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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

ESSURE PRODUCT CASES	No. JCCP004887
	Order
	Motion for Summary Adjudication Granted
(Abbreviated Title)	

The Motion for Summary Adjudication filed for Bayer HealthCare Pharmaceuticals Inc. and Bayer Essure Inc. and Bayer HealthCare LLC and Bayer Corporation was set for hearing on 03/28/2018 at 09:00 AM in Department 21 before the Honorable Winifred Y. Smith. The Tentative Ruling was published and was contested.

The matter was argued and submitted, and good cause appearing therefore,

IT IS HEREBY ORDERED THAT:

The Motion of defendants Bayer Corporation, et al. ("Defendant" or "Bayer") For Summary Adjudication ("Motion") is ruled on as follows:

BACKGROUND:

Although the Notice of Motion could be clearer, it is apparent that the target of this Motion is the Second Amended Complaint filed in these coordinated proceedings on October 31, 2017 related to the included action of Birruete v. Bayer Corp., initiated in Alameda County as case number RG16809875 ("Birruete SAC"). The original Birruete complaint was among the eleven filed in Alameda County to which Defendant, in agreement with counsel for the fourteen women and six spouses in those cases, filed collective demurrers before these coordinated proceedings were initiated, including a demurrer to all causes of action on the basis of preemption under the Medical Device Amendment ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"), 21 USC section 360k(a). On August 2, 2016 an order was entered in all eleven cases, which order is identified by the parties as "Lance v. Bayer Corp, RG16809860, slip op. (Cal. Super. Ct. Aug. 2, 2016), further reference to which in this order will be as the "Order On Preemption Demurrer." The section on Preemption Law at pages 5-8 of the Order On Preemption Demurrer is incorporated herein by this reference.

In the Order On Preemption Demurrer, relying on Stengel v. Medtronic Inc. (9th Cir. 2013) 704 F.3d 1224 ("Stengel III") and Coleman v. Medtronic Inc. (2014) 223 Cal.App.4th 413 ("Coleman"), the court found that the state law failure to warn claims based on allegations of Defendant's failures to comply with its reporting obligations to the FDA are neither expressly not impliedly preempted. The court further found that whether the fraud, negligent misrepresentation, and breach of warranty claims based on allegations of specific statements made by Defendant in advertising materials can escape preemption could not be determined in the context of a challenge to the pleadings.

MOTION:

The instant Motion now queues up the question of whether the claims of plaintiff Yolanda Birruete ("Plaintiff") for fraud/intentional misrepresentation, negligent misrepresentation, concealment, and breach of express and implied warranty, set forth in the First Cause of Action (Negligence) insofar as it rests on negligent misrepresentation, Third Cause of Action (Breach of Express Warranty), Fourth Cause of Action (Breach of Implied Warranty), Fifth Cause of Action (Fraud/Intentional Misrepresentation), Sixth Cause of Action (Negligent Misrepresentation), and Seventh Cause of Action (Concealment) insofar as it rests on affirmative representations allegedly made by Bayer, are preempted by federal law. With respect to certain of the statements allegedly made by Bayer, Bayer also asserts that the statements were not representations or express warranties directed to Plaintiff.

The court notes that the Birruete SAC is also the subject of a demurrer and motion to strike by Bayer directed to the First, Second and Eighth Causes of Action to the extent they are based on allegations of defective manufacturing and inadequate post-market surveillance. Despite having been directed by the court during case management to establish a master-complaint procedure under which rulings regarding pleadings challenges would officially apply to all actions included in these coordinated proceedings, Bayer has chosen, with apparent agreement by liaison counsel for all plaintiffs, to present these challenges to a single complaint. Unless the parties are able to articulate a compelling reason for doing so, the court with not indulge this relatively informal process beyond the matters currently before it.

SUMMARY OF DEFENDANT'S ARGUMENTS:

Defendant points out that in the Order On Preemption Demurrer the court stated that "Plaintiffs' ultimate success in avoiding preemption ... will rest on findings that the challenged contractual commitments are different from the FDA-approved statements (Kanter v. Warner-Lambert Co. (2009) 99 Cal.App.4th 780, 797 ['Kanter'])." The court declined, however, to engage in "the exercise of comparing and contrasting the language of the alleged misrepresentations with the language of the FDA approved materials ... in the context of a demurrer." Defendant now asks the court to engage in that process in the context of the instant Motion, arguing that such a side-by-side comparison shows there is no meaningful difference.

In addition to cases upon which Defendant relied in support of its preemption demurrer in 2016, e.g. De La Paz v. Bayer Healthcare LLC, 159 F.Supp.3d 1085 (N.D.Cal. 2016) ("De La Paz") and McLaughlin v. Bayer Corp., 2016 WL 1161578 (E.D.Penn.) ("McLaughlin I"), Defendant cites several other federal trial court decisions in which the issues presented here have been resolved in Defendants favor in the context of an FRCP 12(b)(6) motion: Norman v. Bayer Corp., 2016 WL 4007547 (D. Conn.) [motion for reconsideration pending] ("Norman"); Burrell v. Bayer Corp., 2017 WL 1955333 (W.D.N.C.) [appeal pending] ("Burrell"); McLaughlin v. Bayer Corp., 2017 WL 697047 (E.D.Pa.) ("McLaughlin II"); and Dunstan v. Bayer Essure, Inc., 2017 WL 4392046 (E.D.Pa.) ("Dunstan"). Defendant also cites a recent decision by a Missouri Court of Appeals, Williams v. Bayer Corp., 2017 WL 6001531 (Mo.Ct.App.).

Defendant argues that it cannot be liable for statements unless they are different from and inconsistent with the labeling language that FDA approved. Defendant then lays out, in chart form, each of the alleged statements in the Birruete SAC, direct quotes from marketing or other Bayer materials, and language from the FDA-approved labeling. Defendant groups these claims as challenges to statements concerning "efficacy", "components and mechanism of action", "the Essure procedure", and "physicians qualifications and training."

Defendant also argues that the challenged statements set forth in paragraph 122 of the Birruete SAC (except 122(a)) and paragraph 120(i) were not directed to patients, but only to physicians and investors, and they were not misleading. The context of the statements demonstrates that they instruct physicians as to the skills and training that physicians need before placing the device or participating in certain programs. The statements do not make any representation or promise to patients that their physicians will have a particular level of skill.

SUMMARY OF PLAINTIFF'S OPPOSITION ARGUMENTS:

Plaintiff asserts that her claims for negligent misrepresentation, fraud, concealment and breach of warranty are based on statements made in Defendant's voluntary advertising that were never approved by the FDA and that, taken as a whole, are misleading. Plaintiff argues that statements beyond what the FDA evaluated in its approval process that mislead medical professionals or the public are considered

"misbranding," and that because there has been no agency adjudication about whether the challenged advertising is false or misleading, a jury finding to that effect would not differ from any federal requirement for the advertising material and would not create any requirement in addition to existing federal prohibition of misbranding.

Plaintiff characterizes Defendant's position as "that its statements in advertising were close enough to approved labeling language to permit an assumption that FDA would have approved them if it had reviewed them" and argues that a reasonable jury could find that the FDA did not or would not have approved the advertising, and that the challenged advertising differed from the product label in a manner that made the advertising misleading.

In Plaintiff's view, the relevant evidence includes the FDA correspondence with Bayer reflecting the FDA's removal of language from the label, the agency reviewer's disapproval of Bayer's advertising, and the evidence that Bayer withheld material adverse event information from the FDA when seeking its approval of the statements at issue. This evidence, which includes evidence that the FDA rejected the use of certain language in the product label that was later used in advertising, shows that FDA permission to use a phrase in a product label cannot simply be assumed to be carte blanche permission to use the identical phrase in advertising.
Plaintiff argues that the cases upon which Bayer relies did not consider any such evidence.

Plaintiff asserts that the evidence raises triable issues as to whether (1) the challenged advertising statements were ever FDA approved in the product label; 2) the challenged advertising statements were different in form and content from the FDA-approved label such that the advertising was misleading - whether or not there were "nearly identical" phrases appearing in both; (3) the FDA approved the challenged advertising statements that Bayer presented to it for review; and (4) the FDA would have approved the other challenged advertising if Bayer had ever presented it;

Plaintiff also presents her own statement-by-statement analysis, grouping the statements as "rejected by the FDA for use in the label", "that do not appear in the FDA-approved label", and "similar to language in the approved label," arguing that all of the materials upon which Plaintiff bases her claims are materially different from the FDA label.

Plaintiff also argues that promotional representations she received were misleading because Defendant failed to timely report thousands of adverse events to the FDA which delayed public availability of material risk information until after she received her implant, and that a reasonable jury could compare the current risk disclosure on Bayer's website, with the peer-reviewed literature discussing Essure's risks, with the adverse event information in Defendant's files before Plaintiff received her implant, and conclude that the risk information disclosed today was available, and wrongfully concealed in a manner that let to Plaintiff's injury.

Plaintiff also argues that the express warranty claims are not preempted for the additional reason that they arise independent of state law (citing, Hofts v. Howmedica Osteonics Corp., 597 F.Supp.2d 830, 839 (S.D.Ind. 2009).

Alternatively, Plaintiffs argue that the Motion is premature under Code of Civil Procedure section ("CCP") 437c(h) because Defendant has only produced "final promotional materials located through reasonable search" and have objected to Plaintiffs' notice of deposition of the Person Most Knowledgeable ("PMK") in Sales and Marketing as overly broad.

DISCUSSION:

Defendant's quotation of the salient portion of the Order On Preemption Demurrer is abbreviated, and its interpretation of the meaning of that order is somewhat overstated. It's true that the court observed that the claims for breach of warranty, which were only found in one of the forms of complaint at issue at that time, and the claims for fraud and negligent misrepresentation, found in both forms of complaint, were all based on the same factual allegations of specific statements allegedly made by Defendant in advertising material. It's also true that the court did not distinguish between breach of warranty, fraud and negligent misrepresentation when it overruled the demurrers to those causes of action, finding that the evaluation of any inconsistency between statements in promotional materials and statements in approved FDA materials would not be done in the context of a demurrer. Those rulings, however, do not relieve Defendant of the need to address all arguments raised by Plaintiff in her opposition,

including the argument that the breach of express warranty claim and the fraud and negligent misrepresentation claims are potentially subject to different analyses.

The court recognizes that the decision in Kanter arose against a different factual backdrop. The plaintiffs in Kanter were attacking the sufficiency of product labels, not promotional materials, and were doing so under a breach of express warranty theory. One of the subject products, NIX, had an EPA approved label, while the other two, RID and CLEAR, did not. The claims regarding the NIX label were found to be preempted because "when a claim is premised ultimately on the inadequacy of a[n] [approved] product label, it is preempted." (Kanter, at 796.) The analysis of the RID and CLEAR labels was based on a comparison between the labels and the applicable monograph, in the context of which the Kanter court stated that "[t]he challenged statements on the ... labels ... do nothing more than express in direct, straightforward, and easily understood language that which is implicit in the mandatory labeling." (Id, at 797.) Kanter supports the court's conclusion in the Order On Preemption Demurrer that statements made by a product manufacturer only escape preemption if they are "different" from those either required or allowed to be included in a label, and its treatment of the label to monograph comparison is consistent with the manner in which the issues regarding the advertisements about Essure have been resolved by other courts in the context of motions to dismiss (e.g.,"functionally equivalent" (Williams, at *5); "materially identical" (Norman, at *6); "de minimis deviations" (Burrell, at **8); "completely consistent" (McLaughlin II, at *12). Kanter does not, however, address the distinction to be drawn, if any, between warranty claims and fraud claims.

In the Order On Preemption Demurrer, the court found the analysis in McLaughlin I to be particularly persuasive. Specifically, the McLaughlin I court recognized that "Plaintiffs can potentially allege cognizable and parallel misrepresentation claims at least insofar as they allege that Bayer made false or misleading statements in unapproved advertising or other promotional materials that were inconsistent with specific statements in approved FDA materials and that undermine the approved and required statements in those materials," and denied Bayer's Motion For Judgment On The Pleadings "insofar as it argues that ... all misrepresentation claims are necessarily expressly preempted." (McLaughlin I, at **15 [citing Riegel v. Medtronic, Inc., 552 U.S. at 330].) At that time the McLaughlin I court declined to address any specific alleged misrepresentations (ibid, and fn. 20), and the misrepresentation counts were dismissed with leave to amend because they were not alleged with sufficient particularity. There, as here, the misrepresentation claims were based on the same alleged misrepresentations contained in the warranties that were the subject of an express warranty claim. However, as noted in the Order On Preemption Demurrer, the McLaughlin I court concluded that the breach of express warranty claims in that case were not preempted because they did not arise from state requirements. Indeed, in doing so the McLaughlin I court expressly relied on Hofts (McLaughlin I, at *11). Like the fraud claims, the warranty claims were dismissed for other reasons, with leave to amend.

After the McLaughlin plaintiffs filed their second amended complaint, which included more specific allegations in support of both their breach of express warranty and their fraudulent misrepresentation claims. Bayer again moved to dismiss. In addressing the fraudulent misrepresentation claims this time the McLaughlin II court honed in on most of the same specific statements that are alleged in the Birruete SAC, including "zero pregnancies in the clinical trials", "most effective", "worry free", "stays secure", "surgery free", "performed easily", "simple procedure", "eliminates risks, discomfort and recovery time", "no down time for recovery", "physician sign off", and "skilled hysteroscopist." However, when it addressed the breach of express warranty claims in the amended complaint, not only did the McLaughlin II court affirm the conclusion in McLaughlin I that those claims were not preempted, it also found that "the SAC alleges sufficient facts to support a reasonable inference that the warranties were the bases of the parties' bargains" and denied the motion to dismiss the express warranty count (McLaughlin II, at *10).

Because the court was not satisfied that the parties has adequately addressed the distinction between fraud/misrepresentation claims and breach of express warranty claims, it called for additional briefing from the parties on that issue. On March 22, 2108 the parties each submitted that additional briefing.

In its supplemental brief, Defendant points out that both McLaughlin I and McLaughlin II arose in the 3rd Circuit, and were based in part on a 3rd Circuit decision that predated Riegel v. Medtronics, Inc. (2008) 552 U.S. 312 ("Riegel"), i.e., Michael v. Shiley, Inc., 46 F.3d 1316 ("Michael"). As already noted, the McLaughlin court also relied on Hofts, a 7th Circuit trial court decision that rested on pre-Riegel 7th Circuit authority. Plaintiff's supplemental brief adds no new decisional authority to the mix, focusing primarily on a comparison of Hofts with Kanter, and arguing that her express warranty claim

is governed by the elements set forth in Cal. Com. Code section 2313, which aligns it with Hofts.

The court agrees with Defendant that the weight of persuasive authority supports the conclusion that where, as here, the alleged warrantees that Plaintiff refers to are the same statements upon which her claims for fraudulent and negligent misrepresentations are based, success on such a cause of action would necessarily depend on a determination that Essure did not conform to the descriptions approved by the FDA. Accordingly, such a warranty claim cannot survive preemption separately from the fraudulent and negligent misrepresentation claims. In other words, those causes of action stand or fall together, and as Plaintiff recognizes in her supplemental brief, the analysis of both requires the comparison of the Essure advertising and its product label.

Essential to Plaintiff's opposition is her argument that the comparison between the FDA approved label and the non-FDA approved advertising is not a mechanical task, but must also consider the correspondence between FDA and Defendants. In Plaintiff's view, the non-binding recommendations in that correspondence reflect the FDA's view that its approval of the Essure label does not constitute a determination that any phrase used in the label is not misleading when used in advertising. Plaintiff appears to argue that a claim challenging a statement made in an advertisement is not preempted (a) unless the FDA approved the advertisement itself, or (b) if Defendant can prove that the FDA would have approved the advertisement, but offers no authority, binding or persuasive, to support that argument. As pointed out by Defendant in its Reply, this court rejected a similar argument made by Plaintiffs in opposition to the earlier preemption demurrer.

Also essential to Plaintiffs' opposition is her argument that Defendants' wrongful conduct in delaying, withholding and/or mischaracterizing its reporting of material information to the FDA is relevant to the question of whether the FDA would have approved certain statements in Defendant's marketing materials. This argument is also is based on the unsupported premise that marketing materials require approval, or that Defendants must show that such materials would have been approved if they had been submitted to the FDA for review. Furthermore, attempts to retroactively question FDA approval, including labeling approvals, are preempted even if the decisions are later changed by the FDA. (See, e.g., In re Medtronic, Inc., Sprint Fidelis Leads Prods., 592 F.Supp.2d 1147, 1156; Baker v. St. Jude Med., S.C., Inc. 178 S.W.3d 127, 134-135 n.5 (Tex. Ct. App. 2005).) That is to say, Plaintiff's assertion that risk information that is currently being disclosed, which has certainly changed over time, can somehow be considered when assessing whether statements made in advertisements in the past amounted to misrepresentations or breaches of express warranties is not well taken. The appropriate comparison is with the approved labeling materials in use at the same time. The court notes that there is nothing in the record that refutes Defendants' assertion that it followed any guidance that it received from the Center for Devices and Radiological Health ("CDRH") regarding the language in advertisement, e.g., avoiding further use of the terms "surgery free" and "gentle." Arguing that they should have done so beforehand would amount to the imposition of an additional or different requirement than those imposed by the FDA.

In sum, the court reaffirms the conclusion it reached in the Order On Preemption Demurrer that Plaintiff's success in avoiding preemption for breach of warranty and misrepresentation rests on findings that the challenged statements, which are set forth in paragraphs 120 and 122(a), are different from the FDA-approved statements, and finds that Plaintiff's attempts to distinguish between them falls short. The court further concludes that the statements in paragraph 122 (with the exception of subparagraph (a)) and a portion of paragraph 120(i) of the SAC fail because they were not directed to directed to patients such as Plaintiff, but only to physicians and investors.

RULING:

The Motion is GRANTED. Plaintiff's fraud/intentional misrepresentation, negligent misrepresentation, concealment, and breach of express and implied warranty, set forth in the First Cause of Action (Negligence) insofar as it rests on negligent misrepresentation, Third Cause of Action (Breach of Express Warranty), Fourth Cause of Action (Breach of Implied Warranty), Fifth Cause of Action (Fraud/Intentional Misrepresentation), Sixth Cause of Action (Negligent Misrepresentation), and Seventh Cause of Action (Concealment) insofar as it rests on affirmative representations allegedly made by Defendants, are DISMISSED.

Defendants' request for judicial notice is GRANTED.

Dated: 03/28/2018

Facsimile

Judge Winifred Y. Smith

SHORT TITLE:	CASE NUMBER:
ESSURE PRODUCT CASES	JCCP004887

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