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March 2, 2021

Via ECF

Honorable Allison D. Burroughs
United States District Court Judge
John Joseph Moakley U.S. Courthouse
1 Courthouse Way
Boston, Massachusetts 02210

Re: *Teva Pharmaceuticals International GmbH et al v. Eli Lilly and Company*,
Civil Action No. 1:18-cv-12029-ADB

Dear Judge Burroughs:

This firm, with Finnegan LLP, represents Eli Lilly and Company in the above-captioned matter. Lilly raises one question with the Court: whether Teva should be compelled to produce relevant documents "created" after September 27, 2018—the date Lilly received FDA approval to sell its accused product and the same day Teva filed its Complaint.[1]

As the parties near the current date for the close of fact discovery (March 31), Lilly has learned that, with limited exceptions, Teva intends to stand on an arbitrary date cutoff for its document production, refusing to produce or even review documents created after September 27, 2018 (the "Post-Complaint Documents"). Teva's date cutoff is arbitrary, allows for cherry-picking, conflicts with the ESI Protocol, and deprives Lilly of ~2.5 years of relevant discovery from "over one hundred thousand" Post-Complaint Documents.

Background

To every one of Lilly's 56 requests for production ("RFPs"), Teva asserted the following improper objection:

> Teva objects to each and every Request to the extent it seeks production of documents generated after Teva's filing of this Action on September 27, 2018 or is otherwise not limited by any appropriate or reasonable time limitation.

[1] Lilly submits this straightforward request by letter pursuant to the Court's guidance. *See* ADB Q15 & Q17 at http://www.mad.uscourts.gov/boston/burroughs.htm.

Ex. 1 at 3 ¶ 9. Lilly promptly complained, *see* Ex. 2 at 2 (Lilly Ltr. dated Oct. 9, 2020), and the parties later met and conferred. On that call, Teva acknowledged it would produce *some* Post-Complaint Documents but maintained its refusal to withdraw its date cutoff, citing only "undue burden." *See* Ex. 3 at 2 (Lilly Ltr. dated Dec. 11, 2020).

To alleviate Teva's purported concerns on burden, Lilly narrowed its request for Post-Complaint Documents to 33 of its 56 RFPs. Ex. 4 at 1–3 (Lilly Ltr. dated Dec. 23, 2020). Despite repeated prodding by Lilly—on January 6, 20, 28, and February 9—Teva ignored Lilly's proposed compromise for nearly two months. *See* Ex. 5 at 2; Ex. 6; Ex. 7 at 1; Ex. 8 at 2. When Teva finally responded, it reiterated its untenable position and only agreed to produce *certain* Post-Complaint Documents responsive to seven Lilly RFPs[2] on "damages and financial issues"—documents Teva needs for its damages case. *See* Ex. 9 at 2 (Teva Ltr. dated Feb. 11, 2021).

In a meet and confer on February 18, Teva repeated that it will not produce—or even review—Post-Complaint Documents captured by the ESI search terms Teva has agreed to. *See* Ex. 10 at 2–3 (Lilly Ltr. dated Feb. 23, 2021). Teva also acknowledged that it is even applying its date cutoff to the damages and financial information it has agreed to produce. For those seven RFPs, Teva revealed it will only produce *select* documents located using so-called "targeted searches." *See id.* While Teva would not disclose the details of these "targeted searches," it confirmed such searching disregards the search terms Teva agreed to run under the ESI protocol. *See id.*; ECF No. 99, Ex. A at Table 2; Ex. 11 at 2 ("Teva agrees to run . . . Lilly's additional proposed ESI terms."). A few days later, Teva "estimate[d]" that removing its improper date cutoff would require reviewing "over 100,000 additional documents at an estimated cost of ~$325,000." Ex. 12.

Teva followed up on February 25, stating it would "consider a compromise" where Teva would produce certain Post-Complaint Documents for six more RFPs[3] "if it would resolve the dispute." Ex. 13 at 2–3. Unsurprisingly, these RFPs also cover damages-related documents Teva presumably wants to produce, including information on alleged lost sales to Lilly (RFP 30), valuations (RFP 33), and licenses (RFPs 50–51). Teva, however, maintained that it would not review ***"over one hundred thousand"*** Post-Complaint Documents that hit on the parties' ESI search terms. *See id.* (emphasis added). Instead, for these RFPs, Teva will again employ "select, targeted searching" that disregards the ESI Protocol.

The parties met and conferred again on February 26 but could not reach agreement.

[2] RFP Nos. 27, 28, 29, 31, 32, 33, and 35.
[3] RFP Nos. 30, 34, 50, 51, 53, and 56.

Teva's Arbitrary Date-Cutoff Objection Should Be Overruled

Teva's objection is improper for at least four reasons.

First, the objection is arbitrary. There is no valid reason a document "created" before September 27, 2018, is discoverable whereas that same document—if "created" *after* September 27, 2018—would somehow be protected from discovery. The date Teva sued does not dictate what is discoverable. Just a few examples quickly illustrate the arbitrary and improper nature of Teva's cutoff:

- Documents concerning—and communications with—the named inventors of the Patents-in-Suit or third parties who have had (or may still have) an interest in the Patents-in-Suit (RFP Nos. 3 and 4).

- Documents and communications relating to the "Tan Thesis"—the main prior art reference on which Lilly has based its §§ 102 and 103 invalidity defenses (RFP Nos. 11 and 12).

- Documents relating to any alleged secondary considerations or objective evidence of non-obviousness, including documents relating to commercial success, industry praise (or the lack thereof), and nexus to the Patents-in-Suit (RFP No. 18).

- Documents relating to Teva's research and development efforts aimed at using Ajovy for treating cluster headache (RFP No. 23).[4]

Teva cannot credibly argue these (or any other) categories of documents should not be produced based on when they were created. The relevance of such requests is beyond dispute—confirmed by Teva's agreement to produce the same documents if they were "created" *before* the arbitrary date cutoff. Lest there be any doubt on this point, Teva just acknowledged to the Court that relevance does turn on an "arbitrary date."[5] *See* ECF No. 99 at 4.

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[4] These documents are directly relevant to Teva's asserted claims, *see, e.g.*, U.S. Patent No. 9,884.908 at claim 5 ("wherein the headache is a . . . cluster headache"), and Lilly's invalidity defenses, *see* Lilly's Preliminary Disclosures Pursuant to Rule 16.6(d)(4) at 11–16 (discussing Teva's abandoned cluster-headache program in the context of invalidity under 35 U.S.C. §112, ¶ 1). Notably, Teva announced it abandoned the clinical studies on cluster headache *after* September 27, 2018.

[5] In its letter to the Court, Teva states, "Lilly has provided no explanation for why development activities occurring before August 2015 are relevant, while those occurring after that

Second, Teva's arbitrary date cutoff allows it to cherry-pick the Post-Complaint Documents it wants to produce. And that is exactly what Teva admits it will do using undisclosed "targeted searches." Under this approach, Teva is free to produce *only* those documents it views as supporting its damages case, while excluding all others, including unfavorable ones—a practice Teva acknowledges is improper. *See* Ex. 14 at 3 (arguing that "cherry-picking certain documents while excluding others" is a "violation" of a party's discovery obligations). But even if Teva does not take such a nefarious approach, Lilly has no way of knowing what Teva will consider and withhold, much less what it will even review.

Third, Teva is attempting to skirt the requirements of the Court-ordered ESI Protocol. ECF No. 57. As Teva recognizes, the parties established an ESI Protocol to "[s]treamline [d]ocument [d]iscovery." ECF No. 99 at 2. If Teva thought a date cutoff was needed to streamline discovery, it should have raised the issue while negotiating the ESI Protocol—it never did. Having agreed to the ESI Protocol, Teva is supposed to "locate potentially responsive ESI" using a set of tailored search terms it accepted, not unidentified "targeted searches." *See* ECF No. 57 at § 3(b). Yet Teva now refuses to even review ***"over one hundred thousand"*** Post-Complaint Documents captured by those very search terms, merely because such documents were created *during the timeframe in which Lilly's accused product has been on the market.* That position is untenable, and it underscores why Teva's cherry-picking enables it to withhold large swathes of relevant information.

And fourth, "[a]s the party resisting discovery, [Teva] bear[s] the burden of showing some sufficient reason why discovery should not be allowed." *Katz v. Liberty Power Corp., LLC*, No. 18-CV-10506-ADB, 2020 WL 3492469, at *2 (D. Mass. June 26, 2020) (internal quotation marks and citation omitted) (Burroughs, J.). Teva's only basis for refusing to produce the requested Post-Complaint Documents—increased costs—lacks support.

Beyond mere attorney argument that removing its improper date cutoff would require reviewing "over 100,000 additional documents at an estimated cost of ~$325,000," Ex. 12, Teva has provided no underlying details and no concrete evidence supporting those purported figures. By any measure, Teva has not met its burden. *See Katz*, 2020 WL 3492469, at *5 (explaining that "[b]oilerplate language that discovery is 'overbroad and unduly burdensome' is insufficient to meet the 'burden of showing by affidavit or otherwise that [discovery] would be unduly burdensome.'"); ECF No. 99 at 6 (Teva acknowledging the Federal Rules require the resisting party to provide "concrete evidence to meet its burden").

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arbitrary date are not." ECF No. 99 at 4. Teva misconstrues Lilly's position, as Lilly has never instituted any such date cutoff. Despite being misguided, Teva's argument underscores why its September 27, 2018, date cutoff is improper.

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Lilly respectfully requests that the Court overrule Teva's blanket date-cutoff objection and compel it to produce all relevant, responsive documents "created" after September 27, 2018. Thank you for Your Honor's kind attention to this matter. Lilly is available for a status call at the Court's convenience.

Respectfully submitted,

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cc: All Counsel of Record (by ECF)