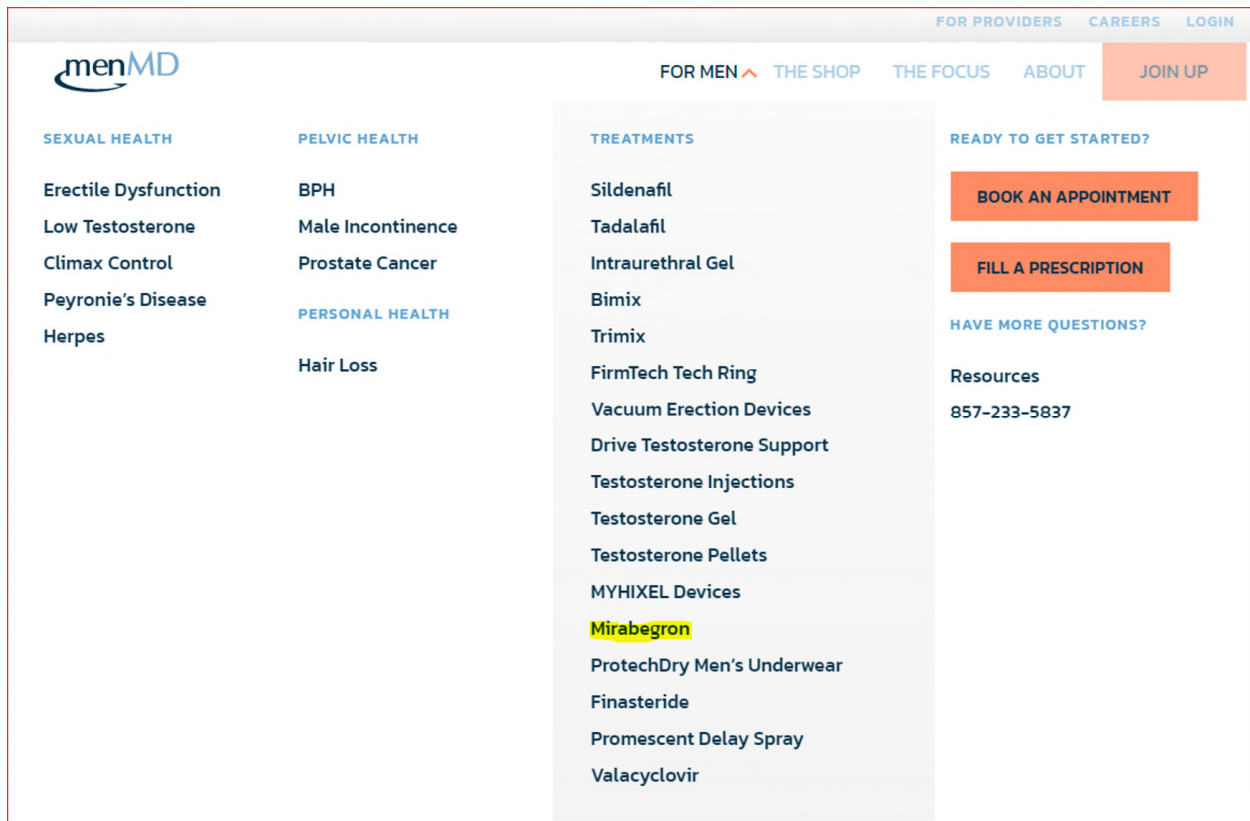
95. On information and belief, PharmaLabs makes, *inter alia*, menMD's Mirabegron Products, and/or provides those products to patients in need thereof. On information and belief, PharmaLabs makes, uses, or imports mirabegron active pharmaceutical ingredient ("API") to make menMD's Mirabegron Products and has done since at least May 2019.

96. On information and belief, when patients filled prescriptions of menMD's Mirabegron Products, PharmaLabs provided instructions to patients in need on how to use those products, including for the treatment of overactive bladder. On information and belief, PharmaLabs directs patients to menMD for instructions on how to use its products, including for the treatment of overactive bladder.

97. On or about April 7, 2023, menMD sent Astellas a follow-up letter to its February 24, 2023 letter. A true and correct copy of this letter is attached Exhibit R. In this April 7, 2023 letter, menMD admitted that the mirabegron used in its Mirabegron Products is crystalline and contains certain peaks as measured by x-ray powder diffraction. On information and belief, menMD's Mirabegron Products contain the crystalline form(s) of mirabegron as claimed in the '117 and '049 Patents.

98. On information and belief, despite menMD's representations in its February 24, 2023 letter that it has taken down all statements about mirabegron from its website, menMD has

continued to sell, and offer to sell menMD's Mirabegron Products through its website <https://menmd.com/>, as excerpted and highlighted below:



99. Despite its representations in its February 24, 2023 letter, menMD continues to sell menMD's Mirabegron Products through its website <https://menmd.com/product/mirabegron/>. menMD continues to offer incentives to its customers to purchase menMD's 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, menMD promote menMD's Mirabegron Products stating that they are "immediate release capsules" and that they are "used to treat urinary incontinence" and helps "prevent urgent, frequent, or uncontrolled urination." In order to promote the efficacy of menMD's Mirabegron Products, 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:

menMD

MALE INCONTINENCE / MIRABEGRON

Mirabegron
Capsules

Mirabegron
Capsules

Mirabegron

Beta-3 Adrenergic Agonist

AT A GLANCE

- Used to treat urinary incontinence
- Used in both men and women
- Immediate-release capsules available in 20mg and 40mg
- Relaxes the detrusor bladder muscle to help hold more urine
- Helps prevent urgent, frequent, or uncontrolled urination

THE DETAILS

Mirabegron is a beta-3 adrenergic receptor agonist used in adults to treat overactive bladder. It works by relaxing the detrusor smooth muscle to reduce symptoms of an overactive bladder.

Transfer and Save! Already have a doctor's prescription for Mirabegron? Transfer your existing prescription to menMD and get your first month free!

Prescription Required

Starts at \$69 for 30 Day Supply

GET STARTED WITH MIRABEGRON

100. On information and belief, at least as of March 28, 2023, menMD continued to sell and offer to sell mirabegron by listing it in its patient-specific price list. *See* Exhibit P.

101. On information and belief, upon receiving orders from customers, menMD will provide its Mirabegron Products, with instructions to use them to treat overactive bladder.

CLAIMS FOR RELIEF

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

102. Plaintiffs incorporate by reference and reallege paragraphs 1 through 101 above as though fully restated herein.

103. menMD has infringed one or more claims of the '532 Patent under 35 U.S.C. § 271(a) at least by importing, using, manufacturing, offering to sell and/or selling mirabegron, and/or products containing mirabegron prior to the expiration of the '532 Patent.

104. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '532 Patent, at least as of June 14, 2019. menMD had actual notice of the '532 Patent at least as of June 14, 2019.

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

106. Plaintiffs incorporate by reference and reallege paragraphs 1 through 105 above as though fully restated herein.

107. PharmaLabs has infringed one or more claims of the '532 Patent under 35 U.S.C. § 271(a) at least by importing, using, manufacturing, offering to sell and/or selling mirabegron, and/or products containing mirabegron prior to the expiration of the '532 Patent.

108. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '532 Patent, at least as of June 14, 2019, at least through common officers of menMD.

PharmaLabs had actual notice of the '532 Patent at least as of June 14, 2019, at least through common officers of menMD.

109. PharmaLabs' acts of infringement have caused damage to Plaintiffs. menMD's 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 MENMD

110. Plaintiffs incorporate by reference and reallege paragraphs 1 through 109 above as though fully restated herein.

111. menMD has infringed, and is infringing, one or more claims of the '117 Patent under 35 U.S.C. § 271(a) at least by offering to sell and/or selling products containing the claimed crystal forms of mirabegron.

112. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '117 Patent, at least as of June 14, 2019. menMD had actual notice of the '117 Patent at least as of February 15, 2023.

113. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '117 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

114. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

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

115. Plaintiffs incorporate by reference and reallege paragraphs 1 through 114 above as though fully restated herein.

116. PharmaLabs has infringed, and is infringing, one or more claims of the '117 Patent under 35 U.S.C. § 271(a) at least by making, using, offering to sell and/or selling products containing the claimed crystal forms of mirabegron.

117. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '117 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '117 Patent at least as of February 15, 2023, at least through common officers of menMD.

118. PharmaLabs' acts of infringement have caused damage to Plaintiffs. PharmaLabs' infringement of the '117 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

119. Plaintiffs have no adequate remedy at law to redress the infringement by PharmaLabs. PharmaLabs' infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

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

120. Plaintiffs incorporate by reference and reallege paragraphs 1 through 119 above as though fully restated herein.

121. menMD has infringed, and is infringing, one or more claims of the '049 Patent under 35 U.S.C. § 271(a) at least by offering to sell and/or selling pharmaceutical compositions comprising the claimed crystal forms of mirabegron and a pharmaceutically acceptable carrier.

122. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '049 Patent, at least as of June 14, 2019. menMD had actual notice of the '049 Patent at least as of February 15, 2023.

123. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '049 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

124. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

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

125. Plaintiffs incorporate by reference and reallege paragraphs 1 through 124 above as though fully restated herein.

126. PharmaLabs has infringed, and is infringing one or more claims of the '049 Patent under 35 U.S.C. § 271(a) at least by making, using, offering to sell and/or selling products containing the claimed crystal forms of mirabegron.

127. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '049 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '049 Patent at least as of February 15, 2023, at least through common officers of menMD.

128. PharmaLabs' acts of infringement have caused damage to Plaintiffs. PharmaLabs' infringement of the '049 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

129. Plaintiffs have no adequate remedy at law to redress the infringement by PharmaLabs. PharmaLabs' infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

COUNT VII: INDUCEMENT OF THE '474 PATENT BY MENMD

130. Plaintiffs incorporate by reference and reallege paragraphs 1 through 129 above as though fully restated herein.

131. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '474 Patent, at least as of June 14, 2019. menMD had actual notice of the '474 Patent at least as of February 15, 2023.

132. menMD actively induces its customers to order mirabegron formulations for the treatment of overactive bladder as described in the '474 Patent.

133. menMD knew that mirabegron is described in claimed in the '474 Patent to treat overactive bladder.

134. On information and belief, when menMD receives an order for mirabegron, it will provide the mirabegron compound in a formulation to treat overactive bladder in manner that infringes one or more claims of the '474 Patent.

135. menMD's actions have induced infringement of, and will continue to induce others to infringe, the '474 Patent under 35 U.S.C. § 271(b).

136. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '474 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

137. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

**COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT BY
MENMD**

138. Plaintiffs incorporate by reference and reallege paragraphs 1 through 137 above as though fully restated herein.

139. menMD offers to sell and sells mirabegron-containing formulations in the United States.

140. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '474 Patent, at least as of June 14, 2019. menMD had actual notice of the '474 Patent at least as of February 15, 2023.

141. menMD's Mirabegron Products constitutes a material part of the invention of the '474 Patent and has no substantial non-infringing uses.

142. On information and belief, menMD has had and continues to have knowledge that its Mirabegron Products are especially adapted for a use that infringes one or more claims of the '474 Patent.

143. On information and belief, menMD has had and continues to have knowledge that there is no substantial non-infringing use of its Mirabegron Products.

144. menMD's actions have constituted as contributory infringement, and will continue to constitute as contributory infringement, of the '474 Patent under 35 U.S.C. § 271(c).

145. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '474 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

146. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

COUNT IX: INDUCEMENT OF THE '474 PATENT BY PHARMALABS

147. Plaintiffs incorporate by reference and reallege paragraphs 1 through 146 above as though fully restated herein.

148. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '474 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '474 Patent at least as of February 15, 2023, at least through common officers of menMD.

149. PharmaLabs, either directly or through menMD actively induces its customers to order mirabegron formulations for the treatment of overactive bladder as described in the '474 Patent.

150. PharmaLabs knew that mirabegron is described in claimed in the '474 Patent to treat overactive bladder.

151. On information and belief, when PharmaLabs receives an order for mirabegron, it will make and sell the mirabegron compound in a formulation to treat overactive bladder in manner that infringes one or more claims of the '474 Patent.

152. PharmaLabs actions have induced infringement of, and will continue to induce others to infringe, the '474 Patent under 35 U.S.C. § 271(b).

153. PharmaLabs' acts of infringement have caused damage to Plaintiffs. PharmaLabs' infringement of the '474 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

154. Plaintiffs have no adequate remedy at law to redress the infringement by PharmaLabs. PharmaLabs' infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless PharmaLabs' infringement is enjoined by this Court.

**COUNT X: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT BY
PHARMALABS**

155. Plaintiffs incorporate by reference and reallege paragraphs 1 through 154 above as though fully restated herein.

156. On information and belief, PharmaLabs makes, offers to sell and sells mirabegron-containing formulations in the United States, including menMD's Mirabegron Products.

157. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '474 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '474 Patent at least as of February 15, 2023, at least through common officers of menMD.

158. menMD's Mirabegron Products constitutes a material part of the invention of the '474 Patent and has no substantial non-infringing uses.

159. On information and belief, PharmaLabs has had and continues to have knowledge that its Mirabegron Products are especially adapted for a use that infringes one or more claims of the '474 Patent.

160. On information and belief, PharmaLabs has had and continues to have knowledge that there is no substantial non-infringing use of its Mirabegron Products.

161. PharmaLabs' actions have constituted as contributory infringement, and will continue to constitute as contributory infringement, of the '474 Patent under 35 U.S.C. § 271(c).

162. PharmaLabs' acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '474 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

163. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

COUNT XI: INDUCEMENT OF THE '872 PATENT BY MENMD

164. Plaintiffs incorporate by reference and reallege paragraphs 1 through 163 above as though fully restated herein.

165. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '872 Patent, at least as of June 14, 2019. menMD had actual notice of the '872 Patent at least as of February 15, 2023.

166. menMD actively induces its customers to order mirabegron formulations for the treatment of overactive bladder as described in the '872 Patent.

167. menMD knew that mirabegron is described in claimed in the '872 Patent to treat overactive bladder.

168. On information and belief, when menMD receives an order for mirabegron, it will provide the mirabegron compound in a formulation to treat overactive bladder in manner that infringes one or more claims of the '872 Patent.

169. menMD's actions have induced infringement of, and will continue to induce others to infringe, the '872 Patent under 35 U.S.C. § 271(b).

170. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '872 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

171. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

COUNT XII: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT BY MENMD

172. Plaintiffs incorporate by reference and reallege paragraphs 1 through 171 above as though fully restated herein.

173. menMD offers to sell and sells mirabegron-containing formulations in the United States.

174. menMD had knowledge of Myrbetriq® and its Orange Book listed patents, including the '872 Patent, at least as of June 14, 2019. menMD had actual notice of the '872 Patent at least as of February 15, 2023.

175. menMD's Mirabegron Products constitutes a material part of the invention of the '872 Patent and has no substantial non-infringing uses.

176. On information and belief, menMD has had and continues to have knowledge that its Mirabegron Products are especially adapted for a use that infringes one or more claims of the '872 Patent.

177. On information and belief, menMD has had and continues to have knowledge that there is no substantial non-infringing use of its Mirabegron Products.

178. menMD's actions have constituted as contributory infringement, and will continue to constitute as contributory infringement, of the '872 Patent under 35 U.S.C. § 271(c).

179. menMD's acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '872 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

180. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

COUNT XIII: INDUCEMENT OF THE '872 PATENT BY PHARMALABS

181. Plaintiffs incorporate by reference and reallege paragraphs 1 through 180 above as though fully restated herein.

182. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '872 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '872 Patent at least as of February 15, 2023, at least through common officers of menMD.

183. PharmaLabs, either directly or through menMD actively induces its customers to order mirabegron formulations for the treatment of overactive bladder as described in the '872 Patent.

184. PharmaLabs knew that mirabegron is described in claimed in the '872 Patent to treat overactive bladder.

185. On information and belief, when PharmaLabs receives an order for mirabegron, it will make and sell the mirabegron compound in a formulation to treat overactive bladder in manner that infringes one or more claims of the '872 Patent.

186. PharmaLabs actions have induced infringement of, and will continue to induce others to infringe, the '872 Patent under 35 U.S.C. § 271(b).

187. PharmaLabs' acts of infringement have caused damage to Plaintiffs. PharmaLabs' infringement of the '872 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

188. Plaintiffs have no adequate remedy at law to redress the infringement by PharmaLabs. PharmaLabs' infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless PharmaLabs' infringement is enjoined by this Court.

**COUNT XIV: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT BY
PHARMALABS**

189. Plaintiffs incorporate by reference and reallege paragraphs 1 through 188 above as though fully restated herein.

190. On information and belief, PharmaLabs makes, offers to sell and sells mirabegron-containing formulations in the United States, including menMD's Mirabegron Products.

191. PharmaLabs had knowledge of Myrbetriq® and its Orange Book listed patents, including the '872 Patent, at least as of June 14, 2019, at least through common officers of menMD. PharmaLabs had actual notice of the '872 Patent at least as of February 15, 2023, at least through common officers of menMD.

192. menMD's Mirabegron Products constitutes a material part of the invention of the '872 Patent and has no substantial non-infringing uses.

193. On information and belief, PharmaLabs has had and continues to have knowledge that its Mirabegron Products are especially adapted for a use that infringes one or more claims of the '872 Patent.

194. On information and belief, PharmaLabs has had and continues to have knowledge that there is no substantial non-infringing use of its Mirabegron Products.

195. PharmaLabs' actions have constituted as contributory infringement, and will continue to constitute as contributory infringement, of the '872 Patent under 35 U.S.C. § 271(c).

196. PharmaLabs' acts of infringement have caused damage to Plaintiffs. menMD's infringement of the '872 Patent has been and continues to be willful and deliberate. Plaintiffs have been and continue to be damaged and otherwise harmed by such willful infringement.

197. Plaintiffs have no adequate remedy at law to redress the infringement by menMD. menMD's infringement will continue, and will continue to cause irreparable harm to Plaintiffs unless menMD's infringement is enjoined by this Court.

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs API, 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, '474, and '872 Patents;

B. An order preliminarily and permanently enjoining each Defendants and their officers, agents, servants, attorneys, employees, all parent and subsidiary corporations, their 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, '474, and '872 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, '474, and '872 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.

Dated: June 9, 2023

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