Exhibit 22

Johnson v. Hologic, Inc.

United States District Court for the Eastern District of California

June 6, 2014, Decided; June 9, 2014, Filed

No. 2:14-cv-0794-LKK-KJN (PS)

Reporter
2014 U.S. Dist. LEXIS 79665; 2014 WL 2581421

MELBA JOHNSON, Plaintiff, v. HOLOGIC, INC., Defendant.

Subsequent History: Later proceeding at Johnson v. Hologic, Inc., 2014 U.S. Dist. LEXIS 120876 (E.D. Cal., Aug. 28, 2014)
Magistrate's recommendation at Johnson v. Hologic, Inc., 2015 U.S. Dist. LEXIS 1105 (E.D. Cal., Jan. 5, 2015)

Core Terms

pleadings, allegations, FDA, judicial notice, requirements, medical device, first amended complaint, defense motion, product liability, manufacture, preempted, premarket, leave to amend, preemption, requests, state law claim, documents

Counsel: [*1] Melba Johnson, Plaintiff, Pro se, Sacramento, CA.

For Hologic, Inc., Defendant: Sharon Mayo, LEAD ATTORNEY, Arnold & Porter LLP, San Francisco, CA.

Judges: KENDALL J. NEWMAN, UNITED STATES MAGISTRATE JUDGE.

Opinion by: KENDALL J. NEWMAN

Opinion

ORDER

Plaintiff Melba Johnson ("plaintiff"), proceeding without the assistance of counsel, originally filed this products liability action in the Sacramento County Superior Court on February 10, 2014.[1] (ECF No. 1-1 (Sacramento County Superior Court Summons and Complaint).) Defendant Hologic, Inc. ("defendant") subsequently removed the case to this court pursuant to the court's diversity jurisdiction. (ECF No. 1.) Presently before the court is defendant's Motion for Judgment on the Pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure seeking to dismiss plaintiff's complaint in its entirety on the basis that plaintiff's claims are preempted by federal law. (ECF No. 8.) Plaintiff filed an opposition to defendant's motion. (ECF No. 10.) Defendant filed a reply. (ECF No. 12.)

The court heard this matter on its June 5, 2014 law and [*2] motion calendar. Plaintiff Melba Johnson appeared on her own behalf. Attorney Sharon Mayo appeared on behalf of defendant Hologic, Inc. The undersigned has fully considered the parties' briefs, the parties' oral arguments, and appropriate portions of the record. For the reasons that follow, defendant's motion for judgment on the pleadings is granted, but with leave to amend.

I. Background

Plaintiff's state court complaint consists of a four-page "personal injury" form complaint along with an additional form page specifically tailored to causes of action based on products liability. (ECF No. 1-1 at 7-11.) Based on the boxes plaintiff has checked off on the form complaint, it appears that plaintiff alleges two causes of action against defendant based on products liability, one claim based on strict liability, and the other based on negligence. (Id. at 11.) More specifically, plaintiff alleges that "[o]n or about . . . March 13, 2012 plaintiff was injured by the following product: Hologic, Inc. manufactured Selenia brand digital 3-D mamography [sic] machine" and that "plaintiff was a patient treated with the device." (Id.) Plaintiff further alleges that "defendant[ ] knew the product would [*3] be purchased and used without inspection for defects," that "[t]he product was defective when it left the control of . . . defendant[ ]," and that "[t]he product at the time of [plaintiff's] injury was being used in a manner intended by defendant[ ]." (Id.) Plaintiff also alleges that her "injury was the legal (proximate) result of . . . [defendant's] manufacture[ ] or

[1] This action proceeds before this court pursuant to Eastern District of California Local Rule 302(c)(21) and 28 U.S.C. § 636(b)(1).

assembl[y of] the product," the "design[ ] and manufacture[ ] [of] component parts supplied to the manufacturer," and "[sale of] the product to the public." (Id.) Finally, plaintiff alleges that defendant owed a duty to her and that her injury was the proximate result of defendant's negligence.[2] (Id.) Plaintiff requests relief in the form of compensatory damages, including hospital and other medical expenses. (Id. at 10.)

II. Requests for Judicial Notice

In support of its Motion for Judgment on the Pleadings, defendant requests that the court take judicial notice of the following three documents: (1) a February 11, 2011 Premarket Approval letter for the Selenia Dimensions 3D System (ECF No. 8-3, Exhibit B); (2) a Food and Drug Administration ("FDA") Summary of Safety and Effectiveness Data for the Selenia Dimensions 3D System" available through the FDA's website [3]; and (3) a product classification listing for the digital breast tomosynthesis mammography system from the FDA's medical device classification database webpage.[4] Plaintiff does not oppose defendant's requests for judicial notice.

Under Federal Rule of Evidence 201, "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) [*5] is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Courts may take judicial notice of "*undisputed* matters of public record," but generally may not take judicial notice of "*disputed* facts stated in public records." Lee v. City of Los Angeles, 250 F.3d 668, 690 (9th Cir. 2001) (emphasis in original). Facts subject to judicial notice may be considered on a Rule 12(c) motion. McCain v. Stockton Police Dept., 2011 U.S. Dist. LEXIS 114469, 2011 WL 4710696 at *2 (C.D. Cal. Oct. 4, 2011) (citing Mullis v. U.S. Bankr. Ct., 828 F.2d 1385, 1388 (9th Cir. 1987)).

The Court finds that the documents here meet the requirements of Federal Rule of Evidence 201. The court may take judicial notice of information in government documents or from a government website when the fact "is not subject to reasonable dispute because it can accurately and readily be determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201; Daniels-Hall v. Nat'l Educ. Ass'n, 629 F.3d 992, 998-99 (9th Cir. 2010); United States v. Head, 2013 U.S. Dist. LEXIS 151805, 2013 WL 5739095 at *1, n.1 (E.D. Cal. Oct. 22, 2013); [*6] Clifford v. Regents of Univ. of California, 2012 U.S. Dist. LEXIS 60280, 2012 WL 1565702 at *5 (E.D. Cal. Apr. 30, 2012); see Erickson v. Boston Scientific Corp., 846 F. Supp. 2d 1085, 1089 (C.D. Cal. 2011) (granting request for judicial notice of FDA's Premarket Approval documents for defendants' pacemaker product); In re Amgen Inc. Sec. Litig., 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008) (granting requests for judicial notice of information posted on the FDA's website). Accordingly, defendant's requests for judicial notice are granted.

III. Legal Standard

Rule 12(c) of the Federal Rules of Civil Procedure permits a party to seek judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." "A motion for judgment on the pleadings should be granted where it appears the moving party is entitled to judgment as a matter of law." Geraci v. Homestreet Bank, 347 F.3d 749, 751 (9th Cir. 2003); Westlands Water Dist. v. Firebaugh Canal, 10 F.3d 667, 670 (9th Cir. 1993) ("[J]udgment on the pleadings is appropriate when, even if all allegations in the complaint are true, the moving party is entitled to judgment as a matter of law.").

"A [*7] judgment on the pleadings is a decision on the merits." 3550 Stevens Creek Associates v. Barclays Bank of California, 915 F.2d 1355, 1356 (9th Cir. 1990). In addition to considering the allegations of the complaint, the court may also take into account materials to which it can take judicial notice. Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981, n.18 (9th Cir. 1999). "[T]he central issue is whether, in light most favorable to the plaintiff, the complaint states a valid claim for relief." Hughes v. Tobacco Inst., Inc., 278 F.3d 417, 420 (5th Cir. 2001). "[A]ll allegations of fact of the opposing party are accepted as true." Austad v. United States, 386 F.2d 147, 149 (9th Cir. 1967). A motion for

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[2] Plaintiff makes a number of additional factual allegations in her opposition to defendant's motion regarding her alleged injury and the specific circumstances leading to this injury. (ECF No. 10.) However, the court cannot consider these additional factual allegations because the court may only consider the allegations within the complaint itself as well as materials to which it can take judicial notice [*4] when assessing a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). See Heliotrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981 (9th Cir. 1999).

[3] This document is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080003b.pdf.

[4] This webpage is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/ classification.cfm?ID=OTE.

judgment on the pleadings may be granted if, after assessing the complaint and matters for which judicial notice is proper, it appears "beyond doubt that the [non-moving party] cannot prove any facts that would support his claim for relief." Morgan v. County of Yolo, 436 F.Supp.2d 1152, 1155 (E.D. Cal. 2006), aff'd, 277 F. App'x 734 (9th Cir. 2008); R.J. Corman Derailment Services, LLC v. Int'l Union of Operating Engineers, Local 150, AFL-CIO, 335 F.3d 643, 647 (7th Cir. 2003).

"A [*8] Rule 12(c) motion challenges the legal sufficiency of the opposing party's pleadings and operates in much the same manner as a motion to dismiss under Rule 12(b)(6)." Morgan v. County of Yolo, 436 F.Supp.2d 1152, 1154-55 (E.D. Cal. 2006). Analysis under Rule 12(c) is "substantially identical" to analysis under Rule 12(b)(6) because, under both rules a court determines whether the facts alleged in the complaint, taken as true, entitle the plaintiff to a legal remedy. Chavez v. U.S., 683 F.3d 1102, 1108 (9th Cir. 2012). Similar to a Rule 12(b)(6) motion to dismiss, when addressing a motion on the pleadings, a court must assess whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). "[A] court considering a motion to dismiss can begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." Iqbal, 556 U.S. at 679.

Mere conclusory [*9] statements in a complaint and "formulaic recitation[s] of the elements of a cause of action" are insufficient. Twombly, 550 U.S. at 555. Thus, a court discounts conclusory statements, which are not entitled to the presumption of truth, before determining whether a claim is plausible. Iqbal, 556 U.S. at 678. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 679.

Courts have discretion to grant leave to amend in conjunction with motions made pursuant to Rule 12(c). Moran v. Peralta Cmty. Coll. Dist., 825 F.Supp. 891, 893 (N.D. Cal. 1993) (citing Amersbach v. City of Cleveland, 598 F.2d 1033, 1038 (6th Cir. 1979). Generally, leave to amend a complaint is denied only if it is clear that the deficiencies of the complaint cannot be cured by amendment. DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992).

IV. Defendant's Motion for Judgment [*10] on the Pleadings

Defendant argues that both of plaintiff's claims are preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, 360c *et seq.*, which contains an express preemption clause.

> The MDA's preemption provision states that:
>
> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The MDA regulatory regime established three classes of medical devices based on the level of risk they present. Riegel v. Medtronic, 552 U.S. 312, 316, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). Class I devices, such as bandages and latex gloves, are subject to the lowest level of regulation, Class II devices, such as powered wheelchairs, receive closer FDA scrutiny, and Class III devices, such as replacement heart valves, receive the most intensive federal oversight. Id. at 316-17. The FDA has [*11] exclusive authority to regulate and assess the safety and effectiveness of medical devices through the premarket approval or an equivalent process. Id. at 316-320 (describing the "rigorous" premarket approval process medical devices falling into one of the three MDA classes must undergo).

Here, the judicially-noticed documents demonstrate that defendant manufactured the Selenia Dimensions 3D System, which forms the basis for plaintiff's products liability claims, and that this machine is a Class III Medical Device that was evaluated under the FDA's premarket approval process. Accordingly, this device falls within the MDA regulatory regime, including the MDA's preemption provision.

In Riegel v. Medtronic, the United States Supreme Court held that the MDA expressly preempts state law claims if "specific federal requirements apply to the particular medical

device that is the subject of the state law claim," and "the state-law tort claim imposes a standard of care or behavior that is 'different from, or in addition to' the specific federal requirements." 552 U.S. at 322 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 498-99, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (holding that MDA preemption applies to common law claims **[*12]** such as "strict products liability, breach of implied warranty, and negligence")). District courts in the Ninth Circuit have applied Riegel to preempt a broad range of state law claims brought against FDA-approved Class III medical devices, including products liability claims under California state law. See, e.g., Norton v. Indep. Tech., LLC, 2011 U.S. Dist. LEXIS 90526, 2011 WL 3584491 (E.D. Cal. Aug. 15, 2011) (granting defendant's Rule 12(c) motion because plaintiff's products liability and negligence claims concerning a Class III motorized wheelchair were preempted by the MDA); Cohen v. Guidant Corp., 2011 U.S. Dist. LEXIS 18786, 2011 WL 637472, at *1 (C.D. Cal. Feb. 15, 2011) (holding that plaintiff's "state law claims are preempted by federal law because the pacemaker at issue in this action . . . is a Class III Medical Device that was evaluated under the equivalent of the FDA's premarket approval process").

Plaintiff's claims as pled are preempted by federal law because they are each premised on the impropriety of a design, manufacturing or labeling process specifically approved by the FDA through its premarket approval procedures, and they thus constitute state law claims imposing requirements that are "different from, or in addition **[*13]** to" federal requirements. Riegel, 552 U.S. at 322; see also Medtronic, Inc., 518 U.S. at 498-99; Norton, 2011 U.S. Dist. LEXIS 90526, 2011 WL 3584491.

Nevertheless, the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 322. In order to properly plead "parallel" claims that survive preemption, however, a plaintiff "must demonstrate facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." Cohen v. Guidant Corp., 2011 U.S. Dist. LEXIS 18786, 2011 WL 637472 at *1 (C.D. Cal. 2011). However, plaintiff does not allege in her complaint that defendant violated FDA requirements in the design, manufacture or labeling of the Selenia Dimensions 3D System. Accordingly, defendant's motion for judgment on the pleadings is granted, but with leave to amend because plaintiff could conceivably allege facts supporting the existence of viable "parallel claims" based on defendant's failure to comply with the FDA-approved standards.[5]

If plaintiff elects to file an amended complaint, it shall be captioned "First Amended Complaint" and shall not exceed 20 pages. Furthermore, the first amended complaint shall be limited to asserting "parallel" claims against defendant, meaning that plaintiff must be able to make good faith factual allegations showing that defendant violated FDA regulations or requirements related to the Selenia Dimensions 3D System and that there was a causal relationship between plaintiff's alleged injury and defendant's violation.[6] See Cohen, 2011 U.S. Dist. LEXIS 18786, 2011 WL 637472 at *1.

Plaintiff is informed that the court cannot refer to a prior complaint, brief, exhibits, or other filing to make plaintiff's first amended complaint complete. Local Rule 220 requires that an amended complaint be complete in itself without reference to any prior pleading. Thus, once the first amended complaint is filed, it supersedes the original complaint, which no longer serves any function in the case.

Importantly, nothing in this order requires plaintiff to file a first amended complaint. If plaintiff determines that she does not wish to pursue the action at this juncture, she may instead file a request for voluntary dismissal of the action without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i).

V. Conclusion

For the foregoing reasons, IT IS HEREBY ORDERED THAT:

1. Defendant's motion for judgment on the pleadings (ECF No. 8) is granted with leave to amend.

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[5] Defendant also argues that plaintiff's **[*14]** allegations are not adequately pled under the Federal Rule of Civil Procedure 8(a) standards announced in Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007), and Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). While the court agrees that plaintiff's form complaint lacks the factual support necessary to undergird a plausible claim under this standard, the court declines to address this argument at this time because defendant's motion for judgment on the pleadings is granted with leave to amend on the basis of preemption.

[6] Plaintiff is cautioned that if she chooses to file an amended complaint, she must have a good faith factual basis for the allegations **[*15]** asserted in that pleading. Failure to make allegations in good faith could result in the imposition of sanctions. See Fed. R. Civ. P. 11(b), (c).

2. Within 30 days of this order, plaintiff shall file either (a) a first amended complaint in compliance with this order or (b) a request for voluntary dismissal of the **[*16]** action without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i).

3. Defendants shall file a response to any first amended complaint within 30 days of service with that pleading.

4. Failure to file either a first amended complaint or a request for voluntary dismissal by the required deadline may result in the imposition of any appropriate sanctions, including monetary sanctions and/or potential dismissal of the action with prejudice pursuant to Federal Rule of Civil Procedure 41(b).

IT IS SO ORDERED.

Dated: June 6, 2014

/s/ Kendall J. Newman

KENDALL J. NEWMAN

UNITED STATES MAGISTRATE JUDGE