Moore v. Medeva, et al. CV-01-311-M 01/13/04

UNITED STATES DISTRICT COURT

DISTRICT OF NEW HAMPSHIRE

Linda E. Moore and
Wallace Moore,
Plaintiffs

v.

Civil No. 01-311-M
Opinion No. 2004 DNH 013

Medeva Pharmaceuticals, Inc.,
a/k/a Celltech Pharmaceuticals, Inc.,
and Celltech Pharmaceuticals Ltd.,
Defendants

O R D E R

Linda Moore says that in October of 1998, after receiving a flu vaccine allegedly manufactured, distributed, and/or sold by defendants (and their predecessors), she contracted a "paralytic ailment known as Guillain-Barre Syndrome and other consequential and incidental ailments." Amended complaint (document no. 28), para. 8. Defendant Celltech Pharmaceuticals, Inc. ("CPI") moves for summary judgment, claiming it did not manufacture, distribute, or sell the vaccine in question. Nor, says CPI, did it develop or supply the package information or other warnings included with the vaccine. Plaintiffs object, asserting that there are genuinely disputed material facts with regard to CPI's involvement in the vaccine's chain of distribution.

Standard of Review

When ruling on a party's motion for summary judgment, the court must "view the entire record in the light most hospitable to the party opposing summary judgment, indulging all reasonable inferences in that party's favor." Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990). Summary judgment is appropriate when the record reveals "no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In this context, "a fact is 'material' if it potentially affects the outcome of the suit and a dispute over it is 'genuine' if the parties' positions on the issue are supported by conflicting evidence." Intern'l Ass'n of Machinists and Aerospace Workers v. Winship Green Nursing Center, 103 F.3d 196, 199-200 (1st Cir. 1996) (citations omitted).

Discussion

I. Background.

Complicating the resolution of CPI's pending motion for summary judgment is the fact that the relationships between the entities responsible for manufacturing, distributing, and selling

the vaccine is, to say the least, complex. In a prior memorandum, CPI described some of the relevant relationships as follows:

> The influenza flu vaccine (the "Vaccine") referenced [in plaintiffs'] interrogatories for the year 1998 was manufactured in the United Kingdom by Medeva Pharma Limited, a corporation organized under the laws of the United Kingdom. Medeva Pharma Limited was formerly known as Evans Medical Limited. The name change to Medeva Pharma Limited occurred on July 6, 1998. Medeva Pharma Limited merged into Celltech Pharmaceuticals, Ltd. on April 2, 2001. Medeva Pharma Limited has since sold the assets related to the manufacture of the Vaccine to Evans Vaccines Ltd. in October, 2000. Evans Vaccines Ltd. is an unrelated company to Medeva Pharma Limited and [CPI].

CPI's Answers to Plaintiffs' Interrogatories, Exhibit 2 to CPI's memorandum in support of its motion in limine (document no. 36). See also CPI's memorandum at 9 n. 3 ("Medeva Pharma Limited [formerly known as Evans Medical Limited] merged into Celltech Pharmaceuticals, Ltd. on April 2, 2001. On September 9, 2002, this Court granted Plaintiffs' Motion to Amend their Complaint to add Celltech Pharmaceuticals, Ltd. as a defendant in this case. As such, Evans is now essentially a defendant in this case.").

Based upon CPI's statement of the relationships between the various parties, it would appear that defendant Celltech Pharmaceuticals, Ltd. ("Celltech") is the successor-in-interest to the entity that manufactured the vaccine in question. In fact, in its answer to plaintiffs' amended complaint, Celltech admitted that "prior to October 2, 1998, it manufactured Fluvirin Lot No. E20228KA" - the vaccine at issue in this case. Celltech's Answer (document no. 55) at para. 6. And, in response to plaintiffs' requests for admissions, Celltech admitted that:

> it manufactured the influenza vaccine, Fluvirin, used during the 1998-1999 vaccine season and was responsible for its sale, including the development and provision of package labeling and other warnings approved by the Food and Drug Administration and/or other governmental entities. During the 1998-99 influenza vaccine season, Celltech Pharmaceuticals, Ltd. shipped packages of Fluvirin, including its approved package labeling directly to, and only to, General Injectables and Vaccines, Inc. ("GIV"), a Virginia corporation. The vaccine was then distributed by GIV. Defendant, Celltech Pharmaceuticals, Ltd. has no knowledge of GIV's distribution methods.

Exhibit 3 to CPI's memorandum (document no. 68), Celltech's Response to Plaintiffs' Request for Admissions at 1-2.

Notwithstanding Celltech's admitted (and, at least according to it and CPI, its exclusive) role in manufacturing the vaccine at issue in this case, preparing and shipping the package inserts approved by the FDA, and contracting for the vaccine's distribution in the United States through General Injectables and Vaccines, Inc., plaintiffs assert that CPI might still be liable to them, based upon the following three factors. First, plaintiffs point out that CPI's "Medical Information department . . . fielded questions from the medical community and its patients regarding medical questions concerning the flu vaccine generally, and Fluvirin, specifically." Exhibit 1 to plaintiffs' memorandum, CPI's Amended Answer to Plaintiffs' Interrogatory No. 10 at 2. Second, CPI was listed in the Physicians' Desk Reference as an American affiliate of the vaccine's foreign manufacturer. Exhibit 2 to plaintiffs' memorandum, 1999 Physicians' Desk Reference at 3456. And, finally, CPI was registered with the Food and Drug Administration as the United States agent for the vaccine's foreign manufacturer. See Plaintiffs' memorandum at 5. See also 21 C.F.R. § 207.40(c)

(each foreign drug manufacturer required to register with the FDA must provide the name and address of its United States agent).[1]

II. Plaintiffs' Claims Against CPI.

Plaintiffs' complaint advances three substantive claims against CPI, as well as three derivative claims by Mr. Moore for loss of consortium. Unfortunately, in opposing CPI's motion for

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[1] Section 207.40(c) of Title 21 of the Code of Federal Regulations provides, in pertinent, part:

> Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.
>
> (1) The United States agent shall reside or maintain a place of business in the United States.
>
> (2) Upon request from the FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

summary judgment, plaintiffs do not describe how the three factors listed above, even if proved at trial, might possibly give rise to liability on the part of CPI - an entity that did not manufacture, distribute, promote, sell, administer, or provide the package warnings or inserts with regard to the vaccine at issue in this case.[2]

In count one of their amended complaint, plaintiffs allege that CPI was negligent insofar as it failed to warn Mrs. Moore of the risks associated with taking the vaccine and that it was "otherwise negligent in manufacturing, selling, and administering the Vaccine to Plaintiff Linda Moore." Amended complaint at para. 14. First, since plaintiffs have failed to point to any evidence that might suggest CPI had a role in "manufacturing, selling, [or] administering" the vaccine, their negligence claim, to the extent it is based upon such conduct, necessarily fails.

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[2] While it appears that CPI did distribute an influenza vaccine during the 1996-1997 flu season, that was the only year during which it did so; CPI did not distribute a vaccine during the 1998-1999 flu season and, perhaps more importantly, it did not distribute the particular vaccine at issue in this case: Fluvirin, Lot No. E20228KA.

Beyond that shortcoming in their amended complaint, plaintiffs have failed to articulate precisely how (or why) CPI had a duty, independent of those borne by the manufacturer and distributor, to warn Mrs. Moore of the potential risks associated with the vaccine. CPI's role as United States agent for the vaccine's manufacturer obligated it only to act as an intermediary between the manufacturer and the FDA; the regulations upon which plaintiffs rely do not purport to impose any further obligations on a United States agent of a foreign drug manufacturer. And, plaintiffs have failed to point to any case law (binding or persuasive) supporting their assertion that, as a result of its status as the United States agent for the manufacturer (or because it fielded questions about the vaccine, or because of its status as an "affiliate" of the vaccine's manufacturer), CPI assumed the obligation to warn potential recipients of the vaccine of the risks associated with its use. Consequently, in light of the undisputed facts of record, CPI is entitled to judgment as a matter of law with regard to count one (negligence) of plaintiffs' amended complaint.

In count three of their amended complaint, plaintiffs allege that the vaccine was defective and unreasonably dangerous. Amended complaint, para. 22. Accordingly, they say CPI is strictly liable to them for damages. As noted above, however, the undisputed material facts demonstrate that CPI did not manufacture, sell, distribute, or administer the vaccine in question. And, plaintiffs have failed to articulate how CPI's status as the manufacturer's United States agent, or its listing in the Physicians' Desk Reference as an "affiliate" of the manufacturer, might give rise to strict liability for an (allegedly) unreasonably dangerous product. Nor have plaintiffs cited any judicial opinions that are supportive of their strict liability claim against CPI. CPI is, therefore, entitled to summary judgment as to count three of plaintiffs' complaint.

Count five of plaintiffs' amended complaint alleges that CPI "warranted to Plaintiff Linda Moore that the Vaccine would be free from defects and free from unreasonably dangerous or unsafe qualities," but that CPI breached that warranty. Amended complaint at para. 28-29. Again, however, plaintiffs' objection to CPI's motion for summary judgment provides little insight into

the precise nature of their claims. Plaintiffs do not, for example, identify whether the "warranties" referenced in count five were express or implied. Nor do they identify any case law supportive of their theory of the case.

In their pre-trial memorandum, plaintiffs do say that their claims are governed by "New Hampshire products liability law and the New Hampshire Uniform Commercial Code." Plaintiffs' Pre-trial Memorandum (document no. 29) at 6. Importantly, however, New Hampshire's Uniform Commercial Code imposes warranties (both express and implied) only upon manufacturers, sellers, and suppliers of goods. See N.H. Rev. Stat. Ann. ("RSA") 382-A:2-318. See also RSA 382-A:2-313, 2-314, and 2-315. Since plaintiffs have failed to point to any evidence suggesting that CPI manufactured, sold, or supplied the vaccine in question, and because plaintiffs have not identified any other legal theory under which CPI might be liable to them for breach of warranty, CPI is entitled to judgment as a matter of law as to plaintiffs' breach of warranty claim.

Finally, since CPI is entitled to summary judgment on all of Mrs. Moore's claims against it, it is also entitled to summary judgment on all of the derivative claims for loss of consortium advanced by Mr. Moore (counts two, four, and six).

Conclusion

For the foregoing reasons, plaintiffs have failed to demonstrate that there are any genuinely disputed material facts. Given the undisputed material facts, Defendant CPI is entitled to judgment as a matter of law. Accordingly, Celltech Pharmaceuticals, Inc.'s motion for summary judgment (document no. 68) is hereby granted.

SO ORDERED.

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Steven J. McAuliffe
United States District Judge

January 13, 2004

cc: David M. Cohen, Esq.
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