

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No. 23-152-JLH
(Consolidated)

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

C.A. No. 23-153-JLH
(Consolidated)

MEMORANDUM OPINION

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September 24, 2026

JENNIFER L. HALL, U.S. DISTRICT JUDGE

Pending before the Court are summary judgment and Daubert motions from both sides. This opinion assesses Defendants' Motion for Summary Judgment #1: Non-Infringement. (No. 23-152, D.I. 297; No. 23-153, D.I. 250.) For the reasons below, the motions will be GRANTED.

I. BACKGROUND

A. Procedural History

Non-24-Hour Sleep-Wake Disorder ("Non-24") is a disease that disproportionately affects blind individuals. Affected individuals cannot naturally synchronize their circadian rhythms with the 24-hour light/dark cycle. In 2014, the Federal Drug Administration ("FDA") approved Plaintiff Vanda Pharmaceuticals Inc.'s ("Vanda's") new drug application to market 20 mg Hetlioz® (tasimelteon) to treat Non-24.

In 2018, Defendants Teva Pharmaceuticals USA, Inc. ("Teva"), Apotex Inc., and Apotex Corp. (collectively, "Apotex") filed Abbreviated New Drug Applications ("ANDAs") to manufacture and sell generic 20 mg tasimelteon capsules. The ANDA filings led to a sprawling Hatch-Waxman case in this district before Chief Judge Connolly ("*Tasimelteon I*"). On December 13, 2022, following a bench trial, Chief Judge Connolly entered a final judgment in Defendants' favor, concluding in a thorough opinion that all of the then-asserted method of treatment claims¹ were invalid as obvious. *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-651-CFC, 2022

¹ Vanda asserted fourteen patents but withdrew ten of them. The remaining four asserted claims related to methods of treating Non-24 by administering 20 mg of tasimelteon. Claim 3 of U.S. Patent No. RE46,604 ("604 patent") claimed a method of treating Non-24 by administering 20 mg of tasimelteon once daily 0.5 to 1.5 hours before a target bedtime. Claim 14 of U.S. Patent No. 10,149,829 ("829 patent") claimed a method of treating Non-24 by discontinuing treatment with a strong CYP1A2 inhibitor and then administering 20 mg of tasimelteon once daily. Claim 4 of U.S. Patent No. 9,730,910 ("910 patent") claimed a method of treating Non-24 by discontinuing treatment with rifampicin and then administering 20 mg of tasimelteon once daily before a target bedtime. And Claim 5 of U.S. Patent No. 10,376,487 ("487 patent") claimed a method of treating Non-24 by orally administering 20 mg of tasimelteon without food.

WL 17593282 (D. Del. Dec. 13, 2022). Vanda appealed. On May 10, 2023, the Court of Appeals for the Federal Circuit affirmed Judge Connolly's finding that the asserted claims were obvious.

In December 2022, while *Tasimelteon I* was on appeal, FDA approved Defendants' ANDA applications. On December 27, 2022 (two weeks after Judge Connolly entered judgment for Defendants in Delaware), Vanda filed separate suits against Defendants in the District of New Jersey, alleging infringement of Vanda's U.S. Patent No. 11,285,129 ("129 patent") (which issued during the *Tasimelteon I* bench trial). (No. 23-152, D.I. 1; No. 23-153, D.I. 1.) On December 29, 2022, Teva launched its generic tasimelteon product.

On February 10, 2023, the New Jersey court transferred the cases to Delaware, observing that there was "judicial economy to be gained from transferring this action to a district that has extensive familiarity with the issues and factors of this matter (including the patent specification, the family of patents, the ANDAs, and the label that forms the basis of the instant action)." (*See* No. 23-152, D.I. 53 (New Jersey transfer opinion).)

In January 2024, the Court reassigned the cases to me. On September 23, 2024, I issued a Scheduling Order coordinating the cases for pretrial purposes only. On December 9, 2024, Vanda filed additional separate suits against Defendants that alleged infringement of U.S. Patent No. 11,918,556 ("556 patent") (which issued on March 5, 2024). (No. 24-1344, D.I. 1; No. 24-1345, D.I. 1.) The Court consolidated the two Teva cases into No. 23-152 and consolidated the two Apotex cases into No. 23-153. The Teva case (No. 23-152) and the Apotex case (No. 23-153) remain coordinated for pretrial purposes only.

On March 9, 2026, the parties filed a bunch of summary judgment and *Daubert* motions. Relevant here, Defendants filed identical motions seeking summary judgment that their respective sales of their generic products do not infringe the '129 or '556 patents. (No. 23-152, D.I. 297; No.

23-153, D.I. 250.) On April 14, 2026, I held a lengthy hearing on the motions. At the hearing, I expressed concern that the parties' arguments about induced infringement might be impacted by an anticipated Supreme Court ruling in *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, which was expected to come out in June 2026. I ordered the parties to file two-page letters addressing the impact of *Hikma* within seven days of the Supreme Court's ruling.

On June 4, 2026, the Supreme Court decided *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. 580 (2026). On June 11, 2026, the parties filed letters addressing *Hikma*. (D.I. 371, 372.²) On June 17, 2026, I told the parties that I thought *Hikma* did have an impact on the induced infringement issue and that I was inclined to grant summary judgment of non-infringement. (D.I. 373.) To ensure that both sides had a full and fair opportunity to be heard, I invited (but did not require) the parties to file supplemental briefs. (*Id.*) Both sides filed supplemental briefs in July 2026. (D.I. 374, 376.)

B. Asserted Patents

The '129 and '556 patents ("Asserted Patents") have the same specification.³ The '129 patent has 3 claims. Claim 1 is the only independent claim, and it relates to a method that conditions tasimelteon administration on whether a patient is being treated with a beta-adrenergic receptor antagonist, also known as a beta blocker. It provides:

1. In a method of administering tasimelteon to a patient, the improvement comprising:

determining whether the patient is being treated with a beta-adrenergic receptor antagonist; and

in the case that it is determined that the patient is not being treated with a beta-adrenergic receptor antagonist,

² Going forward, this opinion will cite to No. 23-152 only, unless otherwise stated.

³ They also share a specification with the '604 and '829 patents asserted by Vanda in *Tasimelteon I*. See *supra*, n.1.

administering to the patient 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime; or

in the case that it is determined that the patient is being treated with a beta-adrenergic receptor antagonist:

instructing the patient to cease treatment with the beta-adrenergic receptor antagonist; and then

administering to the patient 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime.

The '556 patent has 3 claims. Claim 1 is the only independent claim, and it recites a method of treating a patient with tasimelteon who is already taking a beta blocker:

1. A method of treating a patient for a circadian rhythm disorder or a sleep disorder wherein the patient is being treated with a beta-adrenergic receptor antagonist, the method comprising:

discontinuing treatment with the beta-adrenergic receptor antagonist; and then

administering to the patient with 20 mg tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime;

thereby avoiding decreased efficacy of tasimelteon treatment due to co-administration with the beta-adrenergic receptor antagonist.

C. Accused Products

Teva launched its generic tasimelteon product in December 2022. Apotex launched its generic tasimelteon product in January 2024.

Defendants' tasimelteon labels are substantively identical to Vanda's label for Hetlioz.⁴ In section "1 INDICATIONS AND USAGE," the labels say as follows: "Tasimelteon capsules are

⁴ By statute, Defendants' labels were required to be identical to Vanda's, absent specified circumstances. 21 U.S.C. § 355(j)(2)(A)(v); *see also Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. 580, 592 (2026).

indicated for the treatment of Non-24 in adults.” (D.I. 309 at Ex. 3, 4.) In subsection “**2.2 Recommended Dosage for Tasimelteon Capsules for Non-24**,” the labels say as follows: “The recommended dosage of tasimelteon capsules in adults is 20 mg one hour before bedtime, at the same time every night.” (*Id.*)

Section “**7 DRUG INTERACTIONS**” describes various drug interactions with strong CYP1A2 inhibitors (7.1), strong CYP3A4 inducers (7.2), and beta-adrenergic receptor antagonists (7.3). (*Id.*) In subsection “**7.3 Beta-Adrenergic Receptor Antagonists (e.g., acebutolol, metoprolol)**,” the labels state as follows: “Beta-adrenergic receptor antagonists have been shown to reduce the production of melatonin via specific inhibition of beta-1 adrenergic receptors. Nighttime administration of beta-adrenergic receptor antagonists may reduce the efficacy of tasimelteon.” (*Id.*) Unlike subsections 7.1 and 7.2, which expressly warn to “avoid use of tasimelteon in combination with” CYP1A2 and CYP3A4 inducers, respectively, subsection 7.3 does not expressly say to avoid use of tasimelteon with beta-adrenergic receptor antagonists/beta blockers.

The labels do not otherwise mention beta-adrenergic receptor antagonists/beta blockers.

II. LEGAL STANDARDS

A party may move for summary judgment under Federal Rule of Civil Procedure 56. Summary judgment must be granted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).

To defeat a motion for summary judgment, a plaintiff “must point to concrete evidence in the record that supports each and every essential element of his case.” *Nitkin v. Main Line Health*, 67 F.4th 565, 571 (3d Cir. 2023) (quoting *Orsatti v. N.J. State Police*, 71 F.3d 480, 484 (3d Cir. 1995)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). “[W]here a non-moving

party fails sufficiently to establish the existence of an essential element of its case on which it bears the burden of proof at trial, there is not a genuine dispute with respect to a material fact and thus the moving party is entitled to judgment as a matter of law.” *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 265 (3d Cir. 2014) (citing *Lauren W. v. DeFlaminis*, 480 F.3d 259, 266 (3d Cir. 2007)).

The Court must “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). But a factual dispute is only genuine if “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

III. DISCUSSION

Defendants move for summary judgment that they do not infringe the Asserted Patents. The Court will grant the motion.

A. Direct Infringement (35 U.S.C. § 271(a))

Some of Vanda’s operative pleadings reference 35 U.S.C. § 271(a). (No. 23-152, D.I. 94 at 19 (requesting a declaratory judgment that Teva directly infringes under § 271(a)); No. 23-153, D.I. 86 (requesting a declaratory judgment that Apotex directly infringes under § 271(a)).) Section 271(a) sets forth the requirements of a claim of direct patent infringement: “Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a).

Defendants request summary judgment that they don’t directly infringe the Asserted Patents—which, as explained above, cover methods of treating patients—because Defendants are pharmaceutical companies that do not “use” the claimed methods. Vanda’s counsel told the Court

at oral argument that it does not presently contend that either Defendant directly infringes.⁵ Accordingly, I will grant summary judgment that Defendants do not directly infringe under § 271(a).

B. Induced Infringement (35 U.S.C. § 271(b))

Vanda contends that Defendants induce infringement under 35 U.S.C. § 271(b). Defendants request summary judgment that they don't induce infringement because Vanda cannot establish a predicate act of direct infringement and because Vanda cannot show that Defendants took active steps to encourage infringement.

Section 271(b) provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). A claim for induced infringement under § 271(b) has three elements: (1) direct infringement by a third party; (2) knowledge by the defendant that the induced acts constitute patent infringement; and (3) active steps to encourage direct infringement. *Hikma*, 608 U.S. at 586 (citing cases).

I agree with Defendants that no reasonable jury could find that Defendants took active steps to encourage direct infringement. At oral argument I asked Vanda's counsel to list its evidence of active steps that encourage infringement, and counsel acknowledged that the label on Defendants' product was its only evidence. (*See* Tr. at 48:20–50:9.) Vanda's counsel further asserted that the contents of the label were “more than sufficient under the case law” to avoid summary judgment. (Tr. 50:2–9.)

⁵ THE COURT: Well, let's just start by clearing up the record. You're not alleging that either Defendant infringes under 271(a); right?

VANDA'S COUNSEL: We are not. That was not in our final infringement contentions, so we think that was apparent to them.

THE COURT: Okay. Well, it needs to be apparent to me
(Tr. at 37:2–12.)

Whether that was true before the Supreme Court’s decision in *Hikma* is up for debate. After *Hikma*, no reasonable juror could find that Defendants’ labels “encourage, recommend, or promote” an infringing use. *Hikma*, 608 U.S. at 590–93. Active steps need not be express, but they must be “clear” to the relevant audience and “affirmative.” *Id.* at 592, 594–95. The question is not whether the purportedly inducing statements could be “underst[oo]d” to induce infringement, but whether the statements constitute “affirmative steps to bring about the desired result” of infringement. *Id.* at 594 (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011)).

To recap, all of the claims of the Asserted Patents require (among other things) discontinuing beta-blockers before administering tasimelteon. The only mention of beta-blockers on Defendants’ labels is in Section 7.3, which states that “[n]ighttime administration of [beta blockers] may reduce the efficacy of tasimelteon.” (D.I. 309, Ex. 3, 4.) That language is not an affirmative step to bring about the desired result of infringement of the Asserted Patents, as a matter of law.⁶ I will grant summary judgment that Defendants do not induce infringement under § 271(b).

C. Contributory Infringement (35 U.S.C. § 271(c))

Vanda also alleges that Defendants are liable for contributory infringement under 35 U.S.C. § 271(c). Section 271(c) provides that “[w]hoever offers to sell or sells within the United States or imports into the United States . . . a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of

⁶ I reject Vanda’s suggestion that *Hikma* is distinguishable because it pertained to a section viii “carve-out.” See 21 U.S.C. § 355(j)(2)(A)(viii). The reasoning of *Hikma* is not limited to the context of carve-outs.

commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.” 35 U.S.C. § 271(c). “[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). The patent owner has the burden to show that there are no substantial non-infringing uses.

Vanda does not presently contend that Defendants contributorily infringe the ’556 patent. (Tr. at 55:18–21.) Accordingly, I will grant summary judgment that Defendants do not infringe the ’556 patent under § 271(c).

Turning to the ’129 patent, the only independent claim requires first determining whether a patient is being treated with a beta blocker. If not, the method calls for administering the patient 20 mg of tasimelteon once daily approximately 0.5–1.5 hours before bedtime. If it is determined that the patient is being treated with a beta blocker, the method requires instructing the patient to stop the beta blocker and then administering 20 mg of tasimelteon once daily approximately 0.5–1.5 hours before bedtime. The dispute here is whether Defendants’ products have substantial non-infringing uses—that is, whether they can be used in a “not unusual” way without infringing the ’129 patent. Assessing whether Vanda has enough evidence to go to the jury on that issue has been challenging for the Court, in part, because Vanda’s position has been hard to pin down, and the arguments it has made to the Court appear to have morphed.⁷

⁷ In response to Defendants’ motion for summary judgment, Vanda devoted only two paragraphs to the issue of contributory infringement. Vanda’s argument essentially went like this: (1) there is no factual dispute that all prescribers determine what other medications their patient is taking (D.I. 311 at 4); (2) “every administration of tasimelteon to a patient not taking a beta blocker is therefore an infringing use” (*id.* at 30); (3) for those patients who are taking a beta blocker, there is evidence (in the form of an opinion from Vanda’s expert, Dr. Mora) that “some” providers infringe because “most” providers will first take their patient off beta blockers (*id.* at 9, 13, 17); and (4) “[t]hus, taking all inferences in Vanda’s favor, every administration of tasimelteon is an

infringing use, and there is no non-infringing use at all, much less a substantial one” (*id.* at 30). The Court did not follow that logic.

Defendants’ reply brief argued that Vanda had not met its burden to produce evidence that all doctors would take a patient off beta blockers to give them tasimelteon. (D.I. 329 at 12.) Defendants also argued that Vanda’s answering brief advanced a new infringement theory that Vanda hadn’t previously disclosed in discovery. According to Defendants, Vanda had never taken the position that the “determining” step was met simply by the physician determining what medications a patient was taking. Defendants also argued that Vanda’s new position was irreconcilable with the opinions of Vanda’s own expert. And Defendants suggested that the reason Vanda did not previously take that position previously was because such a position would almost certainly render the claims invalid. (Recall that, in *Tasimelteon I*, the Federal Circuit affirmed the finding of invalidity of several of Vanda’s patent claims relating to bedtime administration of tasimelteon for Non-24.)

In an effort to nail down and understand Vanda’s contributory infringement position, I asked Vanda’s counsel about it at oral argument. At that point, counsel took the position that the determining step required a physician to “specifically” determine whether the patient is taking a beta blocker. (Tr. 45:17–46:10.) Vanda also took a position on why Defendants’ products had no substantial non-infringing use: according to Vanda, circumstantial evidence in the record could support a jury finding that, in every case, a physician will specifically determine whether or not the patient is taking beta blockers and, if so, instruct the patient to cease taking beta blockers before administering tasimelteon. When the Court asked about the evidentiary support for that position, counsel responded with an answer about induced infringement (Tr. 53:13–23) and eventually stated that Vanda’s “main argument is § 271(b),” *i.e.*, induced infringement (Tr. 53:6–54:11).

After oral argument, Vanda submitted a letter to the Court to purportedly “clarify” its contributory infringement position “for the record”:

Vanda’s position is that a reasonable jury could conclude from the evidence in this case, including Defendants’ labels ([D.I. 309] Vanda Ex. 26 & 27), FDA’s guidance regarding drug labeling ([D.I. 316] Vanda Ex. 57), and Dr. Mora’s opinions ([D.I. 316] Vanda Ex. 39), that prescribers would follow the label by determining whether a patient is taking a beta blocker and, if so, instructing that the patient cease beta blocker use before commencing tasimelteon treatment. A reasonable jury could further conclude that a prescriber’s decision to ignore the label’s statement telling prescribers to avoid beta blocker co-administration would be a departure from the product’s instructed and expected use and therefore “unusual,” “occasional,” or “aberrant.” *Vita-Mix*, 581 F.3d at 1327. Such a non-infringing use would not be “substantial.”

(D.I. 364.) I found the letter curious. For one thing, it appeared to contain an argument that Vanda had not made to the Court in the briefing or at oral argument. For another, it was imprecise. Contrary to the letter, the accused labels do not contain a “statement telling prescribers to avoid beta blocker co-administration.” (*Id.*) Rather, the labels say that “[n]ighttime administration of [beta blockers] may reduce the efficacy of tasimelteon.” (D.I. 309, Ex. 3, 4.) Nor did the letter or

Vanda's most recent filings contend that the following evidence is sufficient for a reasonable jury to find that Defendants' products have no substantial non-infringing uses:

1. **Defendants' Labels:** Defendants' labels say that "[n]ighttime administration of [beta blockers] may reduce the efficacy of tasimelteon." (D.I. 305, Ex. 26, 27; *see also* D.I. 309 at Ex. 3, 4.)

2. **Expert Testimony from Dr. Mora and FDA Guidance:**

a. Vanda's expert, Dr. Mora, explains that FDA guidance recommends that clinically significant drug interactions be described on the drug labeling. (D.I. 316, Ex. 39 ¶ 80; *see also* D.I. 316, Ex. 57.)

b. Dr. Mora opines that prescribers of tasimelteon would read the label and "would and should, in sound clinical practice, determine whether patients they intend to treat with Hetlioz® are currently taking beta blockers." (D.I. 316, Ex. 39 ¶ 19.) According to Dr. Mora, "if a prescriber determines that the patient is taking beta blockers, the prescriber, based on the warning provided in the Hetlioz® Label regarding co-administration of beta blockers with Hetlioz®, should consider if clinically feasible and medically appropriate, and accordingly instruct the patient to discontinue the beta blocker therapy before administering Hetlioz® to the patient (*i.e.*, one capsule daily about one hour prior to their target bedtime." (*Id.* ¶ 21; *see also id.* ¶¶ 30, 108–111.)

3. **Testimony from Defendants' Experts:** Defendants' experts agree that prescribers always determine what other medications a patient is taking. (Ex. 51 at 257:14–19; Ex. 50 at 36:10–38:9.)

(D.I. 376 at 7–9; D.I. 364 at 2.)

cited evidence sufficiently explain why it would not be a substantial non-infringing use for a tasimelteon prescriber to tell the patient to take his beta blocker in the morning.

A few weeks later, *Hikma* came out. The Court invited the parties to submit supplemental briefs. Notwithstanding that *Hikma* was not about contributory infringement, Vanda took the opportunity to use space in its supplemental brief to reassert and expound further on the contributory infringement argument it made in its letter. (D.I. 376.) Defendants accused Vanda of attempting to "revive" its contributory infringement theory "now that the *Hikma* writing is on the wall." (D.I. 374 at 1.)

Conspicuously absent from Vanda's proffered evidence is any direct evidence that any one physician has ever performed all steps of the claimed methods. Indeed, Dr. Mora admitted in his deposition that he did not know whether prescribers actually practiced the asserted claims. (D.I. 309, Ex. 10, 199:3–200:2.) To be sure, a factfinder can rely on circumstantial evidence to infer that direct infringement has likely occurred and/or would occur again. And Dr. Mora's opinion is some evidence that "some" prescribers practice the claimed method and that "some" prescribers may do so again. So, if the question that needed to be answered was whether some infringement has occurred and would continue to occur, the Court might let a jury decide that question. But that's not Vanda's position: Vanda's position is that there are *no* substantial non-infringing uses because all "usual" uses infringe.

The problem with Vanda's position is that it doesn't match up with the record before the Court. (D.I. 374 at 1 (Defendant's supplemental brief) ("[T]he notion that substantially all uses of the drug will infringe is pure fantasy.")) For starters, the Court has reviewed the portions of Dr. Mora's reports cited by Vanda, and he never actually says anything that would allow a jury to find by a preponderance of the evidence that all "usual" uses of tasimelteon infringe.⁸ But even more

⁸ In paragraph 113 of Dr. Mora's report, for example, he opines as follows:
I have prescribed Hetlioz® in my clinical practice. Consistent with standard practice, I read the Hetlioz® Label to ensure I was prescribing it in a manner consistent with what that label teaches in order to promote the safety and efficacy of the drug. This includes the warning in the label that co-administration of tasimelteon with beta blockers may result in decreased efficacy of tasimelteon. Accordingly, it is standard within my clinical practice, and within the standard practice in the industry, to determine whether patients are taking beta blockers, and to explore the possibility of alternatives to beta blockers if the patient is taking them, prior to administration of tasimelteon. And as I explained in paragraph 85 above, multiple alternatives exist to beta blockers. Thus, I would expect that following the standard practice for clinicians, most prescribers would be able to eventually find an alternative to the beta blockers

problematic for Vanda is that the record contains ample evidence of real-life patients taking both tasimelteon and various beta blockers. (*See, e.g.*, D.I. 309, Ex. 6 at -0511994, -2006, -2064, -2082, -2088, -2094, -2095, -2103, -2118, -2126, -2128, -2137, -2139, -2150, -2178, -2180, -2199, -2203, -2229, -2265, -2288, -2296; *id.* Ex. 40 ¶ 108 n.22.) Thus, even when the evidence is viewed in the light most favorable to Vanda, no reasonable juror could find by a preponderance of the evidence that there are no substantial non-infringing uses of Defendants’ tasimelteon products.⁹ Accordingly, the Court will grant summary judgment of no contributory infringement under § 271(c).

D. Infringement under 35 U.S.C. § 271(e)(2)(A)

Vanda also alleges that Defendants infringe under 35 U.S.C. § 271(e)(2)(A). Defendants move for summary judgment of no infringement under 35 U.S.C. § 271(e)(2)(A). A claim under § 271(e)(2)(A) requires the Court to determine “whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent.” *Bristol-Myers Squibb Co. v. Royce Lab’ys, Inc.*, 69

in most patients if clinically feasible prior to the administration of Hetlioz®. Moreover, because of the beta blocker warning provided in the Hetlioz® label, I would not co-administer Hetlioz® with beta blockers.

(D.I. 316, Ex. 39 ¶ 113.) Even read in the light most favorable to Vanda, at best this establishes only that “most” uses would infringe, not that all “usual” uses would infringe. The remainder of the portions of Dr. Mora’s report cited by Vanda are deficient for the same reason. (*See, e.g., id.* ¶ 133 (“[I]n most cases a prescriber would not necessarily instruct a patient to take their beta blocker in the morning, even assuming that such an instruction can avoid the decreased efficacy caused by co-administration of tasimelteon with beta blockers.”).) Thus, even when read in the light most favorable to Vanda, Dr. Mora’s opinions fail to establish the existence of an essential element of Vanda’s case on which it bears the burden of proof at trial.

⁹ The Court disagrees with Vanda’s assertion that “[t]he record in this case is comparable to that in *Forest Laboratories [Holdings Ltd. v. Mylan Inc.]*, 206 F. Supp. 3d 957 (D. Del. 2016)].” In that case, the label of the accused product “actually warn[ed] against” performing the method that the defendants were claiming was a substantial non-infringing use. *Id.* at 975, 979 (label warned of “potentially life-threatening side effects” from performing the method that defendants suggested was a substantial non-infringing use). That is not the situation here.

F.3d 1130, 1135 (Fed. Cir. 1995). “The only difference in the analysis of a traditional infringement claim and a claim of infringement under [§] 271(e)(2) is the timeframe under which the elements of infringement are considered.” *Allergan, Inc. v. Alcon Lab’ys, Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003).

The Court is skeptical that § 271(e)(2)(A) has any role to play in this case, as Defendants’ ANDAs have both been approved, and Defendants’ products have been on the market for many years. Not only that, the ’556 patent didn’t even come into existence until after both Defendants launched. But even if § 271(e)(2)(A) had some applicability here, the claim fails on the merits because no reasonable jury could find infringement of the Asserted Patents, for the reasons above. The Court will grant summary judgment of no infringement under § 271(e)(2)(A).

IV. CONCLUSION

Defendants’ Motion for Summary Judgment #1: Non-Infringement (No. 23-152, D.I. 297; No. 23-153, D.I. 250) will be GRANTED. A separate Order will issue.