

**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.

ELECTRONICALLY FILED 04/08/2022 U.S. DISTRICT COURT Northern District of WV

Civil Action No. 1:22-CV-32 (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 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, “patents 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 patents in suit.

THE PARTIES

2. 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.

3. 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 ’680, the ’313, the ’679, the ’469, the ’427, the ’057, the ’803 and the ’553 patents.

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

5. 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.

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

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

8. 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.

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

JURISDICTION AND VENUE

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

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

12. 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.

13. 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.")

14. 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.

15. This Court has personal jurisdiction over Viatrix. Upon information and belief, Viatrix 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.

16. 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.

17. 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.

18. 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.

19. 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.

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

21. 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 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> (last visited Apr. 5, 2022).)

22. 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.

23. 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> (last visited Apr. 5, 2022).)

24. 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> (last visited Apr. 8, 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 CANNONBURG PA 15317. (<https://apps.sos.wv.gov/business/corporations/registration.aspx?org=16922> (last visited Apr. 7, 2022).)

25. 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.

26. Upon information and belief, MPI holds itself out to the public as “Mylan Pharmaceuticals Inc., a Viatriis company.” (*See, e.g.*, <https://newsroom.viatriis.com/2022-01-18-Mylan-Pharmaceuticals-Inc,-a-Viatriis-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> (last visited Apr. 5, 2022).)

27. Upon information and belief, Viatriis 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 believe, however, as of March 7, 2022, Viatriis 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-viatriis-facility-auctions-off-equipment> (last visited Apr. 5, 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 Viatriis nor MPI has applied for renewal of a “Permit to Operate.” 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.wdvt.com/2022/03/31/wvu-purchases-former-mylan-plant> (last visited Apr. 5, 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 “Viatriis property.” (*Id.*) Under information and belief, Viatriis sold this property to West Virginia University.

28. Upon information and belief, Robert J. Coury, formerly the executive chairman of Mylan, is now the executive chairman of Viatriis 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> (last visited Apr. 5, 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-f3afcbcbef6.html (last visited Apr. 5, 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> (last visited Apr. 5, 2022).)

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

30. Upon information and belief, MPI has purported to have a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505, notwithstanding that the West Virginia Secretary of State's Office identifies MPI's principal place of business as the divested property at 781 Chestnut Ridge 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, Viatri's subsidiary Viatri Specialty LLC, which is incorporated in Delaware, is also located at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505. Upon information and belief, Viatri's and MPI's use of the same office or business location demonstrates that MPI is an alter ego of and subsumed within Viatri's.

31. Upon information and belief, Viatri's 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: Viatri, 5000 Greenbag Road, Legal IP – GBR, Morgantown, WV 26501. (*See, e.g.*, U.S. Published Patent Appl. No. 2019/0160002 at <https://portal.uspto.gov/pair/PublicPair> (last visited Apr. 5, 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://portal.uspto.gov/pair/PublicPair> (last visited Apr. 5, 2022).) Upon information and belief, MPI and Viatri are located in the same office at 5005 Greenbag Road, Morgantown, West Virginia, and operate as a single integrated unit. Upon information and belief, Viatri's and MPI's use of the same office or business location demonstrates that MPI is an alter ego of and subsumed within Viatri's.

32. 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).)

33. 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> (last visited Apr. 5, 2022).)

34. 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> (last visited Apr. 5, 2022); <https://www.linkedin.com/in/john-miraglia-888238> (last visited Apr. 5, 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> (last visited Apr. 8, 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.

35. 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/> (last visited April 8, 2022).) Upon information and belief, Viatris regulatory affairs employees

have been deposited 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).)

36. 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, (last visited Apr. 05, 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> (last visited Apr. 5, 2022).)

37. 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/> (last visited Apr. 7, 2022).)

38. Upon information and belief, current job listings for MPI indicate employment is with Viatris, demonstrating that MPI is an alter ego of and subsumed within Viatris. (*See, e.g.*, https://www.google.com/search?q=Mylan+Pharmaceuticals+Inc.&rlz=1C1CHBF_enUS951US951&oq=job+postings+mylan+morgantown+wv&aqs=chrome..69i57j33i22i29i30.9875j0j7&sourceid=chrome&ie=UTF-8&ibp=htl;jobs&sa=X&ved=2ahUKEwjAm5D1k4L3AhVTgnIEHZQrDsEQkd0GegQICBAB#fpstate=tldetail&htivrt=jobs&htidocid=c9o-unfqkJ8AAAAAAAAAAA%3D%3D (last visited Apr. 7, 2022).)

39. 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.

40. 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> (last visited Apr. 5, 2022).) Upon information and belief, Viatris thus funds MPI through Viatris’ subsidiary Mylan Securitization LLC.

41. 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.

42. 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. March 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.

43. 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 Symbico (Budesonide 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) (last visited Apr. 5, 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 products first to market and demonstrates the continued deliver of our strong pipeline.’”).)

44. 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 *Viatrix* company” are now listed as Viatrix products on Viatrix’ website. (See, e.g., authorized generic Vusion, <https://www.fda.gov/media/77725/download> (last visited Apr. 8, 2022), <https://www.viatrix.com/en-us/lm/countryhome/us-products/productcatalog/productdetails?id=9b97372b-0871-4f31-bb48-0f72d4194be7> (last visited Apr. 8, 2022), <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b026bc7d-3a18-41e8-88c4-1e063cd2f42c&type=display> (last visited Apr. 8, 2022) and https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021026s013lbl.pdf (last visited Apr. 8, 2022); see also Zovirax, <https://www.viatrix.com/en-us/lm/countryhome/us-products/productcatalog/productdetails?id=7096ceba-cf24-4835-8a2c-59703d674f24> (last visited Apr. 8, 2022).)

45. Upon information and belief, Viatrix filed its 10-K report with the SEC for the fiscal year ending December 31, 2021. Therein, Viatrix refers to itself and its subsidiaries as “the Company” and identifies Mylan Pharmaceuticals Inc. as a “wholly-owned subsidiary.” According to the report, Viatrix invests significant sums in R&D and in manufacturing capacity. “[Viatrix] also often incur[s] substantial litigation expense as a result of defending or challenging brand patents or exclusivities[.]” (*Id.*) Viatrix’ 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, Viatrix identifies multiple Hatch-Waxman litigations in which MPI is involved. (Viatrix 2021 10-K

Report, <https://www.sec.gov/ix?doc=/Archives/edgar/data/1792044/000179204422000010/vtrs-20211231.htm> (last visited Apr. 5, 2022).)

46. Defendants' ANDA filing regarding the patents 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.

47. 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.

48. 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.

49. Upon information and belief, Viatrix, MPI and MLL act as a single enterprise with respect to Defendants' ANDA filing regarding the patents in suit. Upon information and belief, Viatrix' February 28, 2022 Investor Event presentation identifies Viatrix' generic of ABILIFY MAINTENA[®] as part of "The Viatrix Complex Generic Portfolio" and that Viatrix is vertically integrated. (<https://investor.viatrix.com/static-files/6a055dc2-4cd2-4d6c-91c9-c426ec1dcbce>

(last visited Apr. 5, 2022).)

50. 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.

51. 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

52. 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.

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

54. 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 Patents In Suit

55. The PTO issued the ’680 patent on October 5, 2010, entitled “Controlled Release Sterile Injectable Aripiprazole Formulation and Method.” A true and correct copy of the ’680 patent is attached as Exhibit A.

56. Otsuka owns the ’680 patent through assignment as recorded by the PTO at Reel 016811, Frame 0856 and Reel 016335, Frame 0394.

57. The ’680 patent currently expires on October 19, 2024.

58. The '680 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 202971 for ABILIFY MAINTENA®.

59. The PTO issued the '313 patent on October 4, 2011, entitled "Controlled Release Sterile Injectable Aripiprazole Formulation and Method." A true and correct copy of the '313 patent is attached as Exhibit B.

60. Otsuka owns the '313 patent through assignment as recorded by the PTO for the '680 patent at Reel 016811, Frame 0856 and Reel 016335, Frame 0394.

61. The '313 patent currently expires on October 19, 2024, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 1001 days of patent term adjustment granted to the '313 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit C.

62. The '313 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

63. The PTO issued the '679 patent on May 13, 2014, entitled "Controlled Release Sterile Injectable Aripiprazole Formulation and Method." A true and correct copy of the '679 patent is attached as Exhibit D.

64. Otsuka owns the '679 patent through assignment as recorded by the PTO for the '680 patent at Reel 016811, Frame 0856 and Reel 016335, Frame 0394.

65. The '679 patent currently expires on October 19, 2024, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 1314 days of patent term adjustment granted to the '679 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit E.

66. The '679 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

67. The PTO issued the '469 patent on March 19, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A true and correct copy of the '469 patent is attached as Exhibit F.

68. Otsuka owns the '469 patent through assignment as recorded by the PTO for U.S. Patent Appl. No. 10/333,244 at Reel 014173, Frame 0509.

69. The '469 patent currently expires on June 29, 2025, by virtue of 1008 days of patent term adjustment granted to the '469 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit G.

70. The '469 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

71. The PTO issued the '427 patent on December 25, 2012, entitled "Methods for Administering Aripiprazole." A true and correct copy of the '427 patent is attached as Exhibit H.

72. Otsuka owns the '427 patent through assignment as recorded by the PTO at Reel 032959, Frame 0432; Reel 032161, Frame 0475; Reel 030253, Frame 0038; Reel 029116, Frame 0379; Reel 026994, Frame 0186 and Reel 026994, Frame 0245.

73. The '427 patent currently expires on March 15, 2025, by virtue of 587 days of patent term adjustment granted to the '427 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit I.

74. The '427 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

75. The PTO issued the '057 patent on January 7, 2020, entitled "Methods of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '057 patent is attached as Exhibit J.

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

77. The '057 patent currently expires on March 8, 2034, by virtue of 165 days of patent term adjustment granted to the '057 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit K.

78. The '057 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

79. The PTO issued the '803 patent on April 20, 2021, entitled "Methods of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '803 patent is attached as Exhibit L.

80. Otsuka owns the '803 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

81. The '803 patent currently expires on September 24, 2033.

82. The '803 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

83. The PTO issued the '553 patent on October 26, 2021, entitled "Methods of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '553 patent is attached as Exhibit M.

84. Otsuka owns the '553 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

85. The '553 patent currently expires on September 24, 2033.

86. The '553 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA[®].

The ANDA

87. 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).

88. Upon information and belief, ANDA No. 216608 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Defendants’ generic products.

89. Otsuka received a letter sent by Defendants, dated February 23, 2022, purporting to be a “Notice of Paragraph IV Certification” for an ANDA, (“Defendants’ Notice Letter”) pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §§ 314.94-314.95. Defendants’ Notice Letter identified Defendants’ ANDA as “ANDA No. 216608” and notified Otsuka that Defendants had filed ANDA No. 216608 to seek approval to engage in the commercial manufacture, use and/or sale of Defendants’ generic products before the expiration of the patents in suit.

90. Plaintiffs commenced this action within 45 days of receiving Defendants’ Notice Letter.

COUNT I

(INFRINGEMENT OF THE '680 PATENT)

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

92. 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 '680 patent.

93. 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 '680 patent are invalid, unenforceable and/or not infringed.

94. 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[®].

95. Defendants have actual knowledge of the '680 patent, as evidenced by Defendants' Notice Letter.

96. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '680 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 '680 patent.

97. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '680 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 '680 patent and any additional periods of exclusivity.

98. 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.

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

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

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

COUNT II

(INFRINGEMENT OF THE '313 PATENT)

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

103. 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 '313 patent.

104. 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 '313 patent are invalid, unenforceable and/or not infringed.

105. 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®.

106. Defendants have actual knowledge of the '313 patent, as evidenced by Defendants' Notice Letter.

107. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '313 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 '313 patent.

108. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '313 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 '313 patent and any additional periods of exclusivity.

109. 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 '313 patent.

110. Upon information and belief, Defendants have knowledge of the '313 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 '313 patent, either literally or under the doctrine of equivalents.

111. 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 '313 patent.

112. 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.

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

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

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

COUNT III

(INFRINGEMENT OF THE '679 PATENT)

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

117. 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 '679 patent.

118. 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 '679 patent are invalid, unenforceable and/or not infringed.

119. 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®.

120. Defendants have actual knowledge of the '679 patent, as evidenced by Defendants' Notice Letter.

121. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '679 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 '679 patent.

122. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '679 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 '679 patent and any additional periods of exclusivity.

123. 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.

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

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

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

COUNT IV

(INFRINGEMENT OF THE '469 PATENT)

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

128. 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 '469 patent.

129. 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 '469 patent are invalid, unenforceable and/or not infringed.

130. 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®.

131. Defendants have actual knowledge of the '469 patent, as evidenced by Defendants' Notice Letter.

132. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '469 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 '469 patent.

133. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '469 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 '469 patent and any additional periods of exclusivity.

134. 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.

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

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

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

COUNT V

(INFRINGEMENT OF THE '427 PATENT)

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

139. 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 '427 patent.

140. 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 '427 patent are invalid, unenforceable and/or not infringed.

141. 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®.

142. Defendants have actual knowledge of the '427 patent, as evidenced by Defendants' Notice Letter.

143. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '427 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 '427 patent.

144. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '427 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 '427 patent and any additional periods of exclusivity.

145. 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 '427 patent.

146. Upon information and belief, Defendants have knowledge of the '427 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 '427 patent, either literally or under the doctrine of equivalents.

147. 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 '427 patent.

148. 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.

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

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

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

COUNT VI

(INFRINGEMENT OF THE '057 PATENT)

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

153. 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 '057 patent.

154. 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 '057 patent are invalid, unenforceable and/or not infringed.

155. 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®.

156. Defendants have actual knowledge of the '057 patent, as evidenced by Defendants' Notice Letter.

157. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '057 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 '057 patent.

158. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '057 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 '057 patent and any additional periods of exclusivity.

159. 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 '057 patent.

160. Upon information and belief, Defendants have knowledge of the '057 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 '057 patent, either literally or under the doctrine of equivalents.

161. 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 '057 patent.

162. 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.

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

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

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

COUNT VII

(INFRINGEMENT OF THE '803 PATENT)

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

167. 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 '803 patent.

168. 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 '803 patent are invalid, unenforceable and/or not infringed.

169. 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®.

170. Defendants have actual knowledge of the '803 patent, as evidenced by Defendants' Notice Letter.

171. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '803 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 '803 patent.

172. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '803 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 '803 patent and any additional periods of exclusivity.

173. 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 '803 patent.

174. Upon information and belief, Defendants have knowledge of the '803 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 '803 patent, either literally or under the doctrine of equivalents.

175. 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 '803 patent.

176. 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.

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

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

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

COUNT VIII

(INFRINGEMENT OF THE '553 PATENT)

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

181. 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 '553 patent.

182. 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 '553 patent are invalid, unenforceable and/or not infringed.

183. 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®.

184. Defendants have actual knowledge of the '553 patent, as evidenced by Defendants' Notice Letter.

185. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '553 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 '553 patent.

186. Upon information and belief, if ANDA No. 216608 is approved, Defendants will infringe one or more claims of the '553 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 '553 patent and any additional periods of exclusivity.

187. 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 '553 patent.

188. Upon information and belief, Defendants have knowledge of the '553 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 '553 patent, either literally or under the doctrine of equivalents.

189. 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 '553 patent.

190. 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.

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

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

193. 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 each of the patents 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 patents 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 patents in suit will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of each of the patents 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 patents 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 patents 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 patents 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.

Dated: April 8, 2022

Respectfully submitted,

THOMAS COMBS & SPANN, PLLC

/s/ Daniel R. Higginbotham

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