IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANDREA PERRY ET AL.	:	CIVIL ACTION
v.	:	
NOVARTIS PHARMACEUTICALS CORPORATION	:	05-5350

ORDER

AND NOW, this 27th day of July, 2006, upon consideration of defendant's motion to dismiss on federal preemption grounds (docket entry # 28), defendant's motion to dismiss strict liability claim (docket entry # 29), plaintiffs' motion for leave to file a second amended complaint (docket entry # 39), defendant's responses to the motions to dismiss (docket entry # 42 & 43), defendant's response to the motion for leave to file a second amended complaint (docket entries 44 & 45), plaintiffs' motion to hold a Rule 16 conference and establish a new scheduling order (docket entry # 46), and defendant's motion for leave to file a reply brief in support of its motion to dismiss on preemption grounds (docket entry # 47), and the Court finding that:

(a) Andrea and George Perry's son, Andreas, suffered from eczema, a type of skin inflammation;

(b) To treat Andreas's eczema, his parents bought and gave him Elidel, a drug that Novartis designed, manufactured, and sold;

(c) Plaintiffs allege that in addition to treating skin inflammation, Elidel causes cancer, and, in October of 2003, a doctor diagnosed Andreas with lymphoma "[a]s a result of using"

it, Original Compl. ¶ 27;

(d) On October 12, 2005, Andrea and George Perry, individually and for their son, sued Novartis for strict liability (count one), negligence (count two), and deceit and fraud (count three);

(e) On January 12, 2006, we granted Novartis's motion to dismiss count three because it was pleaded with insufficient specificity;

(f) On January 23, 2006, plaintiffs' filed an amended complaint with greater specificity, and we consequently denied Novartis's renewed motion to dismiss on that ground;

(g) After a Rule 16 conference on March 10, 2006, we entered this matter into our special management track and scheduled discovery, motion practice, and pretrial hearings;

(h) Before us are two new motions to dismiss and plaintiffs' motion for leave to file a second amended complaint;

(i) If we grant plaintiffs leave, the motions to dismiss will be moot, and we thus begin with their motion;

(j) In that motion, plaintiffs seek leave to file a seventeen-count complaint;

(k) Because we shall permit them to file an amended complaint that contains seven counts, we shall grant their motion in part;

(l) Fed. R. Civ. P. 15(a) provides that "a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given

when justice so requires;"

(m) The grant or denial of a motion for leave to amend is within our discretion, Zenith Radio Corp. v. Hazeltine Res., 401 U.S. 321 (1971), and we may deny leave for such reasons as undue delay, bad faith, dilatory motive, undue prejudice, or futility of the claims, Foman v. Davis, 371 U.S. 178, 182 (1962);

(n) At the outset, proposed count seventeen is a claim for punitive damages, and punitive damages are a remedy rather than a cause of action;

(o) Moreover, in counts seven and eight, plaintiffs sue Novartis (count seven) and two sales representatives (count eight) for "common law fraud;"

(p) In counts three and five, however, plaintiffs sue the same defendants for "deceit and fraud;"

(q) Because under Pennsylvania law[1] there is no difference between "common law fraud" and "deceit and fraud," we reject proposed counts seven and eight;

(r) In counts one, two, four, and fourteen, plaintiffs sue for strict liability (design defect), negligence, and strict liability (failure to warn);

(s) Allowing these counts would be futile;

(t) Under Pennsylvania law and Section 402A of the Restatement (Second) of Torts, while courts generally impose

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[1] It is undisputed that Pennsylvania law governs. Plaintiffs cite Pennsylvania law in their proposed second amended complaint, and both parties cite Pennsylvania law in their briefs.

strict liability on manufacturers of products sold in a defective condition, the "strict liability rules for prescription drugs . . . are somewhat different. . . ." Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1353 (1992) (applying Pennsylvania law);

(u) Rather than being strictly liable, pharmaceutical manufacturers are instead liable only if they "fail[] to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous," Hahn v. Richter, M.D., 673 A.2d 888, 891 (Pa. 1996) (citing Incollingo v. Ewing, 282 A.2d 206, 220 n.8 (Pa. 1971) (in turn citing Section 388 of the Restatement (Second) of Torts[2]));

(v) This means that a drug manufacturer is liable only if it fails to exercise reasonable care to inform physicians of the facts that make it likely to be dangerous for its intended use, which then permits the consumer to sue for negligent failure to warn, see Incollingo, 282 A.2d at 221; Hahn, 628 A.2d at 866; Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984); Mazur, 964 F.2d at 1353; Luke v. Am. Home Prods. Corp., C.A. No. 1998-C-01977, 1998 WL 1781624, at *7 (Pa. Com. Pl. Nov. 18, 1998); see also Colacicco v. Apotex, Inc., --- F. Supp. 2d ---, 2006 WL 1443357, at *25 (E.D. Pa. Mar. 25, 2006);

(w) Here, while we can permit proposed counts fifteen

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[2] In Incollingo, the Pennsylvania Supreme Court held that the standard of care required for a pharmaceutical manufacturer is found in Section 388 of the Restatement (Second) of Torts, which addresses the liability of a supplier of a chattel known to be dangerous for its intended use. See Incollingo, 282 A.2d at 220 n.8; see also Hahn, 628 A.2d at 891.

and sixteen for negligent failure to warn, we cannot permit counts one and four which are strict liability counts for defective design and failure to warn;

(x) Moreover, we must reject proposed counts two and fourteen, which are general negligence counts not predicated on a failure to warn theory;

(y) Turning to proposed counts eleven and twelve, plaintiffs sue for breach of implied warranty;

(z) Under Pennsylvania law, however, a claim for breach of implied warranty is not available in cases involving prescription drugs, see Makripodis v. Merrell-Dow Pharma., Inc., 523 A.2d 374 (Pa. Super . 1987) (holding that "the very nature of prescription drugs . . . precludes claims for breach of the implied warranty of merchantability"); accord Colacicco, 2006 WL 1443357, at *26 (following Makripodis); Luke, 1998 WL 1781624, at *5-*6; Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 372 (D.N.J. 2004);

(aa) In proposed count thirteen, plaintiffs claim that Novartis violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 Pa.C.S. §§ 201-1 - 201-9.1;

(bb) Pennsylvania courts do not permit UTPCPL actions in pharmaceutical cases, see Luke, 1998 WL 1781624, at *8; Albertson v. Wyeth, Inc., Control No. 020676, 2003 WL 21544488, at *11-12 (Pa. Com. Pl. July 8, 2003); cf. Colacicco, 2006 WL at

*29 (refusing to apply New York's Consumer Protection Law to a pharmaceutical case);

(cc) Applying the UTPCPL to these types of cases would contravene the learned intermediary doctrine, which requires drug manufacturers to give warnings to prescribing physicians, not patients, see Luke, 1998 WL 1781624, at *8;

(dd) Moreover, applying the UTPCPL "would effectively make a drug manufacturer the absolute guarantor of the anticipated results and effects of a prescription drug. Pennsylvania law, however, recognizes that some prescription drugs by their very nature can never be made safe," id. (quoting Makripodis v. Merrell-Dow Pharma., Inc., 523 A.2d 374 (Pa. Super. 1987));

(ee) We reject defendants' arguments as to the remaining proposed counts;

(ff) Most notably, defendants attack the proposed counts for breach of express warranty and intentional/negligent infliction of emotional distress as inadequately pled;

(gg) While that argument might have merit in Pennsylvania's courts, which require fact pleading, we are a federal court, and under our notice pleading system defendants' ability to describe these proposed counts shows that they know what they are being sued for, see Fed. R. Civ. P. 8(a); Conley v. Gibson, 355 U.S. 41, 45-46 (1957) (holding that the complaint need only "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests," Conley, 355 U.S.

at 47;

(hh) As for the joinder of two sales representatives, plaintiffs plead causes of action against them that satisfy Rule 8(a), and we will consider the fraudulent joinder issue (if one exists) when plaintiffs eventually file a motion to remand this case to state court;

(ii) Consequently, we shall grant the motion for leave to amend in part and deny the motions to dismiss as moot;

(jj) We are mindful of the potential preemption issue and Judge Baylson's recent opinion in Colacicco v. Apotex, Inc., --- F. Supp. 2d ---, 2006 WL 1443357 (E.D. Pa. May 25, 2006);

(kk) In Colacicco, Judge Baylson dismissed a pharmaceutical failure-to-warn case, reasoning:

> [W]hen Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), the law which gives the Food and Drug Administration ("FDA") control over the regulation of the prescription drug industry, it vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry.

Id. at *1;

(ll) Aside from the infliction of emotional distress claim, all of today's surviving claims appear to hinge on this issue; and

(mm) We shall thus schedule further briefing after the second amended complaint,[3]

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[3] A key part of Judge Baylson's decision was the Food and Drug Administration's amicus brief "re-affirm[ing] its view that

It is hereby ORDERED that:

1. The motion for leave to file a second amended complaint is GRANTED IN PART;

2. By August 3, 2006, plaintiffs may FILE a second amended complaint that includes proposed counts three, five, six, nine, ten, fifteen, and sixteen;

3. The motions to dismiss are DENIED AS MOOT;

4. By August 17, 2006, defendants may FILE a renewed motion to dismiss, with plaintiffs' response due August 31, 2006 and any reply due September 11, 2006;

5. The request for a Rule 16 conference is DENIED;

6. Discovery is SUSPENDED pending our resolution of the renewed motion to dismiss; and

7. The motion to file a reply brief is DENIED.

BY THE COURT:

Stewart Dalzell, J.

Plaintiff's claims are preempted." Id. at *8. After plaintiffs file their second amended complaint, we shall invite the FDA to state whether its views on the preemption issue here would be the same as expressed in its May 10, 2006 amicus brief to Judge Baylson in C.A. No. 05-5500 (docket entries 45 & 46).