

April 21, 2022

Electronic Submission

Division of Dockets Management
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Re: Supplement to Petition for Stay of Action; FDA-2022-P-0594

The undersigned submits this supplement to the above-referenced Petition for Stay of Action filed on April 14, 2022 on behalf of Exela Pharma Sciences LLC (“Exela”). As noted in the Petition, Exela filed a Temporary Restraining Order (“TRO”) in the patent litigation in the District Court for the District of Delaware (C.A. No. 1:20-cv-00365-MN) to prevent Eton Pharmaceuticals (“Eton”), owner of ANDA No. 214082, from marketing its generic drug product prior to the expiration of the 30-month stay on August 3, 2022. The Court held a teleconference on the TRO on April 19, 2022, and ruled that Eton must provide 30-day’s advance notice when Eton intends to launch its product. Attached is the teleconference Minute Entry from the TRO proceeding.

Upon receipt of any such notice from Eton, the Court will address the motion for TRO and we will keep the FDA informed of ongoing developments as appropriate.

Respectfully Submitted,



Terry G. Mahn
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Counsel to Exela Pharma Sciences LLC

Jamie Kolodziej

From: ded_nefreply@ded.uscourts.gov
Sent: Tuesday, April 19, 2022 1:18 PM
To: ded_ecf@ded.uscourts.gov
Subject: Activity in Case 1:20-cv-00365-MN Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc. Telephone Conference

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U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered on 4/19/2022 at 1:17 PM EDT and filed on 4/19/2022

Case Name: Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.

Case Number: [1:20-cv-00365-MN](#)

Filer:

Document Number: No document attached

Docket Text:

Minute Entry for proceedings held before Judge Maryellen Noreika - Telephone Conference held on 4/19/2022 re Motion for TRO ([215]). The defendant shall provide the Court and plaintiff 30 days notice of when they intend to launch. Upon receipt of that notice, the Court will address the motion for TRO ([215]), focusing on claim 10 of the '713 patent. (Court Reporter Dale Hawkins.) (mdb)

1:20-cv-00365-MN Notice has been electronically mailed to:

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