IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, et al.	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civ. No. 18-88-LPS
	:	
APOTEX INC., et al,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

Megan E. Dellinger and Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE

George F. Pappas, Einar Stole, Christopher N. Sipes, Brianne Bharkhda, Priscilla G. Dodson, Alaina Whitt, Allison Schmitt, and Yiye Fu, COVINGTON & BURLING LLP, Washington, DC

Attorneys for Plaintiffs

Dominick T. Gattuso, HEYMAN ENERIO GATTUSO & HIRZEL LLP, Wilmington, DE

Laura A. Lydigsen, Joshua E. Ney, and Judy K. He, BRINKS GILSON & LIONE, Chicago, IL

Attorneys for Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.

November 15, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court is Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.'s ("Defendants") motion for certification of an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) (D.I. 378). For the reasons stated below, the motion is denied.

BACKGROUND

Plaintiffs H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. ("Plaintiffs") brought this patent infringement case against Defendants based on Defendants' Abbreviated New Drug Applications ("ANDA"), which seek approval from the U.S. Food and Drug Administration ("FDA") to market generic versions of Plaintiffs' Trintellix drug product prior to the expiration of certain of Plaintiffs' patents. Trintellix is indicated for treating Major Depressive Disorder ("MDD").

When Plaintiffs initiated this suit, they alleged that Defendants' proposed ANDA product would infringe three patents: U.S. Patent Nos. 8,722,684 ("the '684 patent"), 8,969,355 ("the '355 patent"), and 9,227,946 ("the '946 patent'"). Thereafter, Plaintiffs made two FDA-approved changes to their Trintellix label. First, Plaintiffs included information related to Trintellix's positive effects on cognitive impairment. Consequently, Plaintiffs also added U.S. Patent 9,125,910 ("the '910 patent") to Trintellix's entry in the FDA's "Orange Book." The '910 patent claims a "method of treating cognitive impairment involving a decline in speed of processing, executive function, attention, or verbal learning and memory in a patient diagnosed with depression." (D.I. 387 Ex. O at 39:31-34) Second, Plaintiffs added data related to Trintellix's positive effects on treatment of emergent sexual dysfunction. Correspondingly, they

also added U.S. Patent 9,278,096 ("the '096 patent") to Trintellix's Orange Book entry. The '096 patent claims (in part) a "method for the treatment of a disease selected from the group consisting of depression, anxiety, abuse and chronic pain . . . wherein [a] patient has previously received medication or is still receiving medication for the treatment of said disease, [and] the medication is ceased or reduced or has to be ceased or reduced due to sexually related adverse events." (D.I. 387 Ex. L at 20:30-43)

Plaintiffs then moved to amend to their complaints, seeking to add claims for a declaratory judgment that Defendants would be liable for contributory infringement of the '910 and '096 patents. (*See* D.I. 224) After considering Defendants' opposition (D.I. 234), the Court granted Plaintiffs' motion to amend (D.I. 260). Defendants then filed their pending motion for certification of an interlocutory appeal of the Court's order granting the motion to amend. (D.I. 378)

LEGAL STANDARDS

Under 28 U.S.C. § 1292(b), the Court has discretion to certify orders for interlocutory review where "exceptional circumstances" merit a departure from the final judgment rule. *See Coopers & Lybrand v. Livesay*, 437 U.S. 463, 475 (1978); *see also Microsoft Mobile Inc. v. Interdigital, Inc.*, 2016 WL 8302609, at *1 (D. Del. June 13, 2016) ("Interlocutory appeal is meant to be used sparingly and only in exceptional cases where the interests cutting in favor of immediate appeal overcome the presumption against piecemeal litigation."). The Court can certify orders that (i) address a "controlling question of law" as to which there is (ii) "substantial ground for difference of opinion" if (iii) an immediate appeal "may materially advance the

ultimate termination of the litigation." 28 U.S.C. § 1292(b); *see also Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754-55 (3d Cir. 1974). The decision to certify an order for appeal under § 1292(b) lies within the sound discretion of the District Court. *See St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elecs. Co.*, 2010 WL 1213367, at *4 (D. Del. Mar. 28, 2010).

A question presented for certification is a "controlling question of law" when it "would result in a reversal of judgment after a final hearing." *Katz*, 496 F.2d at 755. Such questions should not require the appellate court to make "factual determinations better left to the district court." *Miller v. Bolger*, 802 F.2d 660, 666-67 (3d Cir. 1986).

DISCUSSION

Defendants request certification of the following question:

> Whether Plaintiffs can state a cognizable claim for contributory infringement of an Orange Book-listed patent based on the filing of Sandoz Inc.'s ANDA where Sandoz Inc. has submitted a section viii statement with respect to the use claimed in the patent?

(D.I. 380 at 2) Defendants contend that this question is "strictly legal" because the facts show that Sandoz "carved out" the '096 and '910 patents by filing section viii statements, among other things. (D.I. 380 at 10-11) Thus, to Defendants, their interlocutory appeal would pose solely the question of whether Plaintiffs can state a claim for infringement of these patents as a matter of law. (D.I. 380 at 11)

The Court disagrees. Instead, as Plaintiffs contend, the question Defendants seek to certify also "raises a number of factual issues." (D.I. 393 at 14) In order to determine if Plaintiffs can state a claim for contributory infringement despite Defendants' alleged "carve out," the Federal Circuit would need to decide if Plaintiffs can prove that Defendants' ANDA product

has "no substantial non-infringing use." *See In re Bill of Lading Transmission and Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012); 35 U.S.C. § 271(c). This is, at least in part, a factual issue. Answering it depends on whether Defendants' ANDA product, which will treat MDD, claims some use that the '096 and '910 patents (which claim treatment for MDD-related symptoms) do not cover. *See Bill of Lading*, 681 F.3d at 1338 ("[T]he [substantial non-infringing use] inquiry focuses on whether the accused products can be used for purposes other than infringement."). Hence, the proposed certified question is not a controlling question of law. *See In re Venoco, LLC*, 2019 WL 2117638, at *3.

While the Court need not (and will not) decide whether the other prerequisites for an appropriate interlocutory appeal are present, *see generally Cherry Bank USA, N.A. v. Hess*, 2011 WL 4459604, at *2 (D. Del. Sept. 26, 2011), the Court does note that Defendants have failed to identify "exceptional circumstances" justifying an immediate appeal. *See Princeton Digital Image Corp. v. Konami Digital Entm't*, 2017 WL 6290637, at * 2 (D. Del. Dec. 11, 2017).

CONCLUSION

The Court denies Defendants' motion for certification of an interlocutory appeal. An appropriate Order follows.

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APOTEX INC., et al,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

At Wilmington, this **15th** day of **November, 2019**:

For the reasons stated in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that Defendants' motion for certification of an interlocutory appeal (D.I. 378) is DENIED.

UNITED STATES DISTRICT JUDGE