

EXHIBIT 14

REDACTED

Case 1:19-cv-00318-MR Document 26-1 Filed 12/06/19 Page 1 of 10

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA, ASHEVILLE DIVISION**

EXELA PHARMA SCIENCES, LLC,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

Civil Action No.

[REDACTED]

[REDACTED]

DECLARATION OF MARK HARTMAN

I, Mark Hartman, state the following is true to the best of my knowledge, information, and belief:

1. My name is Mark Hartman. I am over the age of twenty-one (21) years, and I am competent to testify to the matters stated herein.

2. I am currently employed as the Chief Commercial Officer for Exela Pharma Sciences LLC (“Exela”). I have worked at Exela in that role since April 2015.

3. In my capacity as the Chief Commercial Officer, I am familiar with Exela’s commercial and marketing operations and strategies. This declaration is based on my personal knowledge and matters that I have investigated within Exela.

4. Exela invested significant effort in preparing for the launch of its L-Cysteine product ELCYST™, including generating a production forecast for meeting the market needs for the product and a market forecast for ELCYST™ based on market data from IQVIA, a healthcare analytics firm. The total L-Cysteine injection market, as estimated from the IQVIA database, is about 1,100,000 vials/year. The Exela marketing team also put together the pricing information,

safety datasheets, and package inserts to be submitted to pricing database companies that customers reference for reimbursement.

5. Towards the end of May 2019, I sent out communications to wholesalers regarding availability of ELCYST™, stocking suggestion, and pricing.

6. On May 21, 2019, Mr. Vaibhav Vaishnav of Sandoz's business development team sent a meeting invite via email to schedule a telephone call regarding Exela's recently approved products entitled "Potential Collaboration Opportunities – Sandoz / Exela," which I accepted. I had not had any contact with Mr. Vaishnav or anyone else at Sandoz prior to this meeting invitation.

7. On May 29, 2019, I sent our new product set up information to all national pricing database companies announcing the approval of ELCYST™ and providing the product and pricing information required by them to establish ELCYST™ in their pricing databases for customers to access to ensure reimbursement for the drug was established prior to shipping product to customers.

8. On May 30, 2019, I sent out the ELCYST™ product launch packet including an initial stocking incentive offer to all major wholesalers in the US soliciting their initial stocking orders for ELCYST™.

9. On May 31, 2019 at 10:30am Eastern time, I forwarded to the Exela sales team the packet of information on the ELCYST™ launch in preparation for our conference call scheduled for Monday, June 3, 2019 to go through the approved marketing materials and pricing information on ELCYST™. Included in this launch packet was a letter to healthcare providers announcing the approval and immediate launch of ELCYST™ as the only FDA Approved cysteine hydrochloride injection on the market in the United States. This letter also noted that

ELCYST™ contains no more than 120 ppb of aluminum. This letter was part of the approved marketing materials that each salesperson was to send to its customers and prospective customers announcing the launch of ELCYST™.

10. On that same day, May 31, 2019, Exela issued a press release on the ELCYST™ launch that stated that ELCYST™ is “available direct from Exela immediately and will be in wholesalers in early June.” As I reported to my sales team at that time, Exela had produced and made ready for this launch over 100,000 vials of ELCYST™, and we were constantly producing more. With the total market demand for L-Cysteine being about 90,000 vials per month, we were prepared to supply the entire market demand for L-Cysteine product immediately.

11. On May 31, 2019, I had a telephone call with Mr. Vaibhav Vaishnav and Ms. Shubhra Mehrotra of Sandoz’s business development team along with Dr. Phanesh Koneru, CEO of Exela. I had not had any contact with Ms. Mehrotra prior to this call. The Sandoz representatives wanted to talk about Exela’s “recent approvals” and whether Exela was set up to do marketing for those products. Exela had received FDA approval for only two products in April 2019, one of which was ELCYST™. During the call, Sandoz provided an overview of Sandoz’s U.S. operations and explained that they were looking for products to in-license. I gave a brief overview of Exela and its product line. I explained that Exela had its own sales and marketing team and that Exela was not interested in licensing its products at this time.

12. Beginning approximately June 3, 2019, Exela began sending out communications directly to customers such as hospitals and infusion centers regarding FDA approval and availability of ELCYST™. Around the same time, Exela also launched its Early Adapter Program, which offered a reduced price for ELCYST™ in exchange for a customer’s commitment to purchase L-Cysteine product from Exela. In the first wave, nineteen customers signed Letters

of Commitment to participate in the Exela Early Adapter Program, plus another twelve customers had signed up for Tier 1 pricing via the Premier ProvideGx program. During the second wave, only two additional customers signed up for the Exela Early Adapter Program.

13. On June 20, 2019, Exela began shipping ELCYST™ to wholesalers.

14. As part of its sales efforts, Exela collects data and observations from its sales team in various forms. The Exela sales team generally uses the program ZENDESK to record notes on calls with customers. Key Account Managers (KAMs) will also report to me with comments from customers, either in person or in emails. The Exela Regional Managers (RMs) also collect customer feedback and data from KAMs and they send that information to me to be compiled into a master summary. I have also communicated directly with customers regarding the sale of ELCYST™ and Sandoz's continued presence in the market. I collected the observations below via these various methods.

15. Exela's sales teams have observed and reported to me several instances of health systems buying or committing to buy several months, and even up to a year's supply of Sandoz's unapproved product, many of these customers having made bulk purchases after the ELCYST™ launch.

16. As reported to me by my team, based on their observations (at my direction) of historical trends, watching what is kept at wholesalers, and conversations with hospitals, multiple customers who normally did not maintain large stocks of L-Cysteine have recently purchased unusually large supplies from Sandoz. For example, [REDACTED] informed Exela that it had purchased a full year's worth of Sandoz's product in July 2019 and, as of October 2019, was still working through that supply and declining to purchase from Exela. Similarly, at least as of early October 2019, [REDACTED]

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.