

**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.)

C.A. No. 17-205-GMS

REDACTED - PUBLIC VERSION

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**BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO STRIKE AND DISMISS
COMPLAINT UNDER FED. R. CIV. P. 12(f) AND 12(b)(6)**

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INTRODUCTION

The Orexo plaintiffs' patent infringement allegations in this case are based on an improper misuse of the confidential information of defendant Actavis Elizabeth LLC ("Actavis") that should not be allowed. Orexo brought this action *for damages*, accusing of infringement two Actavis products that have been on the market for several years. Actavis' accused generic Suboxone® products have been commercially available since 2013, and its generic Subutex® products were launched in 2015. (D.I. 1 at ¶¶ 51, 78.) Despite the fact that the asserted patent, U.S. Patent No. 8,454,996 ("the '996 patent"), was issued in 2013, (*Id.* at ¶ 39), Orexo did not bring this action until almost four years later—on February 28, 2017. That timing is no accident.

Orexo had previously asserted the very same '996 patent against Actavis in a different case in 2014. That lawsuit—*Orexo AB & Orexo U.S., Inc. v. Actavis Elizabeth LLC*, 14-829-SLR-SRF (D. Del.) (the "Zubsolv® litigation")—related to Actavis' generic version of Orexo's brand product, Zubsolv®. During that prior Zubsolv® litigation, Orexo received confidential information from Actavis in discovery that revealed details about the products that Orexo *now* accuses of infringement in this case. In particular, Orexo received the Abbreviated New Drug Application ("ANDA") for Actavis' generic Suboxone® products, which provided extensive confidential details on how those products are made, as well as details about Actavis' related Subutex® products. In addition, Orexo received other confidential documents about the development of Actavis' generic Zubsolv® product that contained likewise confidential statements about Actavis' generic Subutex® and Suboxone® products. Of course, these documents were confidential and subject to a Protective Order that restricts their use to the Zubsolv® litigation only. All the while during the Zubsolv® litigation, Orexo remained silent about any allegation or intention to accuse any other Actavis products of infringing the '996 patent.

The Zubsolv® litigation proceeded to trial, and this Court found the ‘996 patent valid and infringed. Yet still Orexo remained silent. The Court also found that a second and later-expiring patent, United States Patent No. 8,940,330 (“the ‘330 patent”), was invalid as obvious. Orexo appealed the ruling on the ‘330 patent. Actavis declined to appeal the Court’s ruling on the ‘996 patent, which expires in 2019. Then, after Actavis’ decision not to appeal this Court’s decision could not be changed, Orexo filed this lawsuit alleging that the *pre-existing* generic Suboxone® and Subutex® products, about which Orexo had received so much confidential information, also infringed the ‘996 patent.

Orexo’s conduct is a direct violation of the Protective Order in the Zubsolv® litigation. That order provides that the parties “shall use Protected Material *solely* for purposes of assisting Outside Counsel in connection with the above-captioned lawsuit.” (Ex. A at 4; D.I. 38 in 14-829-SLR-SRF (emphasis added).) It was only after Orexo received Actavis’ confidential information that Orexo brought the current lawsuit, despite Actavis’ products having been on the market for years beforehand. To be clear, the confidential Actavis documents do not prove that Actavis’ products infringe (they do not). Rather, the documents contain information about how those products were developed and how they are manufactured—information from which Orexo appears to have concluded they must therefore infringe. But that information was produced in confidence to Orexo in the context of a different case and was subject to restrictions ordered by this Court on how the information could be used—it could be used in the Zubsolv® litigation only. Accordingly, Orexo’s allegations that are derived from Actavis’ confidential information can and should be stricken from the complaint here. *See Whitehead v. Gateway Chevrolet*, No. 03-C-5684, 2004 WL 316413 (N.D. Ill. Feb. 2, 2004); *Dev Industries, Inc. v. Rockwell Graphic Systems, Inc.*, No. 91-C-7197, 1992 WL 100908 (N.D. Ill. May 4, 1992).

Once those key allegations are stricken (paragraphs 56-57, 60, 65-66, 68-70, 83-84, 87, 92-93, and 95-97), there is nothing left of Orexo's complaint upon which a claim for relief can be granted. The stricken complaint wholly ignores multiple elements of the asserted claims and therefore fails to state a claim for patent infringement. The complaint must therefore be dismissed under Fed. R. Civ. P. 12(b)(6). Orexo should have laid its cards on the table when it first received Actavis' confidential information. Instead, Orexo improperly sat on the information, remained silent about its intentions, and then without ever seeking permission from Actavis or this Court, misused Actavis' confidential information by bringing this case only after the '996 patent had already been litigated. Such tactics cannot be countenanced.

FACTUAL BACKGROUND

I. THE ZUBSOLV® LITIGATION

As stated above, this is not the first time Orexo has asserted the '996 patent against Actavis. In 2014, Orexo filed a Hatch-Waxman complaint against Actavis in the Zubsolv® litigation, asserting that the '996 patent was infringed by Actavis' generic Zubsolv® products. The claims of the '996 patent all require "microparticles of buprenorphine" (an active ingredient) to be "presented" or "adhered" to the surface of *larger* "carrier particles." (Ex. B, '996 Patent at claims 1-2.) That particular structure is achieved by mixing the different sized particles together for a sufficient length of time. In the Zubsolv® litigation, Orexo made clear its belief that a manufacturing process known as "dry mixing" necessarily results in a product that satisfies those claim limitations. In its Final Infringement Contentions, Orexo charged that in Actavis' generic Zubsolv® product:

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(Ex. C at Exhibit I thereto at 6, 11-12 (emphasis added).)

After a bench trial, this District Court found the '996 patent valid and found another patent, the '330 patent, invalid. This was a victory for Actavis; according to the Orange Book, the '330 patent would have expired 13 years later than the '996 patent.

II. ACTAVIS' CONFIDENTIAL INFORMATION PRODUCED TO OREXO IN THE ZUBSOLV® LITIGATION RELATED TO GENERIC SUBOXONE® AND SUBUTEX® PRODUCTS

During that prior litigation, Orexo received confidential discovery that described or provided information as to how Actavis' *other* buprenorphine tablet products were made—namely, Actavis' generic Suboxone® and Subutex® products. On June 15, 2015, Actavis produced its Abbreviated New Drug Application (“ANDA”) for the generic Suboxone® products. That production consisted of 995 documents and 22,082 pages of material, not to mention the numerous additional documents that were produced relating to Actavis' generic Zubsolv® product, but that also contained information about the generic Suboxone® and Subutex® products. The generic Suboxone® ANDA, which was submitted to the FDA, disclosed that Actavis' generic Suboxone® product [REDACTED], and also contained information about [REDACTED].

Actavis also produced information disclosing how the generic Subutex® products were made. Some of this information was in the Suboxone® ANDA. For instance, [REDACTED]
[REDACTED]
[REDACTED] (Ex. D at 29.) That is, [REDACTED]
[REDACTED] Furthermore, the ANDA disclosed that [REDACTED]
[REDACTED]

██████████ (Id. at 28.) On August 7, 2015, Actavis also produced a draft copy of the ██████████
██████████
██████████
██████████

██████████ (Ex. E at 42 (emphasis added).) ██████████
██████████

██████████ *Id.*

All of this discovery was subject to a Protective Order entered by this Court, which provided that:

[a]bsent an agreement of the Producing Party or an order to the contrary by this Court or other court of competent jurisdiction, a Receiving Party and its counsel *shall use Protected Material solely for purposes of assisting Outside Counsel in connection with the above-captioned lawsuit*

(Ex. A, D.I. 38, 14-cv-829.)

III. THE PRESENT LITIGATION

Orexo filed its complaint on February 28, 2017, accusing Actavis' generic Suboxone® and generic Subutex® products of infringing the '996 patent. Orexo made these accusations four years after the launch of generic Suboxone® in 2013, and two years after the launch of generic Subutex® in 2015. Critically, Orexo waited until after the '996 patent was held valid in the Zubsolv® Litigation, and Actavis had chosen not to appeal.

Orexo appears to have "use[d]" that confidential information in this case in violation of the Protective Order. Orexo has alleged in conclusory fashion that the accused products "contain microparticles of buprenorphine hydrochloride presented at the exterior surfaces of particles of mannitol and/or lactose (carrier particles)." (D.I. 1 at ¶¶ 60, 87; see also ¶¶ 56, 65, 83, 92.) Just as in the Zubsolv® case, Orexo apparently believes that these limitations are met because of ██████████

[REDACTED]

[REDACTED] Orexo has also alleged that the “microparticles of buprenorphine . . . are smaller” than the alleged “carrier particles.” (*Id.* at ¶¶ 57, 84.) Based on all the available information, in making these allegations Orexo improperly relied on the confidential documentation about Actavis’ generic Suboxone® and Subutex® products obtained in the Zubsolv® litigation.

IV. ACTAVIS IS THE SOLE SUPPLIER OF GENERIC SUBUTEX® AND SUBOXONE® SUED FOR INFRINGEMENT

Actavis is not the only manufacturer of generic Suboxone® and generic Subutex®. According to publically available information on the FDA’s website, six other companies have been approved to market and sell a generic version of Suboxone®, and seven other companies are approved for a generic version of Subutex®. As far as Actavis is aware, *none* of these other companies have been sued by Orexo relating to their generic Suboxone® and Subutex® products. Not coincidentally, and as far as Actavis is aware, Actavis is the only manufacturer of these products that has provided confidential information to Orexo. The conclusion is inescapable: Orexo has based this lawsuit on Actavis’ confidential information.

ARGUMENT

V. OREXO’S ALLEGATIONS OF INFRINGEMENT SHOULD BE STRICKEN BECAUSE THEY IMPROPERLY RELY ON CONFIDENTIAL ACTAVIS INFORMATION GAINED IN ANOTHER LAWSUIT

“Allegations in a complaint predicated on confidential information in violation of a protective order may be stricken under Rule 12(f).” *Whitehead*, 2004 WL 316413 at *4. Here, Orexo violated the Protective Order in the Zubsolv® litigation in order to allege that the accused products contain “microparticles of buprenorphine hydrochloride presented at [or adhered to] the exterior surfaces of” larger carrier particles. (*See* D.I. 1 at ¶¶ 60, 65-66, 87, 92-93; *see also* ¶¶ 56-57, 83-84.) Likewise, Orexo defied the Protective Order to allege the relative sizes of the particles

in the accused products. (*See id.* at ¶¶ 57, 84.) Those allegations, as well as the allegations of infringement that stem therefrom (*see id.* at ¶¶ 68-70, 95-97) should be stricken.

A. Under the terms of the Protective Order, confidential information obtained in the Zubsolv® litigation may be used only in connection with that litigation

Patent infringement cases typically require the parties to exchange a great deal of sensitive technical and business information during discovery. Therefore, it is customary for the court to enter a Protective Order (often stipulated between the parties) to protect and strictly limit the use of confidential information. Such restrictions are necessary and appropriate so as to strike a balance between the need for discovery and the legitimate need to protect the confidential information of business competitors. In the Zubsolv® litigation, Orexo and Actavis agreed upon, and this Court entered, such a Protective Order. (Ex. A.)¹

The Protective Order in the Zubsolv® litigation barred either party from using confidential information in any other litigation. It specifically provided that “a Receiving Party and its counsel *shall use Protected Material solely for purposes of assisting Outside Counsel in connection with the above-captioned lawsuit . . .*” (*Id.* at 4 (emphasis added).) This language is self-explanatory;

¹ “In deciding a Rule 12(b)(6) motion, a court . . . consider[s] only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant’s claims are based upon these documents.” *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010); *see also DiPietro v. Landis Title Co.*, No. CIV.A. 11-5110 NLH, 2012 WL 2116404, at *3 (D.N.J. June 11, 2012) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir.1993)) (courts “may consider . . . ‘an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document.’”). That is precisely the case here, and so this Court may consider the documents attached to Orexo’s Complaint as well as the additional materials attached to this brief as exhibits in deciding this motion. Moreover, this Court can and should take judicial notice of matters of public record (such as filings in the Zubsolv® litigation). *Anspach ex rel. Anspach v. City of Philadelphia, Dep’t of Pub. Health*, 503 F.3d 256, 273 (3d Cir. 2007) (“Courts ruling on Rule 12(b)(6) motions may take judicial notice of public records.”). Finally, the Court may also take judicial notice of any fact “that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2).

a party violates the Protective Order when it “use[s]” Protected Material for any other purpose, such as in connection with a different litigation. Accordingly, given all the available evidence, because Orexo has used Protected Material to provide the basis for some of its central allegations in this action, Orexo has violated the Protective Order.

B. Orexo’s allegations in Paragraphs 56-57, 60, 65-66, and 68-70 of its Complaint improperly rely on confidential Actavis information

Orexo relied on confidential information from the Zubsolv® litigation to allege that Actavis’ accused generic Suboxone® product infringes the ‘996 patent. For instance, Orexo alleges that the “generic Suboxone® products as marketed contain water-soluble carrier particles”, as well as “microparticles of buprenorphine hydrochloride that are smaller than . . . ([the] carrier particles) and are admixed with them,” and that the microparticles of buprenorphine hydrochloride are “presented at” or “adhered to” the surfaces of “substantially larger” carrier particles, as required by the ‘996 patent. (D.I. 1 at ¶¶ 56-57, 60, 65-66.) Orexo then alleges direct, contributory, and inducement infringement based on those allegations. (*Id.* at ¶¶ 68-70.) To be clear, the Actavis documents do not confirm that the accused products actually infringe by having microparticles of buprenorphine that are “presented” or “adhered” to carrier particles. But given Orexo’s apparent chain of reasoning, it has nonetheless relied on those documents to make its infringement allegations here.

As previously stated, the confidential information acquired under Protective Order in the Zubsolv® litigation included the ANDA for the generic Suboxone® products. A key portion of that ANDA [REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

The confidential Suboxone® ANDA also [REDACTED]
[REDACTED]. (Ex. D at 2; Ex. E at 2.)

Based on the fact that the Actavis product is [REDACTED]
[REDACTED] Orexo's logic seems to be that the product must therefore contain microparticles of buprenorphine presented at the surface of carrier particles, as required by the patent claims. In the Zubsolv® litigation, Orexo used this precise chain of reasoning. Orexo asserted in its infringement contentions that [REDACTED]

[REDACTED]
[REDACTED] (Ex. C at Exhibit 1 thereto at 6, 11-12 (emphasis added).) In other words, the confidential information gleaned in the Zubsolv® litigation is what drew Orexo to make the infringement allegations against the accused products in *this* case.

Such allegations must have been based on Actavis' confidential information because there is nothing self-evident about them. Actavis' generic Suboxone® product has been on the market since 2013 (D.I. 1 at ¶ 51), yet Orexo brings this action nearly four years later. As far as Defendants are aware, Orexo has not asserted the '996 patent against the maker of the *branded* Suboxone® tablet product nor the maker of any other generic version of Suboxone® tablets. Indeed, Orexo recently completed a more than two-year litigation against Actavis over the '996 patent, but never

once suggested that the generic Suboxone® products or the generic Subutex® products may infringe the '996 patent.

In sum, the confidential information Orexo obtained during the Zubsolv® litigation necessarily forms the basis for Orexo's complaint and allegations of infringement here. That is apparent not only from the nature of the information itself, but also from the timing of this suit. There is no good reason why Orexo would have waited years to assert the '996 patent against this product, if not for the confidential information it learned in the Zubsolv® litigation.

C. Orexo's allegations in Paragraphs 83, 84, 87, 92-93, and 95-97 of the Complaint rely on confidential Actavis information

Orexo also relied on confidential information from the Zubsolv® litigation to make its infringement allegations against Actavis' generic Subutex® products. As with generic Suboxone®, Orexo simply alleges in conclusory fashion that the Actavis products (i) contain "carrier particles"; (ii) contain microparticles of buprenorphine that are smaller than the carriers, and (iii) contain microparticles of buprenorphine that are presented or adhered at the surfaces of the carrier particles. (D.I. 1 at ¶¶ 83-84, 87, 92-93.) Orexo then alleges infringement (both direct and indirect) based on these allegations. (*Id.* at ¶¶ 95-97.)

As with generic Suboxone®, Orexo obtained confidential information from Actavis in the Zubsolv® litigation that underlies Orexo's chain of reasoning in making these (albeit incorrect) infringement allegations. The confidential information about Actavis' generic Subutex® products that was previously produced to Orexo included [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

Moreover, Orexo had even more confidential information that [REDACTED]

[REDACTED]

[REDACTED] (Ex. F at 42 (emphasis added).) [REDACTED]

[REDACTED]

[REDACTED] Orexo wrongly concluded that generic Subutex® infringes.

In short, it is undeniable that Orexo received confidential information about how Actavis' generic Subutex® product [REDACTED]. Given the nature of this information as well as the timing of this action, Orexo relied on Actavis' confidential information to make the infringement allegations in this case in violation of the Protective Order.

D. Allegations based on confidential information must be stricken

The paragraphs of Orexo's complaint that are based on confidential information should be stricken. Fed. R. Civ. P. 12(f). "Allegations in a complaint predicated on confidential information

in violation of a protective order may be stricken under Rule 12(f).” *Whitehead*, 2004 WL 316413 at *4.

Multiple courts have done exactly that. In *Dev Industries*, the court struck allegations that were “predicated on information obtained in another case” that was subject to a protective order. 1992 WL 100908, at *2. Specifically, the “deposition testimony underlying the allegations in question was taken during the course of pretrial discovery, and the documents referred to in [the complaint] were produced pursuant to the same.” *Id.* Similarly, in *Whitehead*, the district court (relying on *Dev Industries*) struck numerous paragraphs that “incorporate[d] confidential information subject to” a protective order. 2004 WL 316413, at *4; *see also Ibarra v. Sunset Scavenger Co.*, No. C 01-2875 SI, 2003 WL 21244096, at *10 (N.D. Cal. May 21, 2003) (striking portions of plaintiff counsel’s declarations that included confidential third-party information covered by a protective order); *Mitchell Health Techs., Inc. v. Naturewell, Inc.*, No. 02-C-0439-C, 2002 WL 32362650, at *8 (W.D. Wis. Dec. 2, 2002) (striking portions of brief that used testimony obtained from another case in violation of a confidentiality agreement).

The Court should do the same here. Orexo’s key allegations are based on Actavis’ confidential information produced in a separate litigation. (*See supra* I.B-C; D.I. 1 at ¶¶ 56-57, 60, 65-66, 68-70, 83-84, 87, 92-93, and 95-97.) This information is subject to a Protective Order, which provides that Orexo “shall use” the material “solely . . . in connection with” the Zubsolv® litigation. Accordingly, the allegations based on this information must be stricken.

VI. WITHOUT THE STRICKEN ALLEGATIONS, THE COMPLAINT FAILS TO STATE A CLAIM AND MUST BE DISMISSED

After this Court has stricken the improper allegations, it should then consider whether the complaint sufficiently states a claim for relief without those allegations. The *Whitehead* court did just that, and dismissed the claim. 2004 WL 316413, at *6 (dismissing claim where defendant

contended “the amended complaint fails to state a RICO claim in the absence of the stricken allegations”).

After the key paragraphs identified above have been stricken, Orexo’s complaint must be dismissed. In order to plead infringement, a patentee must “plausibly allege that the accused product practices each of the limitations found in at least one asserted claim.” *e. Digital Corp. v. iBaby Labs, Inc.*, No. 15-CV-05790-JST, 2016 WL 4427209, at *3 (N.D. Cal. Aug. 22, 2016); *Raindance Techs., Inc. v. 10x Genomics, Inc.*, No. 15-cv-152, 2016 WL 927143, at *2 (D. Del. Mar. 4, 2016) (finding complaint failed to state a claim for direct patent infringement after conducting a limitation-by-limitation analysis, comparing the asserted claim to the factual allegations in the complaint); *Zimmer Surgical, Inc. v. Stryker Corp.*, No. CV 16-679-RGA-MPT, 2017 WL 1296026, at *5 (D. Del. Apr. 6, 2017) (holding pleading sufficient where patentee “allege[d] that the Neptune systems meet every limitation of at least independent claims 15 and 19 of the patent”). These cases draw from the general rule announced by the Supreme Court that in order to survive a motion to dismiss, a complaint must be “plausible on its face [by] plead[ing] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed. Cir. 2015) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed.Cir.1995)) (“To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly.”).

Without the stricken paragraphs, the complaint contains no allegations whatsoever that the accused products contain carrier particles, nor microparticles of buprenorphine that are “presented at” or “adhered to” the surfaces of those “carrier particles” as required by the asserted ‘996 patent.

(Ex. B, '996 Patent at claims 1-2.) Nor does the complaint make any allegations as to whether Actavis' accused products contain microparticles of buprenorphine that are smaller than the alleged carrier particles, or where the carrier particles are "substantially larger" than the buprenorphine microparticles. *Id.*

In short, Orexo simply cannot allege infringement of each claim limitation of at least one of the two claims of the '996 patent without relying on confidential information in violation of the Protective Order that must be stricken. Accordingly, Orexo's complaint must be dismissed without leave to amend.

CONCLUSION

For the foregoing reasons, paragraphs 56-57, 60, 65-66, 68-70, 83-84, 87, 92-93, and 95-97 of Orexo's complaint in this case should be stricken, and the remainder of the complaint should be dismissed.

Dated: April 28, 2017

Respectfully submitted,

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