UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

INGEBORG KLEIN, et al.,

Plaintiffs

v.

BAYER HEALTHCARE PHARMACEUTICALS INC., et al.,

Defendants

Case No.: 2:18-cv-01424-APG-EJY

Order Granting the Bayer Defendants' Motion to Dismiss and Plaintiffs' Motion for Leave to File Supplemental Authority

[ECF Nos. 32, 61]

Plaintiffs Ingeborg Klein and Karin Klein were injected with gadolinium-based contrast agents (GBCAs) manufactured by the defendants. ECF No. 1 at 5. The gadolinium was retained in their bodies and resulted in "fibrosis in their organs, skin, and bones, retained gadolinium in the neuronal nuclei of her [*sic*] brain, and related injuries." *Id.* The Kleins filed this suit, asserting claims of strict liability and negligence for failure to warn them of the "risks of gadolinium retention." *Id.* at 2.

Defendants Bayer Healthcare Pharmaceuticals Inc., Bayer Corporation, and Bayer Health Care LLC (collectively, Bayer) manufacture, market, and sell Magnevist, one of the GBCAs administered to plaintiff Ingeborg Klein (Ingeborg). *Id.* at 2, 5. Bayer moves to dismiss Ingeborg's claims, arguing that (1) she fails to sufficiently plead personal jurisdiction; (2) her claims are preempted by federal law; and (3) she does not allege a cognizable injury and otherwise fails to meet the pleading standard. I grant Bayer's motion because Ingeborg fails to sufficiently plead personal jurisdiction and Ingeborg's claims, as currently pleaded, are preempted by federal law. However, I grant Ingeborg leave to amend.

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I. BACKGROUND

Bayer's Magnevist "was the first gadolinium-based contrast agent to reach the market after receiving [Food and Drug Administration (FDA)] approval in 1988." *Id.* at 8. Ingeborg alleges that Bayer has "known since the 1980s that [Magnevist] could cause retention of toxic gadolinium," as there have "been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use" of GBCAs. *Id.* at 6-7. Gadolinium retention in patents with abnormal kidney function can result in Nephrogenic Systematic Fibrosis. *Id.* at 10. The FDA issued a black box warning for GBCA users with abnormal kidney function in 2007, and a related Multidistrict Litigation was resolved in 2015. *Id.*

In this case, however, Ingeborg alleges that gadolinium retention in patients like her with normal kidney function can result in fibrosis and other injuries, and that Bayer failed to warn her of those risks. Ingeborg cites numerous studies dating back to the 1980s demonstrating potential gadolinium retention after a GBCA injection, developing into an emerging consensus in 2013-14 that gadolinium could be retained after a GBCA injection. *Id.* at 8-9, 11. In September 2017, the FDA's medical advisory committee voted in favor of adding a warning to GBCA labels that gadolinium could be retained in some vital organs after a GBCA injection. *Id.* at 11-12. Three months later, the FDA issued a safety announcement warning of gadolinium retention in patients with normal kidney function, but also stated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function." ECF No. 33-1 at 2.[1]

[1] Under Federal Rule of Evidence 201, I may take judicial notice of "matters of public record" when deciding motions to dismiss. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001) (quotation omitted). I take judicial notice of the FDA safety announcement, which was published on its website. *See Brandt v. Medtronic, Inc.*, 179 F. Supp. 3d 963, 965 n.1 (D. Nev. 2016) (taking judicial notice of FDA online public records).

The following year, Bayer and other GBCA manufacturers issued a warning to patients with normal kidney function that gadolinium could be retained after a GBCA injection. ECF No. 1 at 12.

Ingeborg was injected with the GBCAs Magnevist, MultiHance, and OptiMark prior to receiving MRIs. ECF No. 1 at 5. Ingeborg had normal kidney function at the time of the injections, but alleges that gadolinium retention in patients with normal kidney function can cause fibrosis and other injuries. *Id.* at 2, 5-7. Ingeborg alleges that the gadolinium was retained in her organs and "resulted in fibrosis in [her] organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries." *Id.* at 2. Ingeborg claims that Bayer knew or should have known of the risks associated with gadolinium retention for patients with normal kidney function and failed to include an appropriate warning on the Magnevist label. *Id.* at 13-15. Ingeborg further alleges that she would not have received a GBCA prior to her MRIs had she or her healthcare providers been aware of such risks. *Id.* at 6.

II. ANALYSIS

A. Personal Jurisdiction

Bayer argues that Ingeborg fails to plead general or specific personal jurisdiction because she includes only conclusory allegations of Bayer's contacts with Nevada and does not allege facts showing how these contacts relate to her claims. Ingeborg responds that her complaint pleads facts showing purposeful availment of the forum state and that her claim arises out of Bayer's activities in Nevada.

"When no federal statute governs personal jurisdiction, the district court applies the law of the forum state." *Boschetto v. Hansing*, 539 F.3d 1011, 1015 (9th Cir. 2008). Nevada's long-arm statute is co-extensive with federal standards, so a court may exercise personal jurisdiction if

doing so comports with federal constitutional due process. Nev. Rev. Stat. § 14.065(1); *Walden v. Fiore*, 571 U.S. 277, 283 (2014). "For a court to exercise personal jurisdiction over a nonresident defendant, that defendant must have at least minimum contacts with the relevant forum such that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice." *Schwarzenegger v. Fred Martin Motor Co.*, 374 F.3d 797, 801 (9th Cir. 2004) (quotation omitted). "There are two forms of personal jurisdiction that a forum state may exercise over a nonresident defendant—general jurisdiction and specific jurisdiction." *Boschetto*, 539 F.3d at 1016. Ingeborg does not argue that general jurisdiction applies, so I address only whether she has established specific jurisdiction.

Specific jurisdiction depends on an "activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). "In contrast to general, all-purpose jurisdiction, specific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction." *Id.* (quotation omitted). I apply a three-prong test to determine whether specific jurisdiction exists: (1) the defendant "must have performed some act or consummated some transaction with the forum by which it purposefully availed itself of the privilege of conducting business" in the forum state; (2) the plaintiff's claims "must arise out of or result from [those] forum-related activities; and (3) the exercise of jurisdiction must be reasonable." *Rio Props., Inc. v. Rio Int'l Interlink*, 284 F.3d 1007, 1019 (9th Cir. 2002).

When a defendant moves to dismiss for lack of personal jurisdiction on the basis of written materials rather than an evidentiary hearing, I must determine whether plaintiff's "pleadings and affidavits make a prima facie showing of personal jurisdiction." *Schwarzenegger*,

374 F.3d at 800 (quotation omitted). In deciding whether a plaintiff has met her burden, I must accept as true the uncontroverted allegations in her complaint, but a plaintiff cannot rest on the "bare allegations" of her complaint. *Id.* (quotation omitted).

i. Purposeful Availment

The term "purposeful availment" describes two distinct analyses: purposeful availment and purposeful direction. *Schwarzenegger*, 374 F.3d at 802. A defendant does not purposefully avail itself of the privilege of doing business in a forum state or purposefully direct an act towards the forum state by merely placing products into the stream of commerce. *Holland Am. Line Inc. v. Wartsila N. Am., Inc.*, 485 F.3d 450, 459 (9th Cir. 2007). Rather, the plaintiff must point to "[a]dditional conduct" that "may indicate [the defendant's] intent or purpose to serve the market in the forum state . . . ." *Asahi Metal Industry Co. v. Superior Court*, 480 U.S. 102, 112 (1987).

Ingeborg alleges that Bayer "purposefully availed itself of the benefits and protections of this state's laws," but such conclusory allegations are insufficient. ECF No. 1 at 2-3. Ingeborg also alleges that Bayer placed Magnevist into "the stream of commerce" and is "licensed to conduct and/or is systematically and continuously conducting business in this state, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including GBCA's [*sic*] of the type received by Ingeborg Klein and Karin Klein, to the residents in this state," and Bayer "does substantial business in this state and within this District." *Id.* at 5, 13. Ingeborg thus alleges some additional conduct that may indicate Bayer's intent to serve Nevada. *Id.* at 5. However, the complaint also alleges each defendant engaged in each of these activities, and this allegation is not plausible absent facts showing that Bayer conducted each (or any) of these activities in Nevada. Ingeborg therefore has not adequately

alleged Bayer availed itself of the forum state or purposefully directed an act towards the forum state.

ii. Connection between Contacts and Claims

Ingeborg must plead facts showing that she would not have suffered an injury "but for" Bayer's activities in Nevada. *Menken v. Emm*, 503 F.3d 1050, 1058 (9th Cir. 2007).

Ingeborg alleges that her "claim arises out of Defendant's forum-related activities," but that conclusory allegation is insufficient. ECF No. 1 at 2-3. Ingeborg also alleges that Bayer marketed, researched, tested, advertised, sold, or distributed "GBCA's [*sic*] of the type" Ingeborg received to residents of Nevada. *Id.* at 5. Ingeborg does not allege that Bayer marketed, researched, tested, advertised, sold, or distributed Magnevist in Nevada, nor does she allege that she used, purchased, or was given or prescribed Magnevist in Nevada. Accordingly, Ingeborg fails to plead that she would have sustained her alleged injury but for Bayer's forum state activities, and thus fails to plead that her claim arises out of Bayer's contacts with Nevada. I therefore dismiss her claims against Bayer for lack of personal jurisdiction.[2]

iii. Amendment

I grant Ingeborg leave to amend because it is not clear that amendment would be futile. *Sonoma Cty. Ass'n of Retired Employees v. Sonoma Cty.*, 708 F.3d 1109, 1118 (9th Cir. 2013) ("As a general rule, [d]ismissal without leave to amend is improper unless it is clear . . . that the complaint could not be saved by any amendment.") (quotation omitted). For example, Ingeborg states in her opposition to Bayer's motion that she was "prescribed, [*sic*] injected Magnevist in the State of Nevada." ECF No. 35 at 16. I do not consider this statement because it was not

[2] Bayer asks to transfer this case to the United States District Court for the District of Delaware as an alternative to dismissal. ECF No. 32 at 9. Because I grant Ingeborg leave to amend, I do not consider Bayer's request for transfer at this time.

included in the complaint or an affidavit. *See Amba Mktg. Sys., Inc. v. Jobar Int'l, Inc.*, 551 F.2d 784, 787 (9th Cir. 1977) (holding a plaintiff cannot "simply rest on the bare allegations of [her] complaint, but rather [is] obligated to come forward with facts, by affidavit or otherwise, supporting personal jurisdiction."). But Ingeborg may amend her complaint to add non-conclusory allegations regarding Bayer's purposeful availment of the forum state and the connection between Bayer's contacts with Nevada and her claim, if she has a factual basis to do so.

iv. Jurisdictional Discovery

Finally, Ingeborg requests jurisdictional discovery. ECF No. 35 at 10. A plaintiff seeking jurisdictional discovery must provide some basis to believe that discovery will lead to relevant evidence, and district courts may deny requests "based on little more than a hunch that it might yield jurisdictionally relevant facts." *Boschetto v. Hansing*, 539 F.3d at 1020. Ingeborg has not articulated a basis for jurisdictional discovery, so I deny her request without prejudice to her reasserting it if she has a basis to support it.

B. Preemption

Bayer argues that Ingeborg's claims are preempted by federal law because if state law required adding Ingeborg's desired warning to Magnevist's label, it would have been impossible to comply with both state law and federal regulations governing that label. Ingeborg responds that Bayer could have changed Magnevist's label at any time following FDA approval under the Changes Being Effected (CBE) regulation.

A properly pleaded complaint must provide a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands

more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Factual allegations must be enough to rise above the speculative level." *Twombly*, 550 U.S. at 555.

In considering a motion to dismiss for failure to state a claim, "all well-pleaded allegations of material fact are taken as true and construed in a light most favorable to the non-moving party." *Wyler Summit P'ship v. Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). However, I do not assume the truth of legal conclusions merely because they are cast in the form of factual allegations. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). I must also consider whether the factual allegations in the complaint allege a plausible claim for relief. *Iqbal*, 556 U.S. at 679. A claim is facially plausible when the complaint alleges facts that allow the court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Id.* at 663. Where the complaint does not permit the court to infer more than the mere possibility of misconduct, the complaint has "alleged—but it has not shown—that the pleader is entitled to relief." *Id.* at 679. When the claims have not crossed the line from conceivable to plausible, the complaint must be dismissed. *Twombly*, 550 U.S. at 570. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the [district] court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

Federal statutes and regulations govern the "the safety information that appears on the labels of prescription drugs that are marketed in the United States." *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668, 1672 (2019). Bayer's argument that it is impossible to comply with the federal regulatory scheme and state warning requirements is "a demanding defense," and Bayer carries the burden of demonstrating impossibility. *Wyeth v. Levine*, 555 U.S.

555, 573 (2009). Bayer must (1) show that it was prohibited by federal law from unilaterally modifying the FDA-approved labeling or (2) present clear evidence that the FDA would not have approved a change to the drug's label. *Id.* at 568-573.

Following approval of a prescription drug, manufacturers "generally seek advance permission from the FDA to make substantive changes to their drug labels." *Albrecht,* 139 S. Ct. at 1673. Alternatively, drug manufacturers may unilaterally alter prescription drug labels without prior FDA approval under the CBE regulation. 21 C.F.R. § 314.70(c)(6)(iii)(A). Alterations are permitted under the CBE regulation "to reflect newly acquired information" if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c)." *Id.* The newly acquired information must provide "reasonable evidence of a causal association" of a "clinically significant adverse reaction[]" to a drug. *Id.* § 201.57(c)(6)(i). A clinically significant adverse reaction includes those that are "potentially fatal" or "serious," *id.*, and has a "significant impact on therapeutic decision-making." 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006). These limitations serve to "exclude '[e]xaggeration of risk, or inclusion of speculative or hypothetical risks,' that 'could discourage appropriate use of a beneficial drug.'" *Albrecht,* 139 S. Ct. at 1672 (quoting 73 Fed. Reg. 2848, 2851 (2008)). Thus, to state a plausible claim for relief, Ingeborg must allege facts showing that Bayer could have unilaterally changed Magnevist's label under the CBE regulation because Bayer had or should have had reasonable evidence of a causal association between Magnevist and a clinically significant adverse reaction.

Ingeborg cites several studies indicating that gadolinium is retained in the organs following injection of a GBCA. Ingeborg alleges that Bayer failed to warn her of the "risks of gadolinium retention," the "risks of serious bodily harm to consumers," and the "risks of serious

bodily injury due to the use of linear GBCAs." ECF No. 1 at 1, 13-14. Although Ingeborg alleges facts suggesting that gadolinium is retained after a GBCA injection, she offers only conclusory allegations that retention causes clinically significant adverse reactions, like fibrosis. She does not allege facts showing that gadolinium retention is in itself a clinically significant adverse reaction. Nor does she sufficiently plead that Bayer had reasonable evidence of a causal association between Magnevist and a clinically significant adverse reaction in patients with normal kidney function. The FDA has stated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function." ECF No. 33-1 at 2. Ingeborg does not plead facts showing that Bayer had or should have had newly acquired information permitting it to unilaterally add her desired warning under the CBE regulation. Consequently, Ingeborg has not stated a plausible claim for relief.

However, I grant Ingeborg leave to amend because it is not clear that amendment would be futile. *Sonoma Cty.*, 708 F.3d at 1118. Ingeborg may amend her complaint if she can plausibly allege facts showing that Bayer had or should have had newly acquired information permitting it to add a warning to Magnevist's label consistent with the CBE's requirements.[3]

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[3] The United States District Court for the Eastern District of New York recently dismissed virtually identical claims against Bayer on preemption and foreseeability grounds. *McGrath v. Bayer HealthCare Pharm. Inc.,* No. 18-CV-2134-RJD-VMS, 2019 WL 2582530 (E.D.N.Y. June 24, 2019). In that case, the plaintiff amended her complaint with additional studies purportedly showing a causal association between gadolinium retention and a clinically significant adverse reaction. But the allegations still failed to state a plausible claim for relief because the newly published studies post-dated the plaintiff's Magnevist injection and did not provide "well-grounded" evidence of a causal association. *Id.* at *4-5. *McGrath*'s analysis is persuasive, and Ingeborg may amend her complaint only if she can offer additional factual allegations of a causal association between Magnevist and clinically significant adverse reactions.

C. Other Pleading Deficiencies

Because I dismiss on these grounds, I do not rule on Bayer's other arguments. If Ingeborg amends her complaint, she may take this opportunity to address other issues identified in Bayer's motion. For example, Ingeborg may add factual allegations showing that Bayer knew or had reason to know that injuries like hers could result from use of Magnevist. Additionally, she may take this opportunity to allege a plausible basis for her pre- and post-marketing claims and to identify the "related injuries," if she has a factual basis to do so.

III. CONCLUSION

IT IS THEREFORE ORDERED that defendant Bayer Healthcare Pharmaceuticals Inc., Bayer Corporation, and Bayer Health Care LLC's motion to dismiss **(ECF No. 32) is GRANTED**.

IT IS FURTHER ORDERED that plaintiff Ingeborg Klein may file an amended complaint on or before September 20, 2019.

IT IS FURTHER ORDERED that the plaintiffs' unopposed motion for leave to file supplemental authority **(ECF No. 61) is GRANTED**.

DATED this 21st day of August, 2019.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE