NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

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U.S. COURT OF APPEALS

In re: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION,

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JEAN ADAMS, On Behalf of Herself and All Other Similarly Situated Plaintiffs,

Plaintiff-Appellant,

v.

MERCK SHARP & DOHME CORP., FKA Merck & Co. Inc.; et al.,

Defendants-Appellees.

No. 15-56997

D.C. No. 3:13-md-02452-AJB-MDD

MEMORANDUM*

Appeal from the United States District Court
for the Southern District of California
Anthony J. Battaglia, District Judge, Presiding

Argued and Submitted October 3, 2017
Pasadena, California

Before: GRABER, MURGUIA, and CHRISTEN, Circuit Judges.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

Plaintiff-Appellant Jean Adams and other plaintiffs in this consolidated, multidistrict litigation appeal the district court's determination that their state-law claims were preempted under *Wyeth v. Levine*, 555 U.S. 555 (2009). We have jurisdiction pursuant to 28 U.S.C. § 1291. We do not decide whether the defendants met their burden under *Levine*'s "clear evidence" test because we hold the district court misapplied *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in two ways: first, the district court relied on *Buckman* to impermissibly circumscribe discovery; and second, the district court relied on *Buckman* to deem the plaintiffs' newly discovered evidence "irrelevant" to the court's preemption analysis at the summary judgment stage. Either of these errors would independently warrant reversal.

1. In *Buckman*, the plaintiffs were injured by the use of orthopedic bone screws in their spines and claimed that the defendant, a consulting company that assisted the screws' manufacturer to secure regulatory approval, made fraudulent representations to the Food and Drug Administration (FDA). *Id.* at 343. The Supreme Court held the plaintiffs' state-law claims were impliedly preempted by

federal law.[1] *Id*. at 348. The Court ruled that the plaintiffs' state-law "fraud-on-the-FDA" claims "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," *id.* at 350, and reasoned, "were plaintiffs to maintain their fraud-on-the-agency claims . . . , they would not be relying on traditional state tort law which had predated the federal enactments" in question, *id.* at 353; "[o]n the contrary, the existence of these federal enactments is a critical element in their case." *Id.*

Conversely, in *Stengel v. Medtronic Inc.*, we held the plaintiffs' state-law failure-to-warn claim was not preempted. 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc), *cert. denied*, 134 S. Ct. 2839 (2014). We explained that because the plaintiffs' claim "rest[ed] on a state-law duty that parallel[ed] a federal-law duty" and was "independent of the FDA's pre-market approval process that was at issue in *Buckman*," *Buckman* did not control and the plaintiffs' claims were not

[1] The federal law at issue in *Buckman*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), and *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir. 2015), was the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FDCA). We have previously suggested that the reasoning and policy of these decisions also applies to drugs. *See Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1234 (9th Cir. 2011) (distinguishing *Buckman* but giving no indication that *Buckman*'s rule was inapplicable to preemption with respect to drug claims), *vacated on other grounds*, 565 U.S. 973 (2011). We therefore assume without deciding that *Buckman* would also preempt state-law fraud-on-the-FDA claims concerning drugs.

preempted. *Id.*; *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040–41 (9th Cir. 2015) (holding the plaintiff's state-law failure-to-warn claims against the manufacturer of an infusion pump were not fraud-on-the-FDA claims preempted under *Buckman* because the claims "did not arise solely by virtue of" federal law, and because there was "no suggestion that Congress intended to displace traditional tort law by making all policing of medical labels and warnings the exclusive province of the FDA").

2. Here, the district court first relied on *Buckman* to circumscribe discovery. Though it acknowledged that "this is not a case like *Buckman* that is predicated upon a fraud-on-the-FDA basis," the district court perceived that the plaintiffs "invoke[d] allegations of misreporting and under-reporting as a justification for additional discovery, and as pertinent to a preemption defense." The court concluded that the plaintiffs were asserting "fraud-on-the-FDA type allegations" that were preempted by *Buckman*, and decided that the discovery they sought, which included adverse event source documents and databases, was irrelevant to whether federal law preempted the plaintiffs' state-law failure-to-warn claims.

First, we disagree with the district court's characterization of the plaintiffs' state-law claims as "fraud-on-the FDA type allegations." The plaintiffs asserted common-law failure-to-warn claims arising from a state-law duty that paralleled an

FDCA-imposed duty, as was the case in *Stengel* and *McClellan*, where we found the state-law claims *not* to be preempted. *Stengel*, 704 F.3d at 1233; *see also McClellan*, 776 F.3d at 1040–41. The discovery the plaintiffs sought was directly relevant to whether any causal connection existed between incretin use and pancreatic cancer. The plaintiffs did argue that it would not be unduly burdensome to produce the data they requested because the defendants were required to collect and submit it to the FDA, but the duty the plaintiffs claim the defendants breached was the parallel common law duty to warn, not a duty arising from the FDCA. As pertinent to the defendants' preemption affirmative defense, whether it would have been possible for the defendants to comply with both their common law duty to warn and the federally imposed reporting obligations is a separate issue that cannot be resolved without knowing what information was available to the defendants. *See Levine*, 555 U.S. at 573. Neither *Buckman*'s holding nor what the district court termed the "policy underlying *Buckman*" can be read to preclude discovery of evidence relevant to the plaintiffs' state-law failure-to-warn claims. *See Stengel*, 704 F.3d at 1233.

The district court also ruled the request to compel production of the defendants' adverse event source documents and databases was unduly burdensome. The plaintiffs sought the "source files" for each pancreatic cancer

event known to the defendants. Such files have been produced in pharmaceutical litigation of this sort, it is undisputed that the defendants already maintained these databases, and here, the volume of the requested data was limited. Defendants established only that producing the files to the plaintiffs would require the relatively modest task of redacting identifying information of patients and reporters.[2] The cost estimate provided to the district court included the cost of producing the source files of both pancreatic cancer and pancreatitis. This figure therefore overestimated the cost required to produce the pancreatic cancer files alone. Thus, the defendants failed to show that complying with the plaintiffs' discovery request would be unduly burdensome, and it was an abuse of discretion to deny the plaintiffs' motion to compel production for this reason. We reverse the district court's discovery orders that were premised on its misapplication of *Buckman*, specifically: (1) the denial of the plaintiffs' motion to compel production of adverse event source documents and databases; and (2) the denial of the plaintiffs' motion to compel production of the defendants' foreign regulatory files.

3. The district court also relied on *Buckman* to preclude its consideration of "new safety information" the plaintiffs uncovered in the discovery they were

[2] The number of pancreatic cancer adverse events (and the corresponding number of source files the defendants would need to produce) appears to be relatively low according to the FDA's adverse event database.

allowed to conduct, including a signal assessment completed by Health Canada and evidence from animal studies and clinical trials. The defendants argue the district court considered and rejected the plaintiffs' "new safety information" as non-material. In its summary judgment order, the district court enumerated the "new safety information" that the plaintiffs proffered, but also unambiguously stated that it "maintain[ed] its position as set forth in previous orders regarding the relevance of this data to the Court's conflict preemption analysis," reiterated its view that "*Buckman* [was] implicated by Plaintiffs' defense to the clear evidence standard," and concluded that the "new safety information" did not constitute "persuasive or *appropriate considerations* in analyzing the clear evidence standard" (emphasis added). These statements strongly suggest that the court deemed the new safety information irrelevant at the summary judgment stage. Further, in its discussion of the materiality of the "new safety information," the district court stated, "it *remains unclear whether the FDA considered this information, and if it did not, whether this data would have altered the FDA's conclusion*" (emphasis added). Uncertainty about whether the FDA considered the "new safety information" and whether it would have altered the FDA's conclusion establishes that a disputed issue of material fact should have prevented entry of summary judgment on the defendants' preemption claim. As the district court correctly noted, the parties'

experts disputed whether the "new safety information" would have been material to the FDA's analysis.

4. Finally, we hold the district court abused its discretion by partially disqualifying the plaintiffs' regulatory expert. The district court's order correctly observed that Dr. Fleming's exposure to confidential information could not be "entirely documented" by discoverable information such as meeting minutes, but failed to account for the fact that this was the only evidence the defendants offered to show they had disclosed to Dr. Fleming information relevant to the current litigation. The defendants did not submit testimony or a declaration of anyone at Novo Nordisk who could attest to whether or how any information provided to Dr. Fleming was relevant to the current litigation, and Dr. Fleming averred that in reaching his opinions and preparing his report for this litigation, he did not rely on any information, confidential or otherwise, that he obtained from his consulting relationship with Novo. Without more, the defendants did not meet their burden of showing "*specific* and *unambiguous*" disclosures required to trigger disqualification, *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1094 (N.D. Cal. 2004) (emphasis added). The district court abused its discretion by partially disqualifying Dr. Fleming.

As an independent ground for disqualifying Dr. Fleming, the district court concluded that he was a "competitor" under the court's protective order. The parties stipulated to the terms of the protective order, Dr. Fleming's involvement with Exsulin did not violate its express terms, and the defendants acknowledge that the drug being developed by Dr. Fleming's company was not a prescription medication. The district court's order concluded that "Plaintiffs' argument distinguishing between a manufacturer and a developer presumes a meaningful difference in the context of the protective order," but the record does not show that the defendants were required to carry their burden of showing the distinction was *not* meaningful. The district court abused its discretion by partially disqualifying Dr. Fleming as a "competitor" under the stipulated terms of the protective order.

VACATED and REMANDED.