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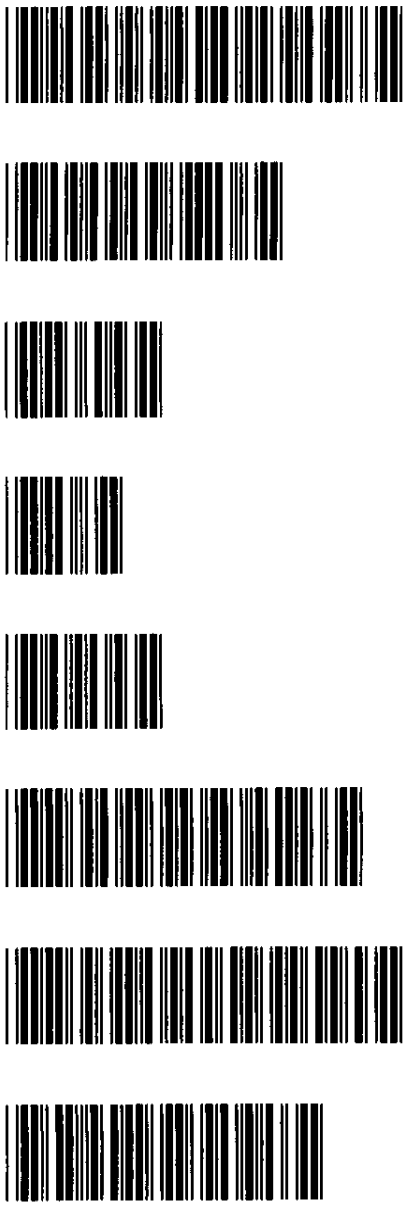

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3:99-CV-00973 MARSHALL V. ZIMMER
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MEMOPNO.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DOUGLAS H. MARSHALL,
Plaintiff,
v.
ZIMMER; HOWMEDICA, INC., et al.,
Defendants.

Civil No. 99-0973E(CGA)

MEMORANDUM DECISION AND ORDER

BACKGROUND

Douglas Marshall filed this products liability action against the manufacturer, Zimmer, Inc., of a hip prostheses. Marshall seeks to amend the complaint to add eight defendants. Zimmer opposes the addition of six of the proposed parties, but does not oppose the addition of two (Howmedica International Inc. and Zimmer Caribe, Inc.).

DISCUSSION

Marshall suspects that his injuries were caused by an unsafe cement used in the surgical implant of the femoral component of his hip prostheses. Through discovery, Marshall has now learned the names of other companies involved in the supply, manufacturer, or distribution of the medical device, its components, or the cement.

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Marshall seeks leave to add these eight defendants to the complaint. Marshall cites the liberal amendment policies of Rule 15(a), and notes that discovery does not close until April 2000.

Defendant Zimmer opposes the motion as to six entities on the ground that the proposed amendment would be futile. Gabrielson v. Montgomery Ward & Co., 785 F.2d 762, 766 (9th Cir. 1986) (motion to amend should not be granted if the amendment could be defeated on a summary judgment). Those six parties fall into two categories: 1) two of them were quality service providers, and 2) four of them were suppliers of materials or components.

A new federal statute, the Biomaterials Access Assurance Act, 21 U.S.C. § 1601-1606, provides suppliers of "raw materials and component parts" of medical devices that are permanently implanted in the human body to save or enhance lives with immunity from suit under "any" legal theory. Congress enacted the statute in August 1998 (three months before Marshall filed this law suit) because suppliers of raw materials and component parts were "very rarely" held liable in products liability actions, but the threat of litigation was leading them to stop supplying the components to make the necessary life saving medical devices. The Act applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." § 1603(b)(1). The Act expressly preempts any state law regarding recovery for harm caused by an implant. § 1603(c)(1). The Act requires the claimant to sue the manufacturer, and allows them to sue the seller as well.

The Act defines a biomedical supplier as one that "directly or indirectly supplies a component part or raw materials for use in the

manufacturer of an implant." § 1602(1)(A). A component part "means a manufactured piece of an implant" that has "significant non-implant applications" and "alone, has no implant value or purpose." § 1602(3). A raw material "means a substance or product that has a generic use; and may be used in an application other than an implant." § 1602(8).

An exception exists in that the supplier may be sued if the claimant shows, by a preponderance of the evidence, that the materials supplied did not meet the specifications in the manufacturer's contract and that the failure to meet those contractual standards was the actual and proximate cause of the claimant's injury. § 1604(d).

The Act sets forth specific procedures. The supplier may bring a motion to dismiss or for summary judgment to assert its statutory immunity rights. § 1603(a)(1), 1605(a). The court may allow discovery limited to the issue of whether the defendant meets the statutory requirements, for example, whether the component met the contractual requirements or if the component had a purpose separate from the medical device. § 1605(c)(1)(B). The court considers the pleadings and the affidavits filed in support of the motion. § 1605(c)(3). Any dismissal on the motion to dismiss "shall be entered with prejudice" except insofar as the supplier may be rejoined in the action if future evidence shows a basis for contribution or indemnification. § 1605(e), 1606.

Zimmer opposes the motion to amend on behalf of its suppliers. Zimmer argues that since Marshall's proposed amendment does not include any allegations to show that the proposed defendants would be excepted from the statutory immunity, that any amendment to add them as defendants would be futile. Zimmer presented affidavits from the

four supplier defendants (Esschem, Inc., KomTek, Inc., Courtesy Corp., and Ashland Chemical) in which they state that they simply supplied raw material or component parts for the medical device, and that they complied with their contractual requirements in providing those parts and materials to Zimmer.

As an alternative argument, Zimmer cites California cases that held suppliers of bulk materials were not liable for the flaws in a finished product since they had no control over the design, packaging, or marketing of the final manufactured good. E.g., Ferarri v. Grand Canyon Dories, 32 Cal. App. 4th 248, 258-59 (1995); Walker v. Stauffer Chemical Corp., 19 Cal. App. 3d 669, 674 (1971); accord Keoloha v. E.I. DuPont De Nemours and Co. Inc., 82 F.3d 894, 899 (9th Cir. 1996).

As to two other proposed defendants (Peerless and SteriGenics International), Zimmer argues that they should not be added because they merely provided quality assurance services to Zimmer during the manufacturing process. By analogy to the Congressional findings of "up-stream" suppliers, Zimmer argues that Marshall cannot state a cause of action against the companies that provided quality control services to Zimmer. Zimmer argues that quality control measures do not constitute being involved in the manufacturing process or the chain of distribution required under the federal statute, or pre-existing state law. An entity that furnishes a service, such as quality control, rather than a product, cannot be held liable under strict products liability.

Marshall responds that the defendant is prematurely seeking a motion to dismiss. The issue before the court is a simple motion to amend the complaint, and that relief should be granted freely. If the court denies leave to amend, the plaintiff will denied the opportunity

to conduct discovery to see if these parties are liable for Marshall's injury. Marshall also argues that the court, like plaintiff, does not have enough information before it to make a valid determination of whether these parties meet the statutory requirements and definitions to be entitled to immunity.

The court concludes that Zimmer's arguments are well-taken. Although the immunity statute is being raised in the context of a motion to amend the complaint, the court discerns no reason to allow an amended pleading that would be subject to a motion to dismiss. Gabrielson, 785 F.2d at 766. The statute, though new, is quite clear that the suppliers can provide affidavits to demonstrate that they are not subject to litigation for their minimal contribution to a medical device ultimately designed, made, and sold by the manufacturer.

As the main defendant in this action, Zimmer has a strong incentive to pass any blame for the alleged defects in its medical device on to any supplier who failed to comply with the contract or whose product may have contributed to Marshall's injury. In addition to having the incentive to pass blame onto its suppliers, the manufacturer would also have access the information necessary to prove that the raw materials or components were defective. The court is confident that if facts arise during the case to indicate that some of these suppliers are to blame for the alleged tort, that Zimmer will ardently endorse the addition of those parties to this action. Until the facts indicate a colorable basis for drawing those parties into this litigation, however, the court's ruling fulfills the purpose of the Act by protecting suppliers from being named in every litigation involving the ultimate product. Accordingly, the court denies the motion for leave to amend as to four supplier companies without prejudice.

The Act does not expressly protect those defendants who were quality service providers. Nonetheless, the preexisting law demonstrates that the addition of those two defendants would be equally futile. E.g., Ferarri, 32 Cal. App. 4th at 258-59; Pena v. Sita World Travel, Inc., 88 Cal. App. 3d 642, 644-45 (1978); Allied Properties v. John A. Blume & Assoc., 25 Cal. App. 3d 848, 855 (1972). Thus, the court denies leave to add the two service companies.

CONCLUSION

Upon due consideration of the parties' memoranda and exhibits, the arguments advanced at hearing, and for the reasons set forth above, the court hereby denies in part and grants in part plaintiff's motion for leave to amend[# 10]. Plaintiff may file a first amended complaint within ten days from the date of entry of this order to add defendants Howmedica International Inc. and Zimmer Caribe, Inc. The court denies without prejudice the motion as to the other six proposed defendants.

DATED: November 4, 1999.

WILLIAM B. ENRIGHT, Judge
United States District Court

Copies to:
Lead Attorneys