IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC.,	
Plaintiffs,	
v.	C.A. No. 18-88-LPS
APOTEX INC., et al.,	**REDACTED PUBLIC VERSION**
Defendants.	

ORDER

At Wilmington this **20th** day of **August, 2020:**

Having reviewed Lupin Limited and Lupin Pharmaceuticals Inc.'s ("Lupin") and Plaintiffs H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc.'s (collectively, "Plaintiffs") recent letters and supporting materials (*see, e.g.*, D.I. 900, 905, 906),

IT IS HEREBY ORDERED that Lupin's motion (D.I. 899) to enforce the Court's June 25, 2020 Order (D.I. 801) ("Prior Order") and strike portions of expert reports is **GRANTED** (except to the extent that it requests an award of attorney fees). Any expert opinions relating to, or alleging the presence of, the [redacted] in Lupin's ANDA products are **STRICKEN.**

Just as Plaintiffs waited far too long to allege that Lupin infringes due to the purported presence of the [redacted], so, too, have Plaintiffs waited far too long to disclose that the purported presence of the [redacted] in Lupin's ANDA products is somehow relevant to its

infringement case. As Lupin correctly observes, Plaintiffs failed to argue – when the Court was evaluating Lupin's earlier motion, leading to the Prior Order – that the [redacted] was somehow relevant to issues of stability and crystallinity. (*See, e.g.*, D.I. 906) ("If the presence of the [redacted] in Lupin's ANDA product is relevant to their claims with respect to the [redacted] why was that never argued in the briefing on Lupin's first motion?") In the overall context of how discovery has proceeded (*see, e.g.*, D.I. 900 at 1) ("Plaintiffs never once alleged the presence of the [redacted] in Lupin's ANDA product – not in contentions (initial or final) or otherwise [until the opening expert report]."), Plaintiffs' approach to [redacted] issues (*see, e.g., id.* at 2) ("Plaintiffs' counsel clearly requested that Dr. Morin perform testing on [redacted] ***after*** this Court's Order prohibiting them from proffering such opinions . . . .") – including its handling of Lupin's motions – leads the Court to conclude that Plaintiffs' proposed use of [redacted] evidence as "rebuttal" would be unfairly prejudicial to Lupin.

As stated in the Prior Order, Lupin could have pursued its infringement and/or invalidity cases differently had Plaintiffs disclosed their [redacted] contentions during fact discovery, as they should have done. Lupin does not have these opportunities now. Even assuming Plaintiffs were correct that "Lupin ***never*** asked this Court to exclude [redacted] being offered as an item of proof of Plaintiffs' timely-asserted [redacted] claims" (D.I. 905 at 1) (emphasis added) – and it is not[1] – such relief is well-justified at this point.

[1] *See, e.g.*, D.I. 748 at 3 ("Lupin therefore requests that any expert opinions relating to, or alleging the presence of, the [redacted] in Lupin's ANDA products be stricken."); *see also* D.I. 905 at 5 (quoting same portion of Lupin's letter (D.I. 748 at 3) and thereby recognizing, contrary to their assertion at page 1 of Plaintiffs' same letter, that Lupin ***did*** ask Court to exclude all [redacted] evidence).

Having reviewed Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.'s ("Macleods") recent letter (D.I. 904) related to enforcement of the Prior Order,

IT IS FURTHER ORDERED that in light of the instant Order, Macleods shall meet and confer with any party opposing the relief requested by Macleods, and then advise the Court in a timely manner as to whether judicial assistance is still required with respect to the issues raised in Macleods' letter.

IT IS FURTHER ORDERED that because this Order is issued under seal, the parties shall meet and confer and advise the Court, by no later than **noon tomorrow, August 21, 2020**, whether they request any redactions (and, if so, the nature and basis for such proposed redactions).

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE