IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC, Plaintiff, v. SANDOZ, INC., Defendant.	Civil Action No.: 1:20-cv-645-MN **JURY TRIAL DEMANDED** [redacted] PUBLIC VERSION

AMENDED COMPLAINT

Plaintiff Exela Pharma Sciences, LLC ("Plaintiff" or "Exela") by its attorneys, hereby alleges as follows in this amended complaint:

NATURE OF ACTION

1. This is an action for infringement of U.S. Patent No. 10,478,453 ("the '453 patent") and U.S. Patent No. 10,583,155 ("the '155 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a)-(c), and for a declaratory judgment of infringement of the '453 and '155 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(a)-(c). Plaintiff institutes this action to enforce its patent rights covering its FDA-approved ELCYS® brand L-cysteine hydrochloride injection.

THE PARTIES

2. Exela is a company existing under the laws of the State of Delaware and having a principal place of business at 1245 Blowing Rock Blvd., Lenoir, NC 28645.

3. On information and belief, Defendant Sandoz, Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado and having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

5. This Court has personal jurisdiction over Sandoz because, on information and belief, Sandoz has purposely availed itself of the benefits and protections of the State of Delaware's laws such that it should reasonably anticipate being haled into court in this judicial district, and because this action arises from activities of Sandoz directed toward the State of Delaware.

6. On information and belief, Sandoz has engaged in systematic and continuous business contacts within the State of Delaware, regularly conducts business in the State of Delaware, and has purposefully availed itself of the privilege of doing business in the State of Delaware.

7. On information and belief, Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells pharmaceutical drug products, including generic drugs, throughout the United States, including in the State of Delaware.

8. On information and belief, Sandoz derives substantial revenue from pharmaceutical drug products, including generic drugs, that are used and/or consumed within the State of Delaware, and which are manufactured by or for Sandoz and for which Sandoz is the named applicant on approved Abbreviated New Drug Applications ("ANDAs").

9. On information and belief, Sandoz contracts with drug wholesalers and distributors to supply pharmaceutical drug products, including generic drugs, for which Sandoz is the named applicant on approved ANDAs, throughout the United States, including in the State of Delaware.

10. On information and belief, the drug wholesalers and distributors Sandoz contracts with to supply pharmaceutical drug products, including generic drugs, are licensed to sell those products in the State of Delaware and are registered with the Delaware Board of Pharmacy as licensed "Pharmacy-Wholesale" and "Distributor/Manufacturer CSR."

11. On information and belief, various products for which Sandoz is the named applicant on approved ANDAs are offered for sale to pharmacies and hospitals in the State of Delaware, distributed to and available at pharmacies and hospitals in the State of Delaware, prescribed by healthcare providers practicing in the State of Delaware, used by healthcare providers, patients, and/or hospitals in the State of Delaware, and/or administered to patients in the State of Delaware.

12. Sandoz has filed ANDA No. 209994 ("Sandoz's ANDA") for Cysteine Hydrochloride Injection, USP, 500 mg/10 mL (50 mg/mL) single-dose vials ("Sandoz's ANDA Product"), which is a generic version of Exela's ELCYS® product, containing paragraph IV certifications to Exela's '453 and '155 patents.

13. Sandoz, through its counsel Abigail Langsam of the law firm Arnold & Porter Kaye Scholer LLP, sent a letter dated April 2, 2020 to Exela, a Delaware corporation, notifying Exela that Sandoz had filed with FDA, and FDA had received, Sandoz's ANDA No. 209994 ("Sandoz's Paragraph IV Letter").

14. Sandoz's filing of ANDA No. 209994 constitutes a formal act that reliably indicates Sandoz's plans to engage in marketing of Sandoz's ANDA Product throughout the United States, including in the State of Delaware, so that Sandoz's ANDA Product will be used throughout the United States, including in the State of Delaware.

15. On information and belief, upon approval of ANDA No. 209994, Sandoz will engage in the marketing of the Sandoz ANDA Product and offer to sell and/or sell its ANDA Product either directly or indirectly through its established channels of distribution via one or more of its drug wholesalers and distributors throughout the United States, including in the State of Delaware.

16. On information and belief, Sandoz knows, expects, and intends that upon approval of ANDA No. 209994, Sandoz's ANDA Product will be offered for sale to hospitals and/or pharmacies in the State of Delaware, distributed to and available at hospitals and/or pharmacies in the State of Delaware, prescribed by healthcare providers practicing in the State of Delaware, used by healthcare providers, patients, and/or hospitals in the State of Delaware, and/or administered to patients in the State of Delaware.

17. Sandoz's marketing, offer to sell, and/or sales of its ANDA Product, and the use of its ANDA Product, throughout the United States, including in the State of Delaware, before expiry of Exela's '453 and '155 patents will constitute infringement of the '453 and '155 patents, resulting in harm and injury to Exela.

18. Further, this Court has personal jurisdiction over Sandoz because Sandoz regularly engages in patent litigation in this judicial district, has previously consented to personal jurisdiction and venue in such litigation in this judicial district, has purposefully availed itself of the rights and benefits of this Court numerous times by asserting claims and/or counterclaims in this Court, and has in the past consented and continues to consent to personal jurisdiction and venue in this judicial district. *See, e.g., Otsuka Pharmaceutical Co., Ltd. et al. v. Sandoz Inc. et al.*, 19-cv-02080, D.I. 11 (D. Del. March 16, 2020); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 19-cv-00312, D.I. 10 (D. Del. April 10, 2019); *Astellas US LLC et al. v. Sandoz Inc.*, 18-cv-

01676, D.I. 13 (D. Del. Nov. 30, 2018); *Pharmacyclics LLC et al v. Sun Pharma Global FZE et al.*, 18-cv-00192, D.I. 12 (D. Del. Feb. 26, 2018); *H. Lundbeck A/S et al. v. Sandoz Inc. et al.*, 18-cv-00177, D.I. 9 (D. Del. April 13, 2018); *ViiV Healthcare Company et al. v. Sandoz Inc. et al.*, 17-cv-01784, D.I. 12 (D. Del. Jan. 24, 2018); *Biogen International GMBH et al. v. Sandoz Inc.*, 17-00874, D.I. 9 (D. Del. Oct. 16, 2017); *Bristol-Myers Squibb Company et al. v. Sandoz Inc.*, 17-cv-00407, D.I. 9 (D. Del. June 12, 2017); *Omeros Corporation v. Sandoz Inc.*, 17-cv-00799, D.I. 11 (D. Del. Sept. 13, 2017).

19. Venue is proper in this judicial district under at least 28 U.S.C. § 1391 and including because Sandoz is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief will consent to venue in this judicial district for the purpose of this case.

20. Exela believes this case belongs in Delaware, but is also filing a case in the United States District Court for the District of Colorado out of an abundance of caution.

FACTUAL BACKGROUND

A. The Development and FDA Approval of Exela's ELCYS® L-Cysteine Hydrochloride Injection Product

21. Exela is a relatively small but fast-growing specialty pharmaceutical company focused on developing, manufacturing, and marketing injectable products.

22. L-cysteine is an amino acid that is important for human life. While healthy adults can naturally synthesize small amounts, high-risk patients such as preterm and/or low birth weight infants and patients with severe liver disease require L-cysteine supplementation by parenteral administration (i.e., injection or intravenous infusion). For these patients, L-cysteine is administered as a component of a nutritional supplement regimen referred to as "total parenteral nutrition" (TPN).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.