**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**



OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S,

Plaintiffs,

v.

MYLAN LABORATORIES LIMITED, VIATRIS INC. AND MYLAN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:22-CV-114 (Kleeh)

**COMPLAINT FOR PATENT INFRINGEMENT**

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Mylan Laboratories Limited ("MLL"), Viatris Inc. ("Viatris") and Mylan Pharmaceuticals Inc. ("MPI") (collectively, "Defendants"), allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement of U.S. Patent No. 11,400,087 ("the '087 patent" or "the patent-in-suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") No. 216608 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell aripiprazole for extended-release injectable suspension, 300 mg/vial and 400 mg/vial ("Defendants' generic

products"), which are generic versions of Otsuka's ABILIFY MAINTENA® (aripiprazole), before the expiration of the patent-in-suit.

2. Plaintiffs filed separate actions involving the same ANDA No. 216608 against Defendants for patent infringement, which included counts for infringement of U.S. Patent Nos. 7,807,680 ("the '680 patent"), 8,030,313 ("the '313 patent"), 8,722,679 ("the '679 patent"), 8,399,469 ("the '469 patent"), 8,338,427 ("the '427 patent"), 10,525,057 ("the '057 patent"), 10,980,803 ("the '803 patent") and 11,154,553 ("the '553 patent") (collectively, "First Suit Patents"), first in the District of Delaware in *Otsuka Pharm. Co., Ltd. v. Mylan Lab. Ltd.*, C.A. No. 1-22-cv-00464-CFC (D. Del. filed Apr. 8, 2022) ("the First Delaware Suit") and second, in this Court in *Otsuka Pharm. Co., Ltd. v. Mylan Lab. Ltd.*, C.A. No. 1-22-cv-00032-TSK (N.D.W. Va. filed Apr. 8, 2022) ("the First West Virginia Suit") (collectively, "the First Suits").

3. The First Suits were filed in response to a letter from Defendants dated February 23, 2022 ("Defendants' First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 216608 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' First Notice Letter notified Otsuka that Defendants had filed ANDA No. 216608 to seek approval to engage in the manufacture, use and/or sale of Defendants' generic products before the expiration of the First Suit Patents.

4. Plaintiffs also filed separate actions involving the same ANDA No. 216608 against Defendants for patent infringement, which included counts for infringement of U.S. Patent No. 11,344,547 ("the '547 patent") ("Second Suit Patent"), first, in the District of Delaware in *Otsuka Pharm. Co., Ltd. v. Mylan Lab. Ltd.*, C.A. No. 1:22-cv-01125-CFC (D. Del. filed Aug. 26, 2022) ("the Second Delaware Suit") and second, in this Court in *Otsuka Pharm. Co., Ltd. v. Mylan Lab.*

*Ltd.*, C.A. No. 1-22-cv-00089-TSK (N.D.W. Va. filed Sep. 9, 2022) ("the Second West Virginia Suit") (collectively, "the Second Suits").

5. The Second Suits were filed in response to a new, second letter from Defendants dated July 26, 2022 ("Defendants' Second Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 216608 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' Second Notice Letter notified Otsuka that Defendants had filed ANDA No. 216608 to seek approval to engage in the manufacture, use and/or sale of Defendants' generic products before the expiration of the '547 patent.

6. Plaintiffs also filed separate actions involving the same ANDA No. 216608 against Defendants for patent infringement, which included counts for infringement of the '087 patent, in the District of Delaware in *Otsuka Pharm. Co., Ltd. v. Mylan Lab. Ltd.*, C.A. No. 1-22-cv-01226-CFC (D. Del. filed Sep. 20, 2022) ("the Third Delaware Suit") and in *Otsuka Pharm. Co., Ltd. v. Mylan Lab. Ltd.*, C.A. No. 1-22-cv-01367-CFC (D. Del. filed Oct. 17, 2022) ("the Fourth Delaware Suit").

7. This complaint is filed in response to a new, third letter from Defendants dated September 29, 2022 ("Defendants' Third Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 216608 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. The Fourth Delaware Action was also filed in response to Defendants' Third Notice Letter. Defendants' Third Notice Letter notified Otsuka that Defendants had filed ANDA No. 216608 to seek approval to engage in the manufacture, use and/or sale of Defendants' generic products before the expiration of the patent-in-suit.

## THE PARTIES

8. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, 101-8535, Japan.

9. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '087 patent.

10. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

11. Upon information and belief, MLL is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, India, 500034.

12. Upon information and belief, MLL is a wholly-owned subsidiary of Viatris. Upon information and belief, MLL is an affiliate and agent of MPI and Viatris.

13. Upon information and belief, Viatris is a corporation organized and existing under the laws of Delaware, having a place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317.

14. Upon information and belief, MPI is a corporation organized and existing under the laws of West Virginia, purporting to have a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505.

15. Upon information and belief, MPI is a wholly-owned subsidiary of Viatris. Upon information and belief, MPI is an agent and affiliate of MLL and Viatris and an alter ego of and subsumed within Viatris.

## JURISDICTION AND VENUE

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

17. Plaintiffs believe this case belongs in Delaware but are filing a case in this district out of an abundance of caution.

18. This Court has personal jurisdiction over MLL. Upon information and belief, MLL is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MLL directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, MLL purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

19. Upon information and belief, MLL is engaged in the development and manufacturing of Defendants' generic products. Upon information and belief, MLL applied for one or more patent applications directed to the preparation of aripiprazole. (*See, e.g.*, U.S. Published Patent Appl. No. 2019/0160002, titled "Process for Preparing Sterile Aripiprazole Formulation.")

20. Upon information and belief, MLL is the holder of FDA Drug Master File No. 31257 for aripiprazole monohydrate and FDA Drug Master File No. 19554 for aripiprazole USP.

21. This Court has personal jurisdiction over Viatris. Upon information and belief, Viatris is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Viatris directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Viatris purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

22. This Court has personal jurisdiction over MPI. Upon information and belief, MPI is in the business of manufacturing, marketing, importing and selling pharmaceutical drug

products, including generic drug products. Upon information and belief, MPI directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, MPI purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

23. Upon information and belief, including, based on, *inter alia*, Defendants' website, Defendants' publicly-available SEC 10-K filings and Defendants' publicly-available press releases, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because MLL is incorporated in India and may be sued in any judicial district in the United States.

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Viatris has committed acts of infringement and has a regular and established place of business in this judicial district. Upon information and belief, Viatris Inc. has a place of business at 5000 Greenbag Road, Morgantown, West Virginia, 26501 and 3711 Collins Ferry Road, Morgantown, West Virginia, 26505. Upon information and belief, Viatris, *inter alia*, in concert with MPI and MLL, developed and/or otherwise contributed to the development and/or filing of Defendants' ANDA for Defendants' generic products in this judicial district and intends to benefit from the ANDA. Upon information and belief, Viatris has committed and/or will commit acts of infringement in this judicial district.

26. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because MPI is incorporated in West Virginia.

27. Upon information and belief, Viatris' website states that "Viatris was formed in 2020 through the combination of Mylan and Upjohn, a legacy division of Pfizer. By integrating the strengths of these two companies, including our global workforce of ~38,000, we aim to deliver increased access to affordable, quality medicines for patients worldwide. Our global portfolio includes . . . generics, including branded and complex generics . . . . [W]e have . . . a balanced reach across North America . . . . We are domiciled in the United States . . . . We operate approximately 40 manufacturing sites, which produce oral solid doses, injectables, complex dosage forms and active pharmaceutical ingredients. . . . As we work to fully transition to the Viatris brand commercially and operationally around the world, you may continue to see both the Mylan and Upjohn names in certain markets." (https://www.viatris.com/en/about-us/our-story (accessed Apr. 5, 2022).)

28. Upon information and belief, Robert J. Coury, Executive Chairman of Viatris' Board, acknowledged "all of [Viatris'] approximately 37,000 employees around the globe for their unwavering commitment, dedication and performance." (*Viatris Inc. FQ3 2022 Earnings Call Transcripts*, S&P GLOBAL (Nov. 7, 2022).) These employees were brought to Viatris from "[two] great complementary organizations," Mylan and Upjohn, which merged "with the purpose of creating a sustainable global health care leader." (*Id.*) Coury emphasized that "[Viatris'] priorities have been clear: integrate the [two] organizations." (*Id.*)

29. Upon information and belief, Michael Goettler, CEO and Executive Director of Viatris, stated that "Mylan and legacy Upjohn['s merger] in November 2020[] really created a one-of-a-kind global biopharmaceutical company." (*Viatris, Inc. Company Presentation*, S&P GLOBAL (Sept. 15, 2022).)

30. Upon information and belief, any corporate separateness that existed between Viatris and MPI shortly after Viatris was formed has dissolved, and MPI is now no more than an alter ego for Viatris.

31. Upon information and belief, Viatris is working to fully transition the Viatris brand commercially and operationally around the world, and as a result, Viatris has been methodically divesting MPI properties, assuming corporate responsibilities of MPI, adopting MPI employees, commingling funds with MPI, and subsuming MPI into Viatris. Upon information and belief, until that process is complete, the public "may continue to see both the Mylan and Upjohn names in certain markets." (*See* https://www.viatris.com/en/about-us/our-story (accessed Apr. 5, 2022).)

32. Upon information and belief, after the announcement of the Mylan-Upjohn merger became public, the name "Viatris Inc." was registered with the Secretary of State in West Virginia. Upon information and belief, that name was initially reserved by Corporations Services Company at 209 WEST WASHINGTON STREET CHARLESTON WV 25302. (https://apps.sos.wv.gov/business/corporations/registration.aspx?org=16603 (accessed Nov. 9, 2022).) Upon information and belief, when Viatris was formed in November 2020, the name registration of "Viatris Inc." in West Virginia was completed by Viatris "c/o MYLAN INC. 1000 MYLAN BLVD CANNONSBURG PA 15317." (https://apps.sos.wv.gov/business/corporations/registration.aspx?org=16922 (accessed Nov. 9, 2022).)

33. Upon information and belief, as part of Viatris working to transition the Viatris brand commercially and operationally around the world, Viatris is methodically taking over the business of various Mylan entities, including MLL and MPI. For example, upon information and belief, before the formation of Viatris, the Customer No. for U.S. Patent Application Publication

No. 2019/1060002 titled "Process for Preparing Sterile Aripiprazole Formulation," was 122945. Upon information and belief, before the formation of Viatris, the correspondence address for that Customer No. was MPI, 5005 Greenbag Rd. Morgantown, WV 26501. Upon information and belief, that same Customer No. is currently associated with Viatris, 5000 Greenbag Road, Legal IP – GBR, Morgantown, WV 26501. Upon information and belief, the attorneys associated with this correspondence address have not changed despite the change in the addressee from MPI to Viatris.

34. Upon information and belief, MPI holds itself out to the public as "Mylan Pharmaceuticals Inc., a Viatris company." (*See, e.g.*, https://newsroom.viatris.com/2022-01-18-Mylan-Pharmaceuticals-Inc-,-a-Viatris-Company,-Conducting-Voluntary-Recall-of-One-Batch-of-Semglee-R-insulin-glargine-injection-,-100-units-mL-U-100-,-3-mL-Prefilled-Pens,-Due-to-the-Potential-for-a-Missing-Label-in-the-Batch (accessed Nov. 9, 2022).)

35. Upon information and belief, Viatris is step-wise dissolving MPI. For example, upon information and belief, MPI purports to have a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505. Upon information and belief, however, as of March 7, 2022, Viatris closed the facility at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505, and auctioned off its equipment. (*See, e.g.*, https://www.wboy.com/news/local/monongalia-and-preston/former-mylan-viatris-facility-auctions-off-equipment (accessed Nov. 9, 2022).) Upon information and belief, a "Permit to Operate" was issued to MPI by the State of West Virginia on March 9, 2017 as Permit No. R30-01600033-2017, which expired on March 9, 2022, and a renewal application was due on September 9, 2021. Upon information and belief, neither Viatris nor MPI has applied for renewal of a "Permit to Operate." *See* The First West Virginia Suit, D.I. 18 at 8 (MPI's Answer, Defenses, and Counterclaims to Plaintiffs' Complaint). Upon information and

belief, on March 31, 2022, West Virginia University took ownership of 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505 for the purchase price of $1. (*See, e.g.*, https://www.wdtv.com/2022/03/31/wvu-purchases-former-mylan-plant (accessed Nov. 9, 2022).) Upon information and belief, a government official released a statement on March 31, 2022, where he referred to the facility at 781 Chestnut Ridge Road as the "Viatris property." (*Id.*) Under information and belief, Viatris sold this property to West Virginia University.

36. Upon information and belief, Robert J. Coury, formerly the executive chairman of Mylan, is now the executive chairman of Viatris following the completion of the $27 billion combination of Mylan with Pfizer's Upjohn business to create Viatris. (https://www.viatris.com/en/about-us/our-leaders/robert-j-coury (accessed Nov. 9, 2022).) Upon information and belief, Mr. Coury "leads the [Viatris] board of directors, oversees the strategic direction of the company in collaboration with executive management, and advises the management team as they execute on the company's strategy to drive value creation . . . ." (*Id.*) Upon information and belief, Mr. Coury owns more than 10% of Viatris' equity securities. (*See* Viatris' SEC Form 5, filed February 11, 2022.) Upon information and belief, Mr. Coury and Viatris were intimately involved in the sale of the property at 781 Chestnut Ridge Road, Morgantown, West Virginia to West Virginia University. A government official stated, "I am thankful to President Gordon Gee, West Virginia University, and Viatris Executive Chairman Robert Coury for working diligently over the last several months to form this significant partnership that will lead to a bright new future for this impressive facility . . . ." (https://www.wvnews.com/ownership-of-mylan-plant-could-be-transferred-to-wvu/article_9f4a0be8-fb93-11eb-91fa-f3afcbcbeef6.html (accessed Nov. 9, 2022).) According to Viatris' executive chairman Mr. Coury, "Our goal has always been to identify a responsible new

steward for this unique site that would secure the best possible future for the facility, our impacted employees and the Morgantown community, a community that continues to play an important and vital role for Viatris." (https://wvutoday.wvu.edu/stories/2022/03/31/wvu-envisions-bright-future-for-former-mylan-chestnut-ridge-property-in-morgantown (accessed Nov. 9, 2022).)

37. Upon information and belief, MPI's articles of incorporation are improper given that MPI's registered local office address with the West Virginia Secretary of State is incorrectly listed as 781 Chestnut Ridge Road, Morgantown, WV 26505 because Viatris sold the property located at this address.

38. Upon information and belief, MPI has purported to have a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505. (*See Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al*., 21-cv-146-TSK, D.I. 15 (N.D. W. Va. Mar. 24, 2022).) Upon information and belief, according to the West Virginia Secretary of State's Office, Viatris' subsidiary Viatris Specialty LLC, which is incorporated in Delaware, is also located at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505. Upon information and belief, Viatris' and MPI's use of the same office or business location demonstrates that MPI is an alter ego of and subsumed within Viatris.

39. Upon information and belief, Viatris' correspondence address for the United States Patent and Trademark Office ("PTO") for patent applications filed by various Mylan entities, including Mylan Inc. and MLL, is a general address for the Mountaineer Mall in Morgantown, West Virginia: Viatris, 5000 Greenbag Road, Legal IP – GBR, Morgantown, WV 26501. (*See, e.g.*, U.S. Published Patent Appl. No. 2019/0160002 at https://patentcenter.uspto.gov/applications/16320713 (accessed Nov. 9, 2022).) Upon information and belief, MPI's correspondence address for the USPTO for patent applications filed by MPI is a

specific address for the Mountaineer Mall in Morgantown, West Virginia: MPI, 5005 Greenbag Road, Morgantown, WV 26501. (*See, e.g.*, U.S. Patent Appl. No. 15/097,010 at https://patentcenter.uspto.gov/applications/15097010/attorney (accessed Nov. 9, 2022).) Upon information and belief, MPI and Viatris are located in the same office at 5005 Greenbag Road, Morgantown, West Virginia, and operate as a single integrated unit. Upon information and belief, Viatris' and MPI's use of the same office or business location demonstrates that MPI is an alter ego of and subsumed within Viatris.

40. Upon information and belief, both Viatris and Viatris Specialty LLC share the same principal place of business at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, PA 15317. Upon information and belief, another Viatris subsidiary Mylan Inc. is also located at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, PA 15317. (*Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. et al*., 21-cv-146-TSK, D.I. 15 (N.D. W. Va. Mar. 24, 2022).)

41. Upon information and belief, officers of MPI, including John Miraglia and Thomas Salus, maintain their offices at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, PA 15317. Upon information and belief, Viatris occupies this same place of business. (https://apps.wv.gov/SOS/BusinessEntitySearch/Details.aspx?Id=gXgVp2V+Lwt5SqTtSSPiAw==&Search=G44EZ4/AqwBYEJid9%20FgGQ==&Page=0 (accessed Nov. 9, 2022).)

42. Upon information and belief, Viatris and MPI share one or more common corporate officers and employees. (*See, e.g.*, https://apps.sos.wv.gov/business/corporations/organization.aspx?org=20402 (accessed Nov. 9, 2022); https://www.linkedin.com/in/john-miraglia-888238 (accessed Nov. 9, 2022); Viatris Inc., Amended and Restated Revolving Credit Agreement (Exhibit 10.1) (July 1, 2021) https://www.sec.gov/Archives/edgar/data/0001792044/000119312521206477/d50384dex101.htm (accessed Nov. 9, 2022) (John Miraglia signing as

Treasurer of Viatris Inc.).) Upon information and belief, the sharing of corporate officers and employees demonstrates that MPI is an alter ego of and subsumed within Viatris.

43. Upon information and belief, upon the combination of Mylan and Upjohn, Viatris Inc. assumed certain retention agreements and retirement benefit agreements between Mylan and certain of its officers. (*See, e.g.*, https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (accessed Nov. 9, 2022).)

44. Upon information and belief, Viatris regulatory affairs employees develop, manage and implement global regulatory affair strategy, which includes the submission of Abbreviated New Drug Applications for MPI. (*See, e.g.,* https://www.linkedin.com/in/beth-britton-0a433651/ (accessed Nov. 9, 2022).) Upon information and belief, Viatris regulatory affairs employees have been deposed in Hatch-Waxman litigations relating to the submission of MPI ANDAs. (*E.g.*, *Pfizer Inc., et al. v. MPI*, Civil Action No. 21-cv-839-CFC, D.I. 76 (D. Del. Nov. 18, 2021).)

45. Upon information and belief, as Mylan entities, including MPI, are now part of Viatris, attempts to access Mylan's website, mylan.com, result in a pop-up window redirecting access to Viatris, along with the statement "Mylan is now part of Viatris, a new global healthcare company committed to empowering people to live healthier at every stage of life." (mylan.com, (accessed Nov. 9, 2022).) Upon information and belief, Mylan's LinkedIn website states: "Follow us on our new journey as Viatris. www.linkedin.com/company/viatris." (https://www.linkedin.com/company/mylan (accessed Nov. 9, 2022).)

46. Upon information and belief, as part of Viatris working to transition the Viatris brand commercially and operationally around the world, Mylan employees are now identified as Viatris employees. (*See, e.g.*, https://www.linkedin.com/in/brandon-mcmahon-2754a263/ (accessed Nov. 9, 2022).)

47. Upon information and belief, MPI job listings indicate employment is with Viatris, demonstrating that MPI is an alter ego of and subsumed within Viatris. (*See, e.g.*, https://mylan.wd5.myworkdayjobs.com/en-US/External/details/Manager-R-D-API-Sourcing_R5623344?locations=13cb69889c52100563f4e879afc9ca8a (accessed Nov. 9, 2022).)

48. Upon information and belief, Viatris Inc. employees conduct pharmaceutical research and publish pharmaceutical research results as part of their employment with Viatris Inc., including with regard to studies funded by Viatris Inc. *See, e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8740218/ (accessed Nov. 9, 2022) (identifying several authors, including Patrick T. Vallano (upon information and belief, Head of Innovative Programs, Research and Development at Viatris) as "employees of Viatris Inc." and stating "Funding for this research was provided by Viatris Inc."); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8208551/ (accessed Nov. 9, 2022) (identifying several authors as "paid employees of Viatris Inc.," stating Viatris Inc. provided financial support for the study and explaining that "[t]he sponsors had a role in the study design, data collection and analysis, and preparation of the manuscript"); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8606731/ (accessed Nov. 9, 2022) (identifying authors as a "[m]ember of advisory board for Viatris (formally Mylan Inc.)" and "[f]ull-time employees of Viatris (formally Mylan Inc.)" that "may hold stock of Viatris (formally Mylan Inc.)").

49. Upon information and belief, on July 1, 2021, Viatris entered into a $4.0 billion revolving facility agreement with certain lenders, referred to in Viatris' 2021 10-K Report as the "2021 Revolving Facility." According to Viatris' 2021 10-K report, MPI has access to the 2021 Revolving Facility. (*Id.*) Upon information and belief, Viatris and MPI operate as a single entity

with the capacity to borrow funds from revolving loan accounts that Viatris has instituted with certain lenders.

50. Upon information and belief, Viatris entered into a two-year $400 million "Receivables Facility" agreement in 2020 which expires April 2022. (*Id*.) According to Viatris' 2021 10-K report, MPI has access to $400 million dollars under the Receivables Facility. (*Id*.) Upon information and belief, under Viatris' Receivables Facility agreement, MPI, operating as a single entity with Viatris, has the capacity to sell its accounts receivables to Viatris' subsidiary Mylan Securitization LLC for the purpose of accessing instant funds from outstanding unpaid invoices. (Viatris 2021 10-K Report, https://www.sec.gov/ix?doc=/Archives/edgar/data/1792044/000179204422000010/vtrs-20211231.htm (accessed Nov. 9, 2022).) Upon information and belief, Viatris thus funds MPI through Viatris' subsidiary Mylan Securitization LLC.

51. Upon information and belief, Viatris' and MPI's joint use of the 2021 Revolving Facility and 2020 Receivables Facility demonstrate the commingling of funds and that MPI is an alter ego of and subsumed within Viatris.

52. Upon information and belief, Viatris agreed to pay $264 million in settlement fees, to resolve the EpiPen® Auto-Injector indirect purchase class action cases pending in the U.S. District Court for the District of Kansas on behalf of defendants Mylan N.V., Mylan Specialty L.P. and MPI and Heather Bresch. (*See* Viatris Inc. Form 8-K, dated February 28, 2022; *In Re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, MDL No. 2785, 17-md-2785-DDC-TJJ (D. Kan. Mar. 11, 2022).) Upon information and belief, as reported in Viatris' February 27, 2022 Form 8-K report, Viatris repaid in 2021 approximately $2.1 billion of debt incurred by Viatris and its subsidiaries. Upon information and belief, Viatris' payment of debts incurred by itself and its subsidiaries demonstrates a commingling of funds between Viatris

and its subsidiaries, a lack of corporate separateness and the various Mylan subsidiaries, including MPI, being subsumed within Viatris.

53. Upon information and belief, Viatris refers to FDA approvals of ANDAs submitted by MPI as Viatris' FDA ANDA approvals. (*See, e.g.*, *Mylan Launches First Generic Restasis. (RX/Generic Drugs)*, CHAIN DRUG REV., Feb. 21, 2022, at 31 ("Rajiv Malik, president of [MPI's] parent company, Viatris Inc., said: 'I am pleased that Viatris has received the first FDA approval for generic Restasis . . . .'") ("Viatris developed markets president Tony Mauro said: 'The approval of generic Restasis reinforces our ongoing commitment to deliver innovative solutions . . . . We look forward to quickly bringing this important product to millions of Americans . . . .'"); *Viatris Inc. Announces Receipt of the First FDA Approval for Generic Version of Symbicort® Inhalation Aerosol, Breyna™ (Brudesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol), in Partnership with Kindeva*, VIATRIS PRESS RELEASES, https://newsroom.viatris.com/2022-03-16-Viatris-Inc-Announces-Receipt-of-the-First-FDA-Approval-for-Generic-Version-of-Symbicort-R-Inhalation-Aerosol,-Breyna-TM-Budesonide-and-Formoterol-Fumarate-Dihydrate-Inhalation-Aerosol-,-in-Partnership-with-Kindeva (Mar. 16, 2022) (accessed Nov. 9, 2022) ("Viatris President Rajiv Malik added: 'The momentous FDA final approval of Breyna is further evidence of our well-established development expertise and proven ability to move up the value chain with more complex products by leveraging our robust scientific capabilities to target gaps in healthcare and patient needs. This approval also builds on our past successes of bringing other complex product[s] first[] to market and demonstrates the continued delivery of our strong pipeline.'"). During Viatris' November 7, 2022 Earnings Call for FQ3 2022, Viatris President Rajiv Malik referred to Viatris' success in marketing generics, stating "I'm very proud of what we have

accomplished in our last [two] years as Viatris." (*Viatris Inc. FQ3 2022 Earnings Call Transcripts*, S&P GLOBAL (Nov. 7, 2022).)

54. Upon information and belief, as part of Viatris working to transition the Viatris brand commercially and operationally around the world, products formerly identified as products of "Mylan Pharmaceuticals Inc, *a Viatris* company" are now listed as Viatris products on Viatris' website. (*See, e.g.*, authorized generic Vusion, https://www.fda.gov/media/77725/download (accessed Nov. 9, 2022); https://www.viatris.com/en-us/lm/countryhome/us-products/productcatalog/productdetails?id=9b97372b-0871-4f31-bb48-0f72d4194be7 (accessed Nov. 9, 2022), https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b026bc7d-3a18-41e8-88c4-1e063cd2f42c&type=display (accessed Nov. 9, 2022) and https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021026s013lbl.pdf (accessed Nov. 9, 2022); *see also* Zovirax, https://www.viatris.com/en-us/lm/countryhome/us-products/productcatalog/productdetails?id=7096ceba-cf24-4835-8a2c-59703d674f24 (accessed Nov. 9, 2022).)

55. Upon information and belief, Viatris filed its 10-K report with the SEC for the fiscal year ending December 31, 2021. Therein, Viatris refers to itself and its subsidiaries as "the Company" and identifies Mylan Pharmaceuticals Inc. as a "wholly-owned subsidiary." According to the report, Viatris invests significant sums in R&D and in manufacturing capacity. "[Viatris] also often incur[s] substantial litigation expense as a result of defending or challenging brand patents or exclusivities[.]" (*Id.*) Viatris' 10-K report further states that "[t]he Company is involved in a number of patent litigation lawsuits involving the validity and/or infringement of patents held by branded pharmaceutical companies including but not limited to the matters described below. The Company uses its business judgement to decide to market and sell certain products, in each

case based on its belief that the applicable patents are invalid and/or that its products do not infringe, notwithstanding the fact that allegations of patent infringement(s) or other potential third party rights have not been finally resolved by the courts." Following this statement, Viatris identifies multiple Hatch-Waxman litigations in which MPI is involved. (Viatris 2021 10-K Report, https://www.sec.gov/ix?doc=/Archives/edgar/data/1792044/000179204422000010/vtrs-20211231.htm (accessed Nov. 9, 2022).)

56. Defendants' ANDA filing regarding the patent-in-suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' generic products in this judicial district.

57. Defendants have taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the Northern District of West Virginia and elsewhere throughout the United States. Upon information and belief, Defendants intend to direct sales of their generic drugs in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. Upon information and belief, Defendants will engage in marketing of their proposed generic products in the Northern District of West Virginia upon approval of their ANDA.

58. Upon information and belief, Defendants operate in unison with respect to preparing ANDAs, including the validity and infringement analyses of Orange Book listed patents and corresponding preparation of Notices of Paragraph IV Certifications (*see* 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV) and 355(j)(2)(B)) to be incorporated into the ANDAs for FDA submission.

59. Upon information and belief, Defendants also operate in unison with respect to readying their generic products for launch and launching their generic products in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. (*See, e.g., Viatris Inc. FQ3 2022 Earnings Call Transcripts*, S&P GLOBAL (Nov. 7, 2022) (Rajiv Malik, President & Executive Director of Viatris, stating that "We are in a state of readiness from the launch perspective [of generic Symbicort]" and "launch at risk is a part of our business plan . . . We'll go back to our IP legal team, understand where the litigation is and then based on that make that call.").)

60. Upon information and belief, Viatris, MPI and MLL act as a single enterprise with respect to Defendants' ANDA filing regarding the patent-in-suit. Upon information and belief, Viatris' February 28, 2022 Investor Event presentation identifies Viatris' generic versions of Otsuka's ABILIFY MAINTENA® as part of "The Viatris Complex Generic Portfolio" and that Viatris is vertically integrated. (https://investor.viatris.com/static-files/6a055dc2-4cd2-4d6c-91c9-c426ec1dcbce (accessed Nov. 9, 2022); *see also* May 9, 2022 Investor Event presentation, https://investor.viatris.com/static-files/f6aa077a-24b0-48ec-afc9-bfb2fe262e1c (accessed Nov. 9, 2022); *see also* Nov. 7, 2022 Strategic Update: Our Path to Return to Growth presentation, https://investor.viatris.com/static-files/8ad63891-ba98-4c42-b103-30ba7946e5e4 (identifying Viatris' generic versions of Otsuka's ABILIFY MAINTENA® as one of its Complex Injectables) (accessed Nov. 9, 2022). Indeed, Viatris President Rajiv Malik stated that Viatris is "confident that [it] will be first to market with [several] generics, including Abilify Maintena, . . . [a] complex injectable[.]" (*Viatris Inc. FQ3 2022 Earnings Call Transcripts*, S&P GLOBAL (Nov. 7, 2022).)

61. Upon information and belief, Viatris was involved in the submission of ANDA No. 216608. Upon information and belief, the preparation of ANDA No. 216608 was "necessarily a group effort, i.e., no single entity can reasonably alone provide all required materials and perform

all related activities." The First West Virginia Suit, D.I. 47 at 2 (Reply in Support of Mylan Laboratories Limited and Viatris Inc.'s Motion to Dismiss).

62. Upon information and belief, Viatris believes that its "complex injectables franchise," including its generic versions of Otsuka's ABILIFY MAINTENA®, "represents at least a $1 billion peak net sales opportunity." (*Viatris Inc. FQ3 2022 Earnings Call Transcripts*, S&P GLOBAL (Nov. 7, 2022).)

63. Upon information and belief, Defendants have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 216608 and intend to benefit from the ANDA.

64. For these reasons and for other reasons that will be presented to the Court if jurisdiction or venue is challenged, the Court has personal jurisdiction over Defendants, and venue is proper in this judicial district.

## FACTUAL BACKGROUND

### The NDA

65. Otsuka is the holder of New Drug Application ("NDA") No. 202971 for ABILIFY MAINTENA® (aripiprazole for extended-release injectable suspension) in 300 and 400 mg strengths in vials and pre-filled syringes.

66. The FDA approved NDA No. 202971 on February 28, 2013.

67. ABILIFY MAINTENA® is a prescription drug approved for the treatment of schizophrenia and maintenance monotherapy treatment of bipolar I disorder. Aripiprazole is the active ingredient in ABILIFY MAINTENA®.

**The Patent-In-Suit**

68. The PTO issued the '087 patent on August 2, 2022, entitled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '087 patent is attached as Exhibit A.

69. Otsuka owns the '087 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

70. The '087 patent currently expires on September 24, 2033.

71. The '087 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 202971 for ABILIFY MAINTENA®.

**The ANDA**

72. Upon information and belief, Defendants filed ANDA No. 216608 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use and/or sale in the United States of aripiprazole for extended-release injectable suspension, 300 mg/vial and 400 mg/vial (defined above as "Defendants' generic products"), which are generic versions of Otsuka's ABILIFY MAINTENA® (aripiprazole).

73. Upon information and belief, ANDA No. 216608 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the patent-in-suit are invalid, unenforceable and/or would not be infringed by Defendants' generic products.

74. Plaintiffs commenced this action within 45 days of receiving Defendants' Third Notice Letter.

**COUNT I**

**(INFRINGEMENT OF THE '087 PATENT)**

75. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

76. Upon information and belief, Defendants filed ANDA No. 216608 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '087 patent.

77. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '087 patent are invalid, unenforceable and/or not infringed.

78. Upon information and belief, in their ANDA No. 216608, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

79. Defendants have actual knowledge of the '087 patent, as evidenced by Defendants' Third Notice Letter.

80. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '087 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216608, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '087 patent.

81. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '087 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 216608 shall be no earlier than the expiration of the '087 patent and any additional periods of exclusivity.

82. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 216608, and therefore will infringe at least one claim of the '087 patent.

83. Upon information and belief, Defendants have knowledge of the '087 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '087 patent, either literally or under the doctrine of equivalents.

84. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '087 patent.

85. Upon information and belief, if ANDA No. 216608 is approved, Defendants intend to and will manufacture, use, import, offer to sell, and/or sell Defendants' generic products in the United States.

86. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 216608 complained of herein were done by and for the benefit of Defendants.

87. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

88. Plaintiffs do not have an adequate remedy at law.

## REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the patent-in-suit through Defendants' submission of ANDA No. 216608 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the patent-in-suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the patent-in-suit will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the patent-in-suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the patent-in-suit and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the patent-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the patent-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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