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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

JERRY HILL,

No. C 11-05637 WHA

Plaintiff,

v.

**ORDER GRANTING
MOTION TO REMAND**

TAKEDA PHARMACEUTICALS
NORTH AMERICA, INC.; TAKEDA
PHARMACEUTICALS
INTERNATIONAL, INC.; TAKEDA
PHARMACEUTICAL COMPANY
LIMITED; TAKEDA
PHARMACEUTICALS, LLC.; TAKEDA
GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC.;
TAKEDA SAN DIEGO, INC.; and
DOES 1 through 100, inclusive,

Defendants.

INTRODUCTION

In this pharmaceutical product-liability action, plaintiff moves to remand to Santa Clara County Superior Court. For the reasons stated below, the motion is **GRANTED**.

STATEMENT

Actos (pioglitazone) was approved by the Food and Drug Administration in 1999 to treat Type 2 diabetes. Plaintiff Jerry Hill used Actos from July 2005 through September 2011 and was diagnosed with bladder cancer in 2009 (Compl. ¶ 41). He alleges that as a result of Actos' defective design, manufacturing, and testing, persons who took Actos for more than a year were at increased risk for developing bladder cancer. He also alleges that defendants failed to warn and concealed their knowledge about the nature and extent of bladder cancer risk. Hill claims for

1 relief in negligence, strict liability, breach of express and implied warranties, deceit by
2 concealment, negligent misrepresentation, unfair business practices, and violations of the
3 California Consumer Legal Remedies Act (Compl. ¶¶ 48–168).

4 Hill is a California citizen who resides in Santa Clara County. He filed this action in
5 Santa Clara County Superior Court on October 21, 2011 (Compl. ¶ 2). The complaint lists the
6 following Takeda entities as defendants: Takeda Pharmaceuticals North America, Inc., Takeda
7 Pharmaceuticals International, Inc., Takeda Pharmaceuticals Company Limited, Takeda
8 Pharmaceuticals, LLC., Takeda Global Research & Development Center, Inc., and Takeda San
9 Deigo, Inc (collectively, “Takeda”). All defendants, with the exception of Takeda San Diego, are
10 non-California citizens (Compl. ¶¶ 14–20). Takeda San Diego (TSD), as its name suggests, is a
11 California corporation having a principal place of business in San Diego. Hill alleges that TSD
12 individually, and in partnership with other Takeda entities, designed, researched, manufactured,
13 tested, promoted, marketed, and distributed Actos.

14 A petition for coordination of Actos bladder cancer cases in California state courts was
15 filed with the Judicial Council of California on October 25, 2011. There were nine cases,
16 involving eleven plaintiffs, that were pending in “courts throughout the State of California” at the
17 time the petition was filed (Robinson Decl. ¶ 3).

18 On November 21, 2011, Takeda removed the instant action to this Court pursuant to 28
19 U.S.C. 1332 diversity jurisdiction, arguing that TSD was fraudulently joined and that its
20 citizenship should therefore be disregarded for purposes of diversity.

21 ANALYSIS

22 The Court may remand a case to state court for lack of subject-matter jurisdiction or
23 defects in removal procedure. 28 U.S.C. 1447(c). Diversity jurisdiction pursuant to 28 U.S.C.
24 1332 requires complete diversity of citizenship. *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061,
25 1067 (9th Cir. 2001).

26 Citizenship of fraudulently joined parties must be ignored in analyzing diversity. If
27 plaintiff fails to state claims against a resident defendant, and the failure is obvious according to
28 the settled rules of the state, then joinder of the resident defendant is fraudulent. Defendants

1 seeking removal to the federal court are entitled to present facts showing the joinder to be
2 fraudulent. *Morris*, 236 F.3d at 1067.

3 **1. REASONABLE BASIS FOR TSD LIABILITY IN NEGLIGENCE.**

4 To prove negligence under California law, the plaintiff must show that the defendant owed
5 him a duty of care, the defendant breached that duty, and the breach was a proximate or legal
6 cause of his injury. The causation element is satisfied when the plaintiff establishes that the
7 defendant's breach of duty (his negligent act or omission) was a substantial factor in bringing
8 about the plaintiff's harm. *Sandoval v. Bank of America*, 94 Cal. App. 4th 1378, 1384–85 (2002).
9 Parties in a joint enterprise are vicariously liable if there is an agreement under which the parties
10 have (1) a joint interest in a common business, (2) an understanding that profits and losses will be
11 shared, (3) a right to joint control, and (4) the wrongdoing falls within the scope of the enterprise.
12 *See Ramirez v. Long Beach Unified School Dist.*, 105 Cal. App. 4th 182, 193 (2002).

13 Takeda argues that Hill has no reasonable basis to claim that an action or inaction of TSD
14 was a proximate cause of his alleged injuries. Takeda contends that TSD has never been a part of
15 the chain of distribution for Actos, and has never had a role in the manufacturing, developing,
16 designing, labeling, marketing, selling, distributing, or safety testing of Actos (Opp. 3). This
17 order disagrees.

18 Keith Wilson, president and chief medical officer of TSD, admitted in his declaration
19 supporting removal that TSD played a role in the study and testing of pioglitazone. Specifically,
20 Wilson admitted that TSD (1) conducted limited pre-clinical testing of potential combination
21 products that have not been approved in the United States, (2) conducted authenticity testing of
22 Actos tablets (that is, to determine whether the tablets were, in fact, manufactured by Takeda
23 Pharmaceutical Company Limited), (3) conducted protein crystallographic evaluation of how
24 pioglitazone binds to and activates PPAR-gama protein, and (4) evaluated the use of pioglitazone
25 as a standard in testing other compounds regarding glucose lowering, induction of CYP3A, and
26 mass spectrometry analysis (Dkt. No. 1 Exh. B [Wilson Decl.] ¶ 6).

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A. Stand-Alone Liability for Negligence.

TSD’s involvement with Actos may have imposed a duty to warn of safety risks that TSD discovered, even if those discoveries were only indirect evidence of potential human risks. For example, TSD conducted non-human evaluations of how pioglitazone binds to PPAR-gamma protein. This testing implicated a potential mechanism of action by which pioglitazone may have caused bladder cancer: PPAR-gamma binding (Reply Br. 7). Even before Hill developed bladder cancer, the connection between PPAR-gamma and bladder cancer had been noted in the medical literature. *See, e.g.*, ROSIGLITAZONE, A PPAR GAMMA AGONIST: POTENT PROMOTER OF OH-BBN INDUCED URINARY BLADDER CANCERS, 123 INTERNATIONAL JOURNAL OF CANCER 2254–2259 (2008). Plaintiff alleged that non-human studies, like the testing TSD conducted, should have raised signals that bladder cancer risk needed to be further tested (Compl. ¶ 28). Testing of PPAR-gamma by TSD could have imposed a duty to warn about bladder cancer risks, and failure to warn could have been a substantial factor in bringing about Hill’s injuries.

B. Liability Under a Joint Enterprise Theory.

It is true that Hill’s pleadings are non-specific and state the same factual allegations against all the defendants: design, research, manufacturing, testing and promotion of Actos (Compl. ¶¶ 26, 27). Nevertheless, the allegations do raise a reasonable possibility that TSD could be held liable under a joint enterprise theory pursuant to California law.

While TSD may not have directly manufactured Actos or measured bladder cancer rates in humans, TSD may have been party to a joint enterprise with other Takeda entities to research and manufacture Actos. It seems plausible, at least at the pleading stage, that defendants, including TSD, shared and relied on each other’s clinical data to make decisions about safety testing and manufacturing. For example, TSD’s preclinical data on PPAR-gama binding and drug interactions may have informed another Takeda entity on designing clinical studies to directly evaluate bladder cancer rates in humans. Another example: TSD’s authenticity testing of Actos tablets may have informed the manufacturing process by another Takeda entity. Hill alleges a joint enterprise theory of liability and that TSD shared profits with other Takeda entities (Compl. ¶ 8).

