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May 8, 2022

Electronic Submission

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

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") to update the record in regards to the patent litigation in the District Court for the District of Delaware (C.A. No. 1:20-cv-00365-MN).

We will keep the FDA informed of ongoing developments as appropriate.

Respectfully Submitted,

Terry G. Mahn
Fish & Richardson P.C.
Counsel to Exela Pharma Sciences LLC

Attachments:
- Letter to The Honorable Maryellen Noreika from Timothy Devlin, dated April 29, 2022
- Letter to The Honorable Maryellen Noreika from Gregory R. Booker, dated May 5, 2022

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April 29, 2022

VIA CM/ECF

The Honorable Maryellen Noreika
United States District Court
for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

Re: *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*
District of Delaware, Civil Action No. 20-cv-365-MN

Dear Judge Noreika,

We write to inform the Court that, after additional investigation, Eton has decided not to launch its generic L-cysteine product at risk notwithstanding having received final approval from the FDA. This decision was made in consideration of the impact to Eton's 180-day exclusivity. As of last week, Eton understood that failing to launch within 75 days of approval might cause Eton to lose its 180-day exclusivity period, regardless of the Court's upcoming decision. Since counsel spoke to the Court last week, and after consultation with counsel, Eton has satisfied itself that it will not lose that exclusivity period by not launching under the current circumstances.

Eton wishes to note, however, that the FDA's final approval does impact this case in other ways. Primarily, since there is now a real product launch at issue, Eton believes that the infringement analysis should be conducted under 35 U.S.C. § 271(a) rather than 271(e). As the Court is well aware, "the act of filing an ANDA constitutes a 'highly artificial' act of infringement under 35 U.S.C. § 271(e)(2)." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004). "Although no traditional patent infringement has occurred until a patented product is made, used, or sold, under the Hatch-Waxman framework, the filing of an ANDA itself constitutes a technical infringement for ***jurisdictional*** purposes." *Sunovion Pharms., Inc., v. Teva Pharms. USA, Inc*., 731 F.3d 1271,1278 (Fed. Cir. 2013) (emphasis added).

As a result of receiving final approval, the infringement analysis moves from the highly artificial act of infringement based on the ANDA filing, to the question of infringement based on the actual product. *See Eli Lilly & Co. v. Actavis Elizabeth LLC, et al.*, 07-cv-3770 (DMC), 2009 U.S. Dist. LEXIS 43003, *7 (D.N.J. 2009) ("while filing an ANDA is sufficient to trigger an action under 35 U.S.C. § 271(e)(2), this subsection 'does not determine the ultimate question whether what will be sold will infringe any relevant patent.'") (quoting *Glaxo, Inc. v. Novopharm, Inc.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)); *see also Bristol-Myers Squibb Co. v. Mylan Pharms., Inc.*, C.A. No.

17-379-LPS, 2017 U.S. Dist. LEXIS 146372, *25 fn 11 (D. Del. 2017) ("An exception to [a finding of infringement under 271(e)] may be an at-risk launch . . . . When an at-risk launch happens, however, the plaintiff may amend its pleadings to add infringement claims under § 271(a) and request a jury trial, so its claims are no longer the forward-looking kind contemplated."), *In re Omeprazole Patent Litig. v. Apotex Corp.*, 536 F.3d 1361, 1366 (Fed. Cir. 2008) (discussing plaintiff amending its complaint post-final approval to include claims for damages under §271(a)-(c)), *In re Gabapentin Patent Litig.*, MDL Docket No. 1384; Master Civil Action No. 00-2931, 2011 U.S. Dist. LEXIS 174363 at *6-7 (D.N.J. April 4, 2011) (noting that plaintiffs' amended complaint contains a second count for infringement under § 271(a) for infringement based on launch and sale subsequent to approval.)

Indeed, the only relief mandated by 271(e), namely that the Court "shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed," 35 U.S.C. § 271(e)(4)(A), has been mooted by the FDA's final approval. As outlined in Eton's previous letter to the Court, (D.I. 213), this approval occurred based on the FDA's analysis of the patents noticed under Paragraph 4, asserted against Eton in a timely fashion, but later dropped from the case by Exela. All other relief under 271(e) is either discretionary or relates to biological products. The discretionary relief involves enjoining an actual product or damages for such a product. Those questions are best resolved under 271(a), particularly here given the distinction in the infringement analysis between 271(e) and 271(a).

Specifically, Eton stipulated to infringement of all but one of the asserted patents only under 271(e), in view of the Court's *Daubert* decision (D.I. 175) adopting the logic of *Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013) regarding overlapping ranges. Your Honor concluded that "the ANDA specification controls the infringement analysis when it speaks to a claim limitation, and the Court should examine other materials to look at the product that the generic company is likely to sell when the ANDA specification is silent on that limitation." (D.I. 175 at 5.) Now that there is an actual product at issue, with actual evidence of its properties rather than the ranges set forth in the ANDA specification, *Sunovion* no longer applies.

Sunovion concerned the impact of the ANDA holder's declaration, made outside the ANDA application, agreeing not to produce the proposed ANDA product within the claimed range. *See Sunovion*, 731 F.3d at 1274-1275. *Sunovion* was in a different posture than the case here as the FDA had not granted final approval for the proposed ANDA product. Thus, in *Sunovion*, "[w]hat [defendant] has asked the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur." *Id*. at 1278. Such is not that case here, where final approval has been granted and the infringement is not determined by what Eton has asked the FDA to approve but based on the characteristics of the actual product.

Under 271(a), Exela cannot show infringement of the asserted claims. Each asserted claim recites the L-cysteine solution with less than 150 ppb of aluminum. All but claim 27 of the '155 patent requires there to be less than 150 ppb of aluminum for at least 12 months. Exela has argued that claim 27 of the '155 patent requires the L-cysteine product to have less than 150 ppb aluminum for the shelf life of the product, in this case 24 months. The evidence adduced at trial shows that

Eton's actual L-cysteine product does not maintain less than 150 ppb of aluminum for 12 months. (*See* PTX 121 (showing the amount of aluminum in Eton's actual L-cysteine product exceeds 150 ppb well before month 12.)) For this reason, and others, Eton's L-cysteine product does not infringe the asserted patent claims under 35 U.S.C. § 271(a).

We are available to discuss these issues further with Your Honor at the Court's convenience.

Respectfully,

Timothy Devlin (No. 4241)

cc: Clerk of the Court (via CM/ECF)
Counsel of Record (via CM/ECF)

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VIA CM/ECF

May 5, 2022

The Honorable Maryellen Noreika
United States District Court
for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

Re: *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*
Civil Action No. 1:20-365-MN

Dear Judge Noreika:

Exela appreciates that Eton has confirmed it will not launch its generic product "at risk." (D.I. 237.) We understand that to mean Eton will not launch the product before the Court renders its final opinion. If that is correct, then Exela's motion for TRO is moot.

Unfortunately, Eton's letter to the Court is also a pretext for what amounts to a sur-reply on non-infringement that the Court did not request and for which Eton did not seek leave to file. Exela respectfully requests that it be stricken and directs the Court to the parties' post-trial briefs on infringement which address the issues and show why Eton's assertions that final approval eliminates § 271(e) from the case, changes the infringement analysis before the Court, and/or moots the Court's ability to order the effective date of Eton's ANDA to coincide with patent expiration are simply *wrong*. (*See* D.I. 220 at 4-5; D.I. 228 at 3-5.)

If the court requires further briefing on the issues raised by Eton, we are prepared to address them at the Court's request.

Respectfully submitted,

/s/ Gregory R. Booker

Gregory R. Booker (#4784)

cc: Clerk of the Court (via CM/ECF)
Counsel of Record (via CM/ECF)