IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC., Plaintiffs, v. ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 17-205-CFC

Jack B. Blumenfeld, Derek J. Fahnestock, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Errol B. Taylor, Fredrick M. Zullow, Anna Brook, Jordan P. Markham, Kyanna Lewis, Nathaniel T. Browand, Venus Allahyarzadeh, MILBANK, TWEED, HADLEY & MCCLOY LLP, New York, New York

Counsel for Plaintiffs

John C. Phillips, Jr., David A. Bilson, PHILLIPS, GOLDMAN, MCLAUGHLIN, & HALL, P.A., Wilmington, Delaware; George C. Lombardi, Michael K. Nutter, Ivan M. Poullaos, John R. McNair, WINSTON & STRAWN LLP, Chicago, Illinois; Nimalka R. Wickramasekera, WINSTON & STRAWN LLP, Los Angeles, California

Counsel for Defendants

MEMORANDUM OPINION

December 11, 2019
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiffs Orexo AB and Orexo US, Inc. (collectively, "Orexo") filed this Hatch-Waxman patent suit against Defendants Actavis Elizabeth LLC, Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively, "Actavis"). Orexo alleged in its complaint that Actavis's generic versions of the anti-opioid-addiction drugs Suboxone® and Subutex® directly and indirectly infringed claim 2 of U.S. Patent No. 8,454,996 (the "#996 patent"). D.I. 1. The Court held a five-day trial, after which the jury found that Actavis did not induce or contribute to infringement.[1] D.I. 274. Consistent with the jury's verdict, this Court entered judgment for Actavis. D.I. 279.

Orexo has moved pursuant to Federal Rule of Civil Procedure 59(a) for a new trial "on the issues of infringement, willfulness, and damages." D.I. 283. Orexo argues a new trial is warranted because (1) I erroneously precluded it from presenting at trial the fact that Judge Sue L. Robinson had ruled in a previous patent case (the "Zubsolv® case") that the #996 patent was not invalid and was

[1] Although the parties argued in the Pretrial Order that direct infringement was disputed, the joint verdict form they submitted did not ask the jury whether Orexo had proven direct infringement of claim 2 of the #996 patent. D.I. 271.

infringed by a generic version of another anti-opioid-addiction drug, Zubsolv®, D.I. 284 at 3–10;[2] and (2) I erroneously "excluded the introduction of Orexo's patents and published patent applications (other than the [#]996 patent)," *id.* at 10, and "other publications," *id.* at 14.

I. BACKGROUND

A. Zubsolv®, Suboxone®, and Subutex®

It is undisputed that Zubsolv® is an embodiment of the #996 patent. It is also undisputed that Zubsolv®, Suboxone®, and Subutex® are sublingual (i.e., applied under the tongue) drugs used to treat opioid addiction, that all three drugs have the same active ingredient (buprenorphine), and that all three drugs have a material that acts as a disintegrant.

The parties also agree that Zubsolv® differs from Suboxone® and Subutex® in certain respects. It is undisputed, for example, that Zubsolv® contains croscarmellose sodium but Suboxone® and Subutex® do not; and that Suboxone® and Subutex® contain crospovidone, but Zubsolv® does not.

It is similarly undisputed that Zubsolv® has a different amount of buprenorphine and a different particle size distribution than do Suboxone® and Subutex®. Actavis attempted at trial to prove Suboxone® and Subutex®'s non-

[2] *Orexo AB v. Actavis Elizabeth LLC*, 217 F. Supp. 3d 756 (D. Del. 2016), *rev'd on other grounds*, 903 F.3d 1265 (Fed. Cir. 2018).

infringement of the #996 patent in part by adducing testimony about these differences. Orexo objected to that testimony. In the words of Orexo's counsel:

> This testimony is irrelevant and it's misleading. Comparisons between the commercial embodiment and the accused product is generally disfavored and it's not the appropriate analysis to do patent infringement. . . . [I]t has to be the accused product and a claim. . . . [T]o be comparing the particle size of Zubsolv with the . . . accused product is going to lead the jury to think that is a relevant comparison and it's not.
>
> * * * *
>
> For infringement, it's not [relevant]. And it also goes to the other issue that [Actavis's counsel] has been arguing. There's a difference in the amount of active ingredient in the [accused] product . . . [and in] Zubsolv . . . .

Tr. at 488:21–491:22. I sustained Orexo's objection. *See* Tr. at 494:5–22.

B. Actavis's Motion in Limine Regarding The Zubsolv® Case

Five days before the pretrial conference, the parties filed a 1,173-page proposed pretrial order (PTO). D.I. 254; D.I. 255; D.I. 256. Each side represented in the PTO that both the validity and infringement of the #996 patent would be litigated at trial. And each side included in the PTO three motions in limine.

Actavis's first in limine motion bears on Orexo's pending motion for a new trial. Actavis sought in its in limine motion to preclude Orexo "from presenting [at trial] evidence or argument concerning the parties' prior litigation over the [#]996 patent and Judge Robinson's order [in the Zubsolv® case] holding the patent valid

and infringed." D.I. 256, Ex. 16, Defendant's Motion *In Limine* No. 1, at 1. Actavis argued that the Zubsolv® case was irrelevant to both invalidity and infringement. And it emphasized in its motion that any "reference [to] the Zubsolv® litigation would be highly confusing to the jury, which will be charged with determining whether the *products at issue in this case* infringe, and extremely and unfairly prejudicial to Actavis." *Id.* (emphasis in the original). Actavis also noted in its motion two undisputed facts: (1) Actavis knew about the #996 patent by 2013—three years before Judge Robinson's 2016 ruling in the Zubsolv® case, *see id.* at 2–3; and (2) Actavis launched its generic Suboxone® and Subutex® in 2013 and 2015, respectively—again, before Judge Robinson issued her ruling in the Zubsolv® case, *see id.* at 2.

In its response to Actavis's motion, Orexo argued that "[t]he Zubsolv decision, finding the [#]996 patent valid and infringed is highly relevant in this case (same defendant, same patent, similar buprenorphine product, and same issues)" and that "[t]he decision is probative of willful infringement and intent, and should not be excluded." D.I. 256, Ex. 16, Orexo's Response to Defendant's Motion *In Limine* No. 1, at 1. Orexo contended that Actavis's Zubsolv® was "based on their generic Suboxone" and that Actavis "knew that their generic Zubsolv had a material [i.e., croscarmellose sodium] that was a disintegrant and bioadhesive, and that their generic Suboxone and Subutex products had a material

[i.e., crospovidone] identified in the [#]996 patent as a disintegrant and bioadhesive." *Id.* Thus, Orexo argued, "[t]he jury should consider whether [Actavis] should have recognized the risk of infringing a patent that survived a validity and infringement challenge by the same defendant[ ] based on a similar product (based on the accused product)." *Id.*

Having reviewed carefully the parties' briefing on Actavis's motion in limine, and mindful of the five other in limine motions, eight *Daubert* motions, jury instructions, and other issues that needed to be addressed before trial, I stated at the pretrial conference that "I'm not going to hear argument on [the motion]" and proceeded to announce my decision. Tr. of Mar. 11, 2019 Hr'g at 74:4. I then explained:

> I've made the determination under [Federal] Rule [of Evidence] 403 that I think the admission of evidence related to [the] Zubsolv litigation would confuse the jury. I think it would unfairly prejudice the defendants. It was a bench trial and not a jury trial. There were different theories of invalidity. There was an appeal, there were litigation decisions made during the course of that [case] for strategic reasons that may be irrelevant. *It involved a different drug.*
>
> So there was prior art not presented in that case that apparently will be in this case,[3] and I think that therefore the degree of unfair prejudice is so significant that it would

[3] Orexo had not argued that Actavis was collaterally estopped from presenting an obviousness defense or from relying in this case on prior art that it had advanced as part of its obviousness defense in the Zubsolv® case. *Orexo AB v. Actavis Elizabeth LLC*, 371 F. Supp. 3d 175, 187 n.7 (D. Del. 2019).

> substantially outweigh the probative value that the [Zubsolv® case] evidence would have, especially since, as I understand it, there's no debate even that the patent was known to the defendants prior to the Zubsolv litigation. . . . [S]o I am going to grant the motion.

Id. at 74:6–25 (emphasis added).

Orexo's counsel immediately asked if he might "be heard on the issue of mostly clarification." *Id.* at 75:2–3. He then proceeded to argue the merits of the motion, essentially repeating the argument Orexo had put forward in its papers—namely that Judge Robinson's rulings in the Zubsolv® case were probative of willfulness and intent. *See id.* at 75:6–76:6. The following exchange then occurred:

> THE COURT: I don't deny there's probative value that the Zubsolv litigation has with respect to that question. I've got to conduct a balancing under Rule 403, and I think the probability is significant that references to the Zubsolv litigation will confuse the jury, will unfairly prejudice the defendant[s], will mislead the jury, and I think that that danger of unfair prejudice substantially outweighs the probative value it would have towards willfulness. . . .
>
> [OREXO'S COUNSEL]: Your Honor, does that ruling apply for example, if defendants themselves put that case and things that happened in that case in issue?
>
> THE COURT: Well, if they put the litigation in issue, that would open the door. I can't imagine [they would]. Now, if you mean by that can they bring in evidence that was adduced in th[e] [Zubsolv®] litigation here, I mean, I would have to see, but my ruling doesn't prevent you from bringing in evidence from th[at] litigation. It's just [that] we're not going to refer to Judge Robinson's rulings, and

> I mean, that's what I understood [the motion in limine covered].

Id. at 76:7–77:16.

Counsel then proceeded to argue again the merits of the motion, *see id.* at 77:19–83:14, after which I stated:

> Look, I will say it again. I'm not saying that the Zubsolv litigation result is not probative of willfulness, knowledge, intent. I'm just doing a [Rule] 403 balanc[ing]. I've got to do it. I've got to weigh probative [value] versus potential unfair prejudice, and I don't think it's a close call. I think that the prejudicial value, the unfair prejudicial value, the potential for misleading the jury, confusing the jury and unfairly prejudicing the defendant substantially outweighs the probative value. That's my discretionary call and that's where we are.

Id. at 83:15–24. When I finished explaining my ruling, counsel stated:

> Thank you, Your Honor. And I appreciate your statement that, you know, should it come up at trial where I believe that defendants opened the door on this issue . . . you will hear [from] me again.

Id. at 84:18–21.

On the Monday morning that trial began, I learned that the parties had filed over the weekend a stipulation that removed the issue of the #996 patent's invalidity from the case. *See* Tr. at 3:8–5:6. In light of the stipulation, I asked the parties if I should reduce the amount of time I had originally set aside for the trial. *See id.* at 5:3–13. Orexo's counsel responded: "[W]e believe that our affirmative case [i.e., for infringement] will be essentially the same even though validity is out

of the case." *Id.* at 5:19–21. Counsel did not argue or suggest in any way that Actavis's decision not to pursue an invalidity defense warranted reconsideration of my decision to preclude Orexo from presenting argument or evidence about the Zubsolv® case.

At the end of the first day of trial, the following exchanged occurred:

> [OREXO'S COUNSEL]: I was reminded there's one other issue, and this is following up on Your Honor's order . . . precluding us . . . [from] referring to the . . . [Zubsolv®] litigation.
>
> THE COURT: Yes.
>
> [OREXO'S COUNSEL]: Even today there have been issues that in our view have touched on that litigation and things that we might have wanted to respond to by referring to the litigation. For example, things that allude to why we didn't sue other generic companies or the timing of this lawsuit.
>
> THE COURT: Well, wait. I don't think in fairness, Mr. Taylor [Orexo's counsel], I don't recall any testimony about the timing of this lawsuit. . . .
>
> [OREXO'S COUNSEL]: I don't want to argue that. But I was just going to mention, Your Honor, that we'd like leave to submit to Your Honor an offer of proof on evidence that we would have permitted on the issues in this case.
>
> THE COURT: Well, I think it's kind of late in the game for that. We litigated that motion. But what I said to you is if the door were opened, you would have the opportunity [to argue that evidence of the Zubsolv decision was admissible]. So if you thought the door were opened today, then you should ask for a sidebar and say, ["]Judge,

I think the door was opened. This is what I want to do.["] But if you are talking about making an offer of proof on a motion I've already decided, I mean --

[OREXO'S COUNSEL]: I'm not seeking to reconsider the motion.

THE COURT: Okay.

[OREXO'S COUNSEL]: I'm just saying so we can have an evidentiary record on possibly down the road if there's an appeal in this case.

THE COURT: But that's too late. You should have made that [record] when I made the ruling. So if you want to make an offer of proof -- for instance, if a witness in your mind opened the door, then --

[OREXO'S COUNSEL]: I'm not saying that. I said there were some allusions to things that implicated that.

THE COURT: Right.

[OREXO'S COUNSEL]: If I thought the door was opened, why didn't I ask you to reconsider that issue, I would certainly have come to you.

THE COURT: What's the point of the offer of proof?

[OREXO'S COUNSEL]: Well, the offer of proof, Your Honor, is just, you know, we have a burden in this case on intent, and, you know, I thought when I argued this motion before, I tried to impress on you the relevancy of this evidence to this issue.

THE COURT: Right.

[OREXO'S COUNSEL]: And I just am asking for leave to file an offer of proof as to what the evidence would have been.

> THE COURT: And that's denied. We litigated that motion. I spent a lot of time reading your [1,]750 pages of a Pretrial Order, and I think based on my questions and based on my comments to date, it should have been apparent, and I hope it's apparent to the Federal Circuit, I spent a lot of time reviewing the papers and thinking about the issues. And you had your opportunity to litigate that motion. I pressed you on the relevance of [the Zubsolv® case] and why it should be admitted.
>
> I made a ruling under the Federal Rules of Evidence. I think I articulated the ruling particularly in my analysis under [Rule] 403, the other applicable rules, and I decided, I granted the motion.
>
> So, no. You had your opportunity to litigate the motion. You made your record. You were offered an opportunity to litigate your record in the Pretrial Order. As far as I'm concerned, the record stands. I guess you can file a motion for reconsideration if you want.

Tr. at 273:18–276:13.[4]

Orexo never filed a motion for reconsideration. It did, however, revisit the issue of the Zubsolv® case during the presentation of its infringement case, at which point I reiterated for the record that "there's lots of really good reasons not

[4] Federal Rule of Evidence 103(b) provides that "[o]nce the court rules definitively on the record—either before or at trial—a party need not renew an objection or offer of proof to preserve a claim of error for appeal." Since Orexo had briefed and argued at the pretrial conference the merits of Actavis's motion in limine and I had made a definitive ruling on that motion before trial, there was no reason to make an additional offer of proof at trial. As the Third Circuit held in *Walden v. Georgia–Pacific Corp.*, 126 F.3d 506 (3d Cir. 1997), "[w]hen a definitive evidentiary ruling is made pretrial, there is surely no point to taking the time at trial to make an objection if the in limine ruling admitted certain evidence, *or to make an offer of proof if the in limine ruling excluded it.*" *Id.* at 517 (emphasis added).

to permit the Zubsolv litigation to be mentioned in front of a jury," *id.* at 447:16–18, including the facts that "Zubsolv [was] a bench trial" and involved "a different product," *id.* at 445:20–21. Accordingly, I reminded counsel that "we're not going to open that can of worms." *Id.* at 447:18–19.

At no point before or during trial did Orexo ever argue that I should reconsider my decision to grant Actavis's motion in limine in light of Actavis's decision to drop its invalidity defenses.

C. Evidentiary Rulings Regarding "Other" Patents and Publications

Orexo called as its first witness its CEO, Nikolaj Sorensen, "to testify about our company, Orexo, about our technology, about Zubsolv, the treatment of opioid dependence, [and] the damages that we have incurred by the infringement of Actavis." *Id.* at 164:3–6. He described Orexo as a "small pharmaceutical company" that "[f]or many years . . . focus[ed] on sublingual medicines" and in "recent years . . . focus[ed] more and more on improving [the] treatment of opioid dependence." *Id.* at 164:9–12. Soresen testified that Orexo's "core technology basically is a sublingual medicine where you mix the carrier particle with an active ingredient with a bioadhesive." *Id.* at 165:20–22. He explained that "[y]ou . . . place the sublingual medicine under the tongue where it will disintegrate. The bioadhesive will stick to the mucosal membrane and improve the absorption of the active ingredient." *Id.* at 165:23–166:1. Sorensen testified that Orexo had

"developed three products that incorporate the technology[:] Abstral, for treatment of breakthrough cancer treatment[,] Edluar for treatment of insomnia, and most lately Zubsolv for treatment of opioid dependence." *Id.* at 166:22–25.

During Sorensen's direct examination, Orexo offered to admit exhibit PTX-250, which consisted of a copy of U.S. Patent No. 6,761,910 (the "#910 patent") and the #910 patent application. *Id.* at 190:21–191:6. Actavis objected to the admission of PTX-250 as irrelevant, prejudicial, and confusing under Rule 403. *Id.* at 191:7–9. The following exchange then occurred:

> THE COURT: Why is it admissible?
>
> [OREXO'S COUNSEL]: Your Honor, it is the patent that is the parent application to the patent-in-suit. It is absolutely relevant to the case because it's the publication of Orexo's core technology . . . .
>
> * * * *
>
> It was filed in 1998 and published in 2010. Now, we just had a discussion about Orexo's other patents, other products, Abstral and [Elduar]. Those products and the patents covering those products, most of them emanate from this [#]910 patent. . . . The [#]996 patent just happens to be the patent that emanated from this core group of patents that is specific to a buprenorphine[-]containing product like Zubsolv.
>
> THE COURT: So why is it relevant -- we don't have validity anymore. . . .
>
> [OREXO'S COUNSEL]: Well, if their intent was not in the case, Your Honor, then it would not be relevant. But when you hear counsel speak about how they developed

this independently without knowledge of Orexo's technology, because the patent issued in 2013 --

THE COURT: Right.

[OREXO'S COUNSEL]: -- it becomes very relevant as to these other disclosures of the technology that we know that their scientists were aware of.

THE COURT: But the only thing relevant in my mind to willfulness is whether they knowingly and intentionally infringed the [#]996 patent and to prove that you've got to establish that they knew or should have known of the patent, and so anything prior to the patent seems to me to be irrelevant.

[OREXO'S COUNSEL]: Yes, but that's not what the jury is hearing, Your Honor. If that were the only evidence in the case, then I would agree with you. We just heard a long exposition about things that we heard before. I mean --

THE COURT: It's relevant that they came up with these ideas before the patent. That's relevant because that negates evidence that they were willfully infringing it. But that seems to me to be totally consistent.

[OREXO'S COUNSEL]: Right. But it's relevant if they came up with those ideas without relying on or knowledge of the Orexo disclosures.

THE COURT: Only if it is the [#]996 patent.

[OREXO'S COUNSEL]: Well, when you have the same disclosure, when it's the same technical information that --

THE COURT: The claims of the patent. That's the big thing. Both of you have said the metes and bounds of the patents are defined by the claims, whether they willfully

infringed the claims of the [#]996 patent. I'm going to deny it. I don't think it's relevant.

* * * *

[OREXO'S COUNSEL]: There's another reason why these are relevant, Your Honor. Now, you've heard counsel talk that, say that, you know, crospovidone is a disintegrant and not a bioadhesive. Right. And that they would not, never have known that crospovidone served as a bioadhesive.

These patent publications from Orexo and others,[5] they disclosed that.

THE COURT: So if you have a witness on the stand from Actavis and you want to cross-examine them when they say I never thought that it was a bioadhesion, that seems to me fair game to bring it up at that time.

[OREXO'S COUNSEL]: That doesn't get the -- that document into evidence.

THE COURT: Well, it may not. It all depends. But it seems to me this is only relevant in terms of the witness' mens rea, whether they knew or didn't know, or should have known. And so I guess, you know, if you could prove that they read this particular patent and that undermines their credibility or somebody from Actavis read the patent, therefore they should have known that it wasn't a disintegrant or at least it wasn't only a disintegrant, that seems to me to be relevant, but not through this witness.

Id. at 191:10–195:23.

---

[5] Orexo never identified before or during trial these "other[]" publications. Orexo first identified an "other publication" in the 14-page "Addendum of Evidence" it filed with its brief submitted in support of its motion for a new trial. D.I. 284 ¶¶ 10–14. And even at that point, Orexo identified only "examples" of "other publications." *Id.* ¶ 14.

On the third day of trial, Orexo again raised the issue of the admissibility of the #910 patent and other, unidentified patents and "publications" that disclosed Orexo's "core technology." *See id.* at 448:6–451:15. I reiterated my earlier ruling that Orexo could introduce any such patent or publication into evidence to show willfulness if it could establish that an Actavis witness was aware of the existence of the patent or publication at the time of the alleged infringement. *See id.*

II. LEGAL STANDARDS FOR MOTION FOR A NEW TRIAL

Federal Rule of Civil Procedure 59(a) permits a district court judge, "on motion," to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." The decision to grant a new trial is committed to the district court's discretion. *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem Corp.*, 9 F.3d 282, 289 (3d Cir. 1993) (reviewing a district court's grant or denial of a motion for a new trial under deferential "abuse of discretion" standard).[6] "And, when the motion for a new trial is predicated on asserted errors in evidentiary rulings that were themselves discretionary, the motion is subject to particularly 'broad discretion.'" *St. Clair Intellectual Prop. Consultants, Inc. v. Toshiba Corp.*, 2015 WL 5826815, at *1 (D. Del. Oct. 2, 2015). Although the standard for granting a

[6] Regional circuit law governs the standards for deciding a motion for a new trial in a patent case. *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012).

new trial is less demanding than the standard for ordering judgment as a matter of law, the bar is high. A new trial is appropriate when "the verdict is contrary to the great weight of the evidence" such that another trial is "necessary to prevent a miscarriage of justice." *Roebuck v. Drexel Univ.*, 852 F.2d 715, 736 (3d Cir. 1988).

III. DISCUSSION

A. Exclusion of Evidence of The Zubsolv® Case

Orexo argues that my ruling to exclude evidence of Judge Robinson's decision in the Zubsolv® case "was in error for two independent reasons." D.I. 284 at 3. First, it argues that my ruling was "based largely on the dismissed invalidity allegations" and therefore "was clearly erroneous." *Id.* at 7; *see also id.* at 8 ("By basing its exclusion ruling on clearly erroneous facts (the dismissed invalidity claims), the Court abused its discretion warranting a new trial."). Second, it argues that my Rule 403 analysis "did not properly weigh the necessity and highly probative nature of this evidence against any prejudice to [Actavis]." *Id.* at 3–4.

1. Whether My Pretrial Ruling Was Based Largely on The Dismissed Invalidity Allegations

Orexo's initial argument fails for two reasons. First, Orexo waived the argument. Second, I did not "largely base" my pretrial ruling on the dismissed invalidity allegations.

a. Orexo Has Waived The Issue

Although Orexo revisited my pretrial ruling on numerous occasions during the trial, *see, e.g.*, Tr. at 273:18–276:14; *id.* at 444:5–446:2; *id.* at 447:2–449:23; *id.* at 525:4–526:23, it never argued or suggested that I should reconsider that ruling because of Actavis's decision to forgo an invalidity defense. When I asked the parties on the first morning of trial if the removal of invalidity issues from the case affected the amount of time needed for the parties to make their presentations to the jury, Orexo's counsel responded that Orexo's "affirmative [infringement] case will be essentially the same even though validity is out of the case." *Id.* at 5:19–21. He did not say or suggest that the removal of invalidity issues affected in any way the case Orexo wished to present at trial.

At the end of the first day, when Orexo's counsel asked for the opportunity to make a belated "offer of proof" with respect to my pretrial ruling, he did not state or suggest that the proposed offer of proof had any connection to Actavis's decision not to pursue an invalidity defense. To the contrary, counsel seemed to suggest that his request was prompted by issues Actavis had put in front of the jury that day:

> [OREXO'S COUNSEL]: I was reminded there's one other issue, and this is following up on Your Honor's order . . . precluding us . . . [from] referring to the . . . [Zubsolv®] litigation.
>
> THE COURT: Yes.

> [OREXO'S COUNSEL]: Even today, there have been issues that in our view have touched on that litigation and things that we might have wanted to respond to by referring to the litigation. For example, things that allude to why we didn't sue other generic companies or the timing of this law suit.
>
> THE COURT: Well, wait. I don't think in fairness, Mr. Taylor, I don't recall any testimony about the timing of this lawsuit. . . .
>
> [OREXO'S COUNSEL]: I don't want to argue that. But I was just going to mention, Your Honor, that we'd like leave to submit to Your Honor an offer of proof on evidence that we would have permitted on the issues in this case.

Id. at 273:18–274:10.

But most important, when I pressed counsel on why I should entertain "an offer of proof on a motion I've already decided," *id.* at 274:17–18, counsel responded: "I'm not seeking to reconsider the motion," *id.* at 274:19–20. And although I ended the discussion with the comment "I guess you can file a motion for reconsideration if you want," *id.* at 276:12–13, Orexo never asked me (by motion or otherwise) to reconsider my pretrial ruling to exclude evidence of Judge Robinson's decision in the Zubsolv® case.

"A Rule 59 motion may not be used as a vehicle to advance additional arguments that a party could have made before judgment but neglected to do so." *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 15 F. Supp. 2d 406, 409 (D.

Del. 1998). As Judge Hardiman explained in *United States v. Dupree*, 617 F.3d 724, 728 (3d Cir. 2010):

> Th[e] raise-or-waive rule is essential to the proper functioning of our adversary system because even the most learned judges are not clairvoyant. *See United States v. Nee*, 261 F.3d 79, 86 (1st Cir. 2001). Thus, we do not require district judges to anticipate and join arguments that are never raised by the parties. *See United States v. Griffiths*, 47 F.3d 74, 77 (2d Cir. 1995). Instead courts rely on the litigants not only to cite relevant precedents, but also to frame the issues for decision. *See id.* ("The government was required to offer some argument or development of its theory. It failed to do so, and has therefore waived the issue.").
>
> Moreover, "[a] fleeting reference or vague allusion to an issue will not suffice to preserve it for appeal[.]" *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 262 (3d Cir. 2009). Rather, a party "must unequivocally put its position before the trial court at a point and in a manner that permits the court to consider its merits." *Shell Petroleum, Inc. v. United States*, 182 F.3d 212, 218 (3d Cir. 1999).

The "cardinal principle that issues not squarely raised in the district court will not be entertained on appeal," *Nee*, 261 F.3d at 86 (internal quotation marks and citation omitted), applies with equal force to Rule 59 motions. "This raise-or-waive rule prevents sandbagging . . . [and] precludes a party from making a tactical decision to refrain from objecting, and subsequently, should the case turn sour, assigning error (or, even worse, planting an error and nurturing the seed as insurance against an infelicitous result)." *Id.* (internal quotation marks and citation

omitted); *see also Puckett v. United States*, 556 U.S. 129, 134 (2009) (noting that "the contemporaneous-objection rule prevents a litigant from sandbagging the court—remaining silent about his objection and belatedly raising the error only if the case does not conclude in his favor" (internal quotation marks and citations omitted)).

Orexo had ample opportunities to seek reconsideration of my pretrial ruling and to argue that the removal of invalidity issues from the case necessitated a new Rule 403 balancing analysis. But not once before or during trial did it make even a "fleeting reference or vague allusion" that would have put before me the issue of whether Actavis's withdrawal of its invalidity defenses warranted reconsideration of my decision to grant Actavis's motion in limine. On the contrary, Orexo's counsel expressly stated that he was "not seeking to reconsider [my ruling on Actavis's] motion." Tr. at 273:19–20. Having failed to raise before or during trial that the Rule 403 analysis I employed in granting Actavis's motion in limine needed to be redone in light of the removal of invalidity from the case, Orexo cannot now raise that issue in a Rule 59 motion.

b. The Pretrial Ruling Was Based on The Prejudicial Effect of the Zubsolv® Case on Both Infringement and Invalidity Defenses

Orexo's assertion that I "largely based" my pretrial ruling on the dismissed invalidity allegations is incorrect. D.I. 284 at 4. The thrust of Actavis's motion in

limine was that Orexo should be precluded from "suggest[ing] to this jury that because Actavis was found to infringe in [the Zubsolv®] suit, the same result should follow here." D.I. 256, Ex. 16, Defendant's Motion *In Limine* No. 1, at 2. Actavis argued that allowing Orexo to adduce evidence of the Zubsolv® case would lead to a "trial-within-a-trial on issues having nothing to do with infringement" in this case. *Id.* And, it is clear from my oral ruling, that I based my decision to grant Actavis's motion on the substantial risk of jury confusion and unfair prejudice Actavis would suffer with respect to both its invalidity and its non-infringement defenses:

> I've made the determination under [Federal] Rule [of Evidence] 403 that I think the admission of evidence related to [the] Zubsolv litigation would confuse the jury. I think it would unfairly prejudice the defendants. It was a bench trial and not a jury trial. There were different theories of invalidity. There was an appeal, there were litigation decisions made during the course of that [case] for strategic reasons that may be irrelevant. *It involved a different drug.*

Tr. at 74:6–21 (emphasis added); *see also id.* at 447:6–19 (Court reiterating that "there's lots of really good reasons not to permit the Zubsolv litigation to be mentioned in front of a jury," including the fact that it involved "*a different product.*" (emphasis added)).

The drugs at issue in the Zubsolv® case and this case have no bearing on the validity of the #996 patent. The only reason I mentioned that the Zubsolv® case

involved a different drug was to make the point that evidence of Judge Robinson's decision in the Zubsolv® case would lead to jury confusion and unfair prejudice to Actavis on infringement issues. I sought to avoid a trial-within-a-trial about the similarities and differences between Zubsolv® and the accused products; and I deemed it unfair to allow Orexo to attempt to prove that Suboxone® and Subutex® infringed the #996 patent by adducing evidence about their similarities with Zubsolv® and then linking that evidence to Judge Robinson's decision that Zubsolv® infringed the same patent. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) ("Infringement, either literally or under the doctrine of equivalents, does not arise by comparing the accused product with a preferred embodiment described in the specification, or with a commercialized embodiment of the patent[ ]." (internal quotation marks and citation omitted)). Indeed, when Actavis tried at trial to employ the other side of this same coin—that is, to argue *non-infringement* of the #996 patent based on testimony that Suboxone® and Subutex® *differed* from the patent's commercial embodiment, Zubsolv®—Orexo cried foul, arguing that such "testimony is irrelevant and . . . misleading" and "not the appropriate analysis" for patent infringement. Tr. at 488:21–25. I sustained Orexo's objection because the Zubsolv® case involved a different drug—the same rationale I articulated when I granted Actavis's motion in limine before trial.

Finally, had I been asked to revisit my pretrial ruling after Actavis withdrew its invalidity defenses, I would still have granted Actavis's motion in limine. In my view, litigation of issues related to Zubsolv® would have created a significant risk of jury confusion about the relevance of Judge Robinson's decisions and would have necessitated a trial-within-a-trial without any assurance that the jury would have been able to sort through the irrelevancies to determine the only actual issue in the case—i.e., whether Actavis's sale of its generic Suboxone® and Subutex® induced or contributed to the infringement of the #996 patent. That risk substantially outweighs the probative value of Judge Robinson's decision in the Zubsolv® case. As I acknowledged numerous times during the pretrial conference, the Zubsolv® case is probative of Actavis's knowledge and willfulness. *See* Tr. of Mar. 11, 2019 Hr'g at 74:15–83:24. Actavis's participation in the Zubsolv® case shows that it had knowledge of the #996 patent and knowledge that a court decided that Zubsolv® infringes that patent. It *arguably* shows—to the extent that Zubsolv® is similar to Suboxone® and Subutex®—that Actavis had knowledge of the possibility that Suboxone® and Subutex® infringe the patent. But the Zubsolv® case has limited probative weight, since (1) it was undisputed that Actavis had knowledge of the #996 patent before the Zubsolv® case, and (2) the Zubsolv® case involved a different drug than the accused

products in this case.[7] Thus, for the reasons stated above and at the pretrial conference, the evidence's limited probative value is substantially outweighed by the jury confusion and unfair prejudice its admission at trial would have caused.

2. Whether I Weighed The Necessity and Highly Probative Nature of The Zubsolv® Case Evidence Against Any Prejudice to Actavis

Orexo argues that "[w]hile the Court agreed that the Zubsolv action was probative of 'willfulness, knowledge, [and] intent', the Court's analysis did not consider the substantial impact that exclusion of this highly probative evidence would have on Orexo's indirect infringement case." D.I. 284 at 4 (second alteration in original) (citation omitted). According to Orexo, "[t]he Zubsolv action is particularly probative given [Judge Robinson's] findings relating to dry mixing and the [#]996 patent disclosures relating to bioadhesives." *Id.*

My oral pretrial ruling, *see* Tr. of Mar. 11, 2019 Hr'g at 74:15–83:24, explains how I balanced the relevant Rule 403 factors and concluded that the probative value of the Zubsolv® case was substantially outweighed by the

[7] Although I did not state so explicitly at the pretrial conference (due to time constraints and the fact that I was dealing with experienced patent counsel), the fact that Zubsolv® is a different drug means that Judge Robinson's ruling that Zubsolv® infringes the #996 patent is not highly probative of Actavis's knowledge that Suboxone® and Subutex® infringe the #996 patent. I think the ruling can at least arguably be characterized as probative of Actavis's knowledge of potential infringement—to the extent the accused products in this case are similar to Zubsolv®—but I think it an overstatement to call it highly probative.

significant risks of jury confusion and unfair prejudice to Actavis. I did not mention in my oral ruling anything about Judge Robinson's "findings relating to dry mixing and the [#]996 patent disclosures relating to bioadhesives" because *Orexo* did not mention those findings in its response to Actavis's motion in limine or during its arguments at the pretrial conference, or, for that matter, at any time before or during trial in connection with Actavis's motion. D.I. 284 at 4. Orexo first made this argument in its brief filed in support of its Rule 59 motion and its 14-page "Addendum of Evidence" attached thereto. *Id.* Accordingly, Orexo has waived the issue. But even if I had considered the findings of Judge Robinson on which Orexo now relies, for the reasons articulated above and in my oral ruling on Actavis's motion in limine, I would still have precluded Orexo from putting in front of the jury Judge Robinson's decision in the Zubsolv® case. And, as I do not agree that Orexo suffered a miscarriage of justice from its inability to introduce at trial evidence of the Zubsolv® case, I will deny its motion for new trial to the extent it is based on my decision to preclude it from adducing at trial evidence of Judge Robinson's rulings in the Zubsolv® case.

B. Conditional Exclusion of The #910 Patent, Its Application, And Unidentified "Other Publications"

Orexo argues that "[t]he Court's exclusion of evidence concerning Orexo's other public disclosures besides the [#]996 patent issuance was an error." D.I. 284 at 10. The only "public disclosures" Orexo identified at trial besides the #996

patent and its application were the #910 patent and its application, which Orexo sought to introduce as a combined exhibit during the direct examination of its CEO. *See* Tr. at 190:21–191:6. Thus, Orexo appears to have waived its right to seek a new trial based on the exclusion from evidence of any publication other than the #910 patent and its application.

Orexo did make two passing references at trial to unidentified "other publications." *See id.* at 448:6–451:15. And in the "Addendum of Evidence" attached to its brief filed in support of its Rule 59 motion, Orexo identifies for the first time at least some of these publications. *See* D.I. 284 ¶¶ 10–14. But consistent with its trial strategy of not squarely raising issues before the Court, Orexo asserts in the Addendum that it "has numerous other publications" (of which it merely provides "examples") that were erroneously excluded from evidence. *See id.* ¶ 14.

Leaving aside the question of waiver, Orexo's argument that the other publications were erroneously excluded from evidence fails for the same reason that its argument that the #910 patent and its application were erroneously excluded from evidence fails: none of the publications are relevant unless Actavis knew about them.

Orexo argued at trial that the publications were relevant to Actavis's willfulness because they disclosed that crospovidone was a bioadhesive. *See id.* at

448:6–451:15. As a matter of logic, Actavis can only have known about disclosures in a publication if it was aware of the publication. Accordingly, I ruled at trial that any publication that disclosed that crospovidone was a bioadhesive would be admissible if it was established that an Actavis witness was aware of the publication. As I explained to Orexo's counsel: "I already said if [an Actavis witness] admits that he was aware of the existence of a particular patent or article or an advertisement or [a] signed con[f]ession about what crospovidone is, you can, once you get that, [']I'm aware of that,['] sure, you can put it now in . . . the case." *Id.* at 449:15–19.

Orexo argues that this ruling "left [it] unable to respond to Defendants' arguments that they independently developed the accused products and could not have known that use of the accused products would infringe the [#]996 patent." D.I. 284 at 11. But that is not true. My ruling allowed Orexo to ask Actavis's witnesses if they knew about any "other publication" and, if any witness did, to test with that witness whether the disclosures in that publication undermined testimony that Actavis developed its products independently and with no knowledge that the accused products infringed the #996 patent. *See* Tr. at 449:15–19. Orexo chose, however, to ask only two Actavis witnesses about other publications. *See* Tr. at 518:1–533:14; D.I. 256, Ex. 1F, Jones Dep. 338:9–339:16. Only one of those witnesses had knowledge about an "other publication," and Orexo questioned that

witness about other publications without objection or limitation. *See* Tr. at 518:1–533:14.

Orexo cannot now complain that it was unable to introduce a publication for which it failed or did not even try to lay a proper foundation. To this day, Orexo has not identified a single publication that an Actavis witness was aware of that was excluded from evidence. It was the lack of evidence, not my ruling, that prevented Orexo from overcoming Actavis's defense that it independently developed its products without knowledge that those products infringed the #996 patent. Thus, Orexo's inability and unwillingness to adduce evidence of other publications did not result in a miscarriage of justice and do not warrant a new trial.

IV. CONCLUSION

For the reasons stated above, I will deny Orexo's motion for a new trial.

The Court will issue an order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC., Plaintiffs, v. ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS, USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 17-205-CFC

ORDER

At Wilmington this 11th day of December, 2019, for the reasons stated in the Memorandum Opinion issued this same date;

IT IS HEREBY ORDERED that Orexo AB and Orexo US, Inc.'s Motion for a New Trial (D.I. 283) is denied.

UNITED STATES DISTRICT JUDGE