# IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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No. 96-9249

D. C. Docket No. 2:94-CV-118-WCO

ELAN PHARMACEUTICAL RESEARCH CORPORATION,

Plaintiff-Appellant, Cross-Appellee,

versus

EMPLOYERS INSURANCE OF WAUSAU, a Wisconsin corporation, WAUSAU UNDERWRITERS INSURANCE COMPANY, a Wisconsin corporation

Defendants-Appellees, Cross Appellants.

Appeals from the United States District Court for the Northern District of Georgia

(June 26, 1998)

Before TJOFLAT and BIRCH, and  $MARCUS^*$ , Circuit Judges.

BIRCH, Circuit Judge,

<sup>\*</sup> Honorable Stanley Marcus was a U.S. District Judge for the Southern District of Florida, sitting by designation as a member of this panel, when this appeal was argued and taken under submission. On November 24, 1997, he took the oath of office as a United States Circuit Judge of the Eleventh Circuit.

This diversity case requires us to determine the extent of an insurer's duty, under Georgia law, to defend a claim of patent infringement as an "advertising injury" covered in a pair of commercial liability insurance policies. The appeal also presents the questions of whether Georgia law permits an insured to recover litigation expenses incurred before tendering notice to the insurer and whether a parent company's liability for patent infringement falls within insurance coverage for stockholder liability. The plaintiffappellant appeals the district court's decision to grant the insurer's motion for summary judgment on the issues of pre-tender litigation expenses and stockholder liability. The defendant-cross-appellant appeals the district court's decision to grant the insured's motion for summary judgment on the question of coverage under the "advertising injury" clause of the policies. We AFFIRM.

## BACKGROUND

Elan Corporation, Plc ("Plc") is an Irish corporation engaged in the manufacture and sale of pharmaceutical drugs. Plaintiffappellant, Elan Pharmaceutical Research Corporation ("EPRC"), a Georgia corporation, is one of a number of United States subsidiaries of Plc. On July 9, 1992, Pfizer, Inc. ("Pfizer") filed a lawsuit against EPRC and Plc (collectively "Elan") in the United States District Court for the District of Delaware alleging that Elan had infringed a patent licensed to Pfizer. The patent concerned a formulation of nifedipine, a drug used to treat angina and hypertension. Pfizer's complaint asserted that Elan had infringed its patent rights by commercializing a competing version of the drug. EPRC retained legal counsel to defend the Pfizer action and the same legal counsel represented Plc in its special appearance to contest personal jurisdiction in the Delaware district court.

EPRC previously had purchased two commercial liability insurance policies from Employers Insurance of Wausau and

Wausau Underwriters Insurance Company<sup>2</sup> (collectively "Wausau"): a commercial general liability policy (the "CGL policy") and a commercial umbrella liability policy (the "CUL policy"). Both the CGL and CUL policies provided a one-year period of coverage, from April 1, 1992 to April 1, 1993. On September 11, 1992, approximately two months after Pfizer filed its complaint, EPRC notified Wausau of the Pfizer suit and asked it to provide a defense in accordance with the policies. On November 16, 1992, Wausau acknowledged notice of the Pfizer lawsuit but denied any obligation to defend EPRC under the policies. Wausau similarly denied two subsequent requests from EPRC to reconsider its position.

The Pfizer litigation terminated on February 4, 1993, when the Delaware district court held that Pfizer, as a licensee, did not have standing to assert the patent rights of its licensor. See Pfizer, Inc. v. Elan Pharm. Research Corp., 812 F. Supp. 1352 (D. Del. 1993). After the disposition of the Pfizer action, EPRC brought this claim

<sup>&</sup>lt;sup>2</sup> Both Employers Insurance of Wausau and Wausau Underwriters Insurance Company are Wisconsin corporations.

against Wausau in the Northern District of Georgia, seeking to recover the costs of defending the lawsuit. On August 29, 1995, the district court found that Wausau owed a duty to defend EPRC against Pfizer's claims of patent infringement under the "advertising injury" coverage of the CGL and CUL policies and entered summary judgment in favor of EPRC. On August 8, 1996, the district court entered partial summary judgment in Wausau's favor, finding that the policies did not cover the litigation expenses EPRC incurred before giving Wausau notice of the Pfizer suit on September 11, 1992 and that the policies did not cover Plc's litigation expenses because Plc's conduct, rather than its status as EPRC's sole shareholder, provided the basis for Pfizer's allegations of liability against Plc. EPRC appeals the district court's 1996 order and Wausau cross-appeals the district court's 1995 order.

#### **DISCUSSION**

The district court's summary judgment rulings in this case involve the interpretation and application of the pertinent terms of the insurance contracts. The construction of an insurance contract is a question of law and is subject to <u>de novo</u> review. <u>See LaFarge Corp. v. Travelers Indem. Co.</u>, 118 F.3d 1511, 1514-15 (11th Cir. 1997) (per curiam). Our review of the district court's grant of summary judgment is plenary and we apply the same legal standards as those employed by the district court. <u>Id.</u> Summary judgment is appropriate when no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. <u>See</u> Fed. R. Civ. P. 56(c).

#### I. Coverage for Advertising Injury

First, we address Wausau's contention that the district court erred when it granted summary judgment in EPRC's favor on the issue of whether the CGL and CUL policies required Wausau to defend the Pfizer lawsuit. We note that, under Georgia law, the duty

to defend an insured is separate and independent from the obligation to indemnify. See Penn-America Ins. Co. v. Disabled Am. Veterans, Inc., 268 Ga. 564, 490 S.E.2d 374, 376 (1997). Although an insurer need not indemnify an insured for a liability the insured incurs outside the terms of the insurance contract, an insurer must provide a defense against any complaint that, if successful, might potentially or arguably fall within the policy's coverage. Id. To determine whether an insurer owes its insured a duty to defend a particular lawsuit, Georgia law directs us to compare the allegations of the complaint, as well as the facts supporting those allegations, against the provisions of the insurance contract. See Great Am. Ins. Co. v. McKemie, 244 Ga. 84, 85-86, 259 S.E.2d 39, 40-41 (1979). As we construe the insurance contract in this case, we are mindful of our obligation to carry out the parties' true intentions. See Tennessee Corp. v. Hartford Accident and Indem. Co., 463 F.2d 548, 551 (5th Cir. 1972) (applying Georgia law). If the claim is only one of potential coverage, however, any

"doubt as to liability and [the] insurer's duty to defend should be resolved in favor of the insured." Penn-America, 490 S.E.2d at 376 (quoting 7C John Alan Appleman, Insurance Law and Practice § 4684.01, at 98-100 (Walter F. Berdal ed., 1979)).

Both of the insurance contracts at issue in this case contain a provision insuring against liability for an "advertising injury" that occurs during the policy period and in the course of advertising the insured's goods, products, or services.<sup>1</sup> The policies define "advertising injury" to include injury arising out of patent infringement committed in the course of the insured's "advertising activities."<sup>2</sup>

The CGL, under Coverage B, states in pertinent part: We will pay those sums that the insured becomes legally obligated to pay as damages because of . . "advertising injury" to which this coverage part applies. We will have the right and duty to defend any "suit" seeking those damages.

CGL § I(B)(1)(a); see also CUL § I(1)(c) (providing similar coverage).

The CGL, as modified by an endorsement, provides: "Advertising injury" means injury . . . arising out of one or more of the following offenses committed in the course of "your advertising activities."

d. Infringement of copyright, title, trademark, patent or slogan.

CGL, Endorsement No. 5, § V(1) (emphasis added); see also CUL § VI(1) (identical language).

The contracts further define those advertising activities as "the wide spread distribution of material promoting your goods, products or services." CGL, Endorsement No. 5, ¶ D(1); CUL § VI(20). To fall within the coverage of the insurance policies, therefore, (1) Pfizer's suit must have alleged a cognizable advertising injury; (2) EPRC must have engaged in advertising activity; and (3) there must have been some causal connection between the advertising injury and the advertising activity. See e.g., New Hampshire Ins. Co. v. R. L. Chaides Constr. Co., 847 F. Supp. 1452, 1455 (N.D. Cal. 1994) (interpreting similar policy language).

Pfizer's lawsuit asserted two claims of patent infringement in connection with Elan's attempts to obtain the Food and Drug Administration's ("FDA") approval of Nifelan, Elan's nifedipine product. In order to comprehend Pfizer's claims, a brief review of the applicable patent regime is necessary. Federal law provides a cause of action for patent infringement against "whoever without authority makes, uses, offers to sell, or sells any patented invention

Section 271(e) creates an exemption for those who wish to make, use, or sell a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs . . . ." 35 U.S.C. § 271(e)(1).<sup>3</sup> Section 271(e)(2), however, states that it shall be an act of infringement to submit an application pursuant to a number of specific sections of the Federal Food, Drug and Cosmetic Act, "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a [patented]

Congress added § 271(e) to address a specific problem caused by the intersection of FDA regulations and the patent laws. Prior to the adoption of § 271(e), drug manufacturers who wished to sell a generic version of a patented drug immediately upon the expiration of the patent could not do so because of the lengthy delay associated with obtaining the legally-required, pre-market FDA approval of any such drug. See Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1524 (Fed. Cir. 1992). 1984, these manufacturers could not conduct the clinical tests necessary to submit their products for FDA approval before the patent expired on the brand name drug without risking liability for an infringing manufacture or use. <u>Id.</u> at 1524-25 (citing <u>Roche Prod. Inc. v. Bolar Pharm. Co.</u>, 733 F.2d 858 (Fed. Cir. 1984)). As a result, generic versions of drugs could not become available on the market until long after the patent on the brand name drug had expired. Congress responded by amending the law to permit those who wish to market a competing generic drug to make, use, and sell that product as long as their efforts are reasonably related to obtaining the required federal approvals. <u>Id.</u> at 1525.

drug . . . before the expiration of such patent." 35 U.S.C. § 271(e)(2).

Count I of Pfizer's complaint alleged that Elan infringed Pfizer's patent by filing a New Drug Application (the "NDA") for FDA approval of a patented drug in the manner described in section 271(e)(2), i.e., for the purpose of engaging in commercial sales before the expiration of Pfizer's patent. Both parties, however, agree that Count I of Pfizer's complaint did not implicate Wausau's insurance policies. Count II of the complaint alleged that Elan filed the NDA based on certain clinical studies, and that those clinical studies were "not solely for a use reasonably related to the development and submission of information for the Nifelan NDA, but were for the purpose of commercializing Nifelan . . . . " Pfizer Comp. ¶ 32. Count Il further alleged that the studies themselves constitute an infringing use of Pfizer's patent and that the studies fell outside the protection of section 271(e)(1). See id. ¶ 33. Elan argues that Count II of the

complaint brought the Pfizer law suit within the confines of the CGL and CUL policies.

Wausau concedes that its policies include coverage for suits alleging patent infringement, as an enumerated advertising injury, committed in the course of the insured's advertising activities. We, therefore, begin our analysis by considering whether the commercialization of the clinical studies described in Count II of Pfizer's complaint amounts to advertising activity, as defined in the contracts. Courts have differed over precisely what type of conduct constitutes advertising activity. A number of courts have defined the term expansively to include even individual sales pitches to individual consumers; but other courts have defined it more narrowly. Compare John Deere Ins. Co. v. Shamrock Ind., Inc., 696 F. Supp. 434, 440 (D. Minn. 1988) (relying on Black's Law Dictionary for the proposition that the solicitation of one person's business constitutes advertising), aff'd 929 F.2d 413 (8th Cir. 1991) with First Bank and Trust Co. v. New Hampshire Ins.

Group, 124, N.H. 417, 418, 469 A.2d 1367, 1368 (1983) ("the mere explanation of bank services to a couple in a private office cannot be considered 'advertising'"). Although Georgia's courts have yet to voice an opinion in this debate, it appears that the facts of this case meet even the narrowest readings of advertising activity advanced in the cases that Wausau cites in its briefs.

As noted above, the CGL and CUL policies define "advertising activity" as the widespread distribution of material promoting Elan's goods, products, or services. Unambiguous terms of an insurance contract are to be understood in their "plain, ordinary, and popular sense." Horace Mann Ins. Co. v. Drury, 213 Ga. App. 321, 322, 445 S.E.2d 272, 274 (1994). A plain and ordinary reading of the definition of advertising activity in Wausau's policies would include an insured's dissemination of information to promote a product or service. Black's Law Dictionary defines advertising in a manner that would include such dissemination of information:

Any oral, written, or graphic statement made by the seller in any manner in connection with the solicitation of business . . . .

Black's Law Dictionary 54, (6th ed. 1990). Moreover, the courts that have considered the issue of advertising activity in similar contexts have defined it in terms that include the dissemination of information to promote a product. See e.g., Smartfoods, Inc. v. Northbrook Property & Cas. Co., 35 Mass. App. Ct. 239, 243-44, 618 N.E.2d 1365, 1368 (1993) ("advertising means a public announcement to proclaim the qualities of a product . . . . Wide dissemination of information is typically the objective of advertising.") (citations omitted).

Count II of Pfizer's complaint accuses Elan of using the clinical studies at issue to "commercialize" Nifelan in the United States. As Wausau admits, the common definition and usage of the term "commercialize" includes developing commerce in a particular item.<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> The term "commercialize" also appears to be a term of art in this particular area of practice before the FDA. Federal regulations prohibit the commercialization of an investigational device being sold to generate testing data for FDA approval "by charging the subjects or investigators . . . a price larger than

The dissemination of clinical studies to develop a market for one of Elan's products, therefore, appears to fall well within the definition of advertising activity provided in the insurance policies and in the case law. Moreover, even if Wausau credibly could argue that Pfizer's complaint did not alert it to the fact that Elan's advertising activities were *potentially* or *arguably* at issue, thus triggering Wausau's duty to defend, the record shows that when asked in an interrogatory to clarify Count II of its complaint, Pfizer specifically cited Elan's advertising of its Nifelan product in the United Kingdom and Canada as giving rise to their cause of action.<sup>5</sup> Although Elan provided Pfizer's response to this interrogatory to Wausau in its second

that necessary to recover costs of manufacture, research, development, and handling." 21 C.F.R. § 812.7(b); see also Telectronics, 982 F.2d at 1523 n.2 (discussing this regulation in the context of a § 271(e)(1) case). Since there has never been any suggestion, either in Pfizer's complaint or the record in this case, that Elan ever sold Nifelan, the regulation appears to have no application to this case.

<sup>&</sup>lt;sup>5</sup> Georgia law does not permit an insurer to rely on the allegations of the complaint to deny coverage when the facts that the insurer knows or can ascertain show that the claim is within the coverage of the policy. See Loftin v. United States Fire Ins. Co., 106 Ga. App. 287, 296, 127 S.E.2d 53, 59 (1962).

request for a defense, Wausau maintained its position that Pfizer's lawsuit fell outside the policies.

Wausau urges that the record in the Pfizer action demonstrates that Elan's use of the clinical studies in this case did not amount to a "wide spread distribution" as required by the insurance policies. In support, Wausau cites Fox Chem. Co. v. Great Am. Ins. Co., 264 N.W.2d 385, 386 (Minn. 1978), for the proposition that a corporation's internal distribution of a pamphlet to educate the corporation's sales force did not constitute an advertising activity because the insured had not engaged in a widespread distribution of this material to the public and had not included it in direct mailings to the corporation's customers.<sup>6</sup> Id. at 386. The Fox court, however, found it significant that the insured had not reproduced the

The <u>Fox</u> case is one of the few that Wausau cites that does not focus on the relatively narrow question of whether sales pitches to individuals constitute advertising. Although the majority of the cases appear to hold that these sales pitches do not constitute advertising activity, such authority does little to help us resolve the questions presented in this appeal.

pamphlet outside the company in "the general media or <u>trade</u> <u>publications</u>." <u>Id.</u> (emphasis added).

In this case, the record shows that Elan distributed the information in question outside its own corporate structure in a number of fora with an eye towards developing interest in its products and services. See R3-13, Exh. B, Mulligan Decl. ¶¶ 13-18 (describing Elan's promotion of Nifelan). Significantly, Elan discussed its Nifelan product in trade journals, using clinical studies to promote its version of the drug. See e.g., R4-16, St. Peter Aff., Exh. E. Elan also made the Nifelan product a part of its presentations to security analysts as part of its efforts to promote the drug as a potential source of significant revenue and profit for the company. These external distributions of the clinical studies to

Wausau's contention that Elan was not engaged in advertising activity because the clinical data did not promote a "good, product, or service" is unpersuasive. Pfizer's complaint clearly concerns the commercialization of Nifelan, the product Elan hoped would compete with Pfizer's drug. Moreover, the fact that the FDA had not then approved Nifelan for sale in the United States does not detract from our conclusion that Elan's efforts to promote the drug were advertising activities. In April 1992, Elan publically announced that the FDA's approval of Nifelan was imminent and engaged in a campaign to drum up interest in the drug to begin sales immediately upon approval.

promote commercial interest in Nifelan are different in kind than the internal distribution at issue in <u>Fox</u>. Moreover, the publication of the clinical studies to promote Nifelan in the trade press presents the very case that the <u>Fox</u> court used as a counter example to show what would constitute "advertising activity."

Wausau also emphasizes the fact that Elan never distributed the information to the general public and argues that without such a public distribution, the dissemination of clinical studies cannot constitute advertising. We find this argument unpersuasive. As an initial matter, we note that the insurance contracts contain no express requirement that the insured must direct its advertising activity either towards the general public or actual consumers. Moreover, Wausau's argument would have us ignore the reality of how drugs make their way to market. Identifying and contacting the target market for a prescription drug certainly will require marketing strategies and solutions that differ from the tactics used for products

that have a more ubiquitous appeal.<sup>8</sup> A number of courts have considered the relative size of the target audience in their analyses of what constitutes a widespread distribution (and hence advertising activity) in this context. In R. L. Chaides, for example, the district court explained that as long as the insured directed its efforts at influencing a significant portion of its client base, the advertising activity requirement was satisfied, regardless of the size of the audience. See 847 F. Supp. at 1456.<sup>9</sup>

<sup>&</sup>lt;sup>8</sup> Beer producers, for example, find it effective to advertise their wares with television commercials during the Superbowl, when they expect a large segment of their target market to be watching. A drug manufacturer, however, may find such a strategy unproductive. We would expect the target audience for Nifelan to be far narrower and more discrete than that for Budweiser, and what amounts to a "widespread distribution of materials" necessarily will be far more circumscribed for Elan than for the Anheuser-Busch Corporation.

<sup>&</sup>lt;sup>9</sup> The R.L. Chaides court noted that:

Advertising activity must be examined in the context of the overall universe of customers to whom a communication may be addressed; to hold otherwise would effectively preclude small businesses . . . from ever invoking their rights to coverage for advertising injury liability . . . This court . . . concludes here, that where the advertising audience is small but nonetheless constitutes all or a significant portion of the insured's client base, the advertising activity element is satisfied.

<sup>847</sup> F. Supp. at 1456.

Similarly, we find it insignificant that Elan directed its efforts at doctors, hospitals, and other health professionals through the trade press rather than at actual consumers. Given that physicians, who prescribe drugs to their patients, often serve as a conduit between drug manufacturers and consumers, it is hardly surprising that Elan would focus its efforts on medical professionals rather than taking out an advertisement in a newspaper of general circulation. 10 We find it significant that the language in question appears in commercial general liability and commercial umbrella liability policies, of the sort a wide variety of companies rely upon. The language at issue is general and permits ready application in different situations to reflect this reality. We will not import a limitation on coverage for advertising activities, namely that the

As one commentator has observed:

<sup>[</sup>C]ommunications intended to induce the doctors to prescribe a pharmaceutical manufacturer's drugs for the doctors' patients would constitute "advertising" even though the communications were never observed by the ultimate consumers, the patients . . . [just as] a cereal manufacturer's Saturday morning commercials "advertising" even though they are aimed at children, not their parents who actually buy the product . . . .

Jan T. Chilton, Expanding Boundaries of the Advertising Injury Coverage, 620 PLI/Comm 165, 175 (1992) (citations omitted).

distribution of material in question address the general public or the final consumer, when such a limitation would not fit the reasonable expectations of the different types of businesses that have purchased similar coverage. Accordingly, we find that the distribution of information in this case satisfies the advertising activity requirement in Wausau's policies.

Having determined that Count II of Pfizer's complaint set forth an enumerated advertising injury and that Elan was engaged in advertising activity, we must address whether the injury and the activity were sufficiently related to support coverage under the policies. Although Georgia's courts have not yet had occasion to address the causal connection required in this context, Wausau points us to persuasive authority from other jurisdictions that requires the insured to show a significant causal connection between the injury alleged in the suit and the insured's advertising activities. In a representative case, the California Supreme Court, interpreting policy language very similar to that at issue here,

explained that such a causal connection was necessary to avoid the conclusion that any harmful act committed by a defendant who advertised in any fashion would fall under the grant of coverage. Such an expansive reading of the coverage would contradict both the reasonable expectations of the insured and the language of the insurance contract in question, which limited coverage to injuries likely to occur in connection with advertising activity. 11 See Bank of the West v. Superior Court of Contra Costa County, 2 Cal. 4th 1254, 1274-77, 833 P.2d 545, 558-60, 10 Cal. Rptr. 2d 538, 551-54 (1992). To provide an example, the Bank of the West court explained that a claim for patent infringement did not occur in the course of advertising activities even though the insured had advertised the infringing product, because the patent holder based its claim of infringement on the insured's sale or importation of the

<sup>&</sup>lt;sup>11</sup> The California Supreme Court examined a contract that, much like the insurance contracts at issue in this case, limited the types of injury contemplated as "advertising injury" to those that might occur in advertising—such as libel, slander, and copyright infringement. See Bank of the West, 2 Cal. 4th at 1276, 833 P.2d at 560, 10 Cal. Rptr. 2d at 553.

infringing product rather than on its advertisement. Id. at 1275, 833 P.2d at 559, 10 Cal. Rptr. 2d at 552. A federal district court, purporting to apply Georgia law (albeit without the benefit of controlling authority), recently made a similar ruling in the copyright context. See Robert Bowden, Inc. v. Aetna Cas. and Sur. Co., 977 F. Supp. 1475 (N.D. Ga. 1997). In that case, the insured argued that it illegally copied the plaintiff's computer software (and thus infringed the copyright at issue) because it needed the software to construct an advertising campaign. Rejecting coverage under the advertising injury clause, the district court held that "an insured's advertising must have been the cause of whatever injury is alleged in the underlying suit." Id. at 1480.

Elan does not contest the contractual requirement that the patent injury must have occurred within the scope of its advertising activities but argues that the patent infringement alleged in Count II of Pfizer's complaint provides the required causal connection. Pfizer's complaint, particularly its use of the term "commercialize,"

gives rise to a number of varied interpretations. The most natural reading of the complaint, particularly its allegation that the clinical studies themselves, standing apart from Elan's filing of the NDA, are infringing uses that fall outside the protection of section 271(e)(1), however, is as a claim for infringement under section 271(a). In 1992, when Pfizer filed its complaint, it was an open question of federal patent law whether the subsequent dissemination of clinical studies and information developed for the purpose of obtaining FDA approval for a drug or medical device deprived a defendant of the protections of section 271(e)(1) and therefore gave rise to an action under section 271(a). Under such a theory of liability, the

We, for example, could, as Wausau suggests, read Pfizer's complaint to state a claim under 271(e)(2) because the use of the term "commercialize" evokes the forbidden purpose of that section, namely, the <u>commercial</u> manufacture, use, or sale of a patented device before the expiration of the patent. Given the complaint's isolation of the studies from Elan's filing of the NDA, however, section 271(e)(2) appears inapplicable. <u>See also supra</u> note 4.

<sup>&</sup>lt;sup>13</sup> A number of cases before the <u>Telectronics</u> opinion had suggested that such a theory of liability was viable. <u>See Ortho Pharm. Corp. v. Smith</u>, 18 U.S.P.Q.2d (BNA) 1977, 1992 (E.D. Pa. 1990), <u>aff'd</u>, 959 F.2d 936 (Fed. Cir. 1992); <u>Scripps Clinic & Research Found. v. Genentech, Inc.</u>, 666 F. Supp. 1379, 1396-97 (N.D. Cal. 1987), <u>modified</u>, 678 F. Supp. 1429 (N.D. Cal. 1988), <u>aff'd in part and rev'd in part</u>, 927 F.2d 1565 (Fed. Cir. 1991).

dissemination of the data in a company's advertising would give rise to an action for patent infringement, because the dissemination would retroactively deprive the protected use of the patented drug to collect the data of its exemption. Construed this way, Pfizer's lawsuit provided the necessary causal connection between the alleged patent infringement and Elan's advertising activities, because without and until that activity took place, the clinical studies at issue would have been exempt. Moreover, Pfizer essentially confirmed this reading of its claims during discovery by stating that the use of the clinical studies to *advertise* Nifelan in the United

Contrary to Wausau's arguments, the Ninth Circuit's decision in Iolab Corp. v. Seaboard Sur. Co., 15 F.3d 1500 (9th Cir. 1994), supports this result. In that case, the insured was found liable for patent infringement for engaging in sales of a patented device. The patent holder overcame a § 271(e)(1) defense by proving that the insured's sales were for profit rather than to elicit data for FDA approval, in part, by citing the insured's efforts to advertise the device. Contrary to the insured's arguments and as the <u>Iolab</u> court found, however, the insured's liability depended on the sales of the device, not the advertising of the device. Id. at 1506-07. Accordingly, the Iolab court found that the insure $\overline{d's}$  advertising of the patented device was not an element of the claim and therefore could not provide the requisite link to advertising activity to support coverage under the policy. <u>Id.</u> at 1507. In this case, however, Elan never sold Nifelan and Pfizer relied on the non-exempt use of the patented drug in Elan's advertising activities to assert liability. Elan's advertising, therefore, was a necessary element of Pfizer's claim, and Iolab, therefore, supports our decision in this case.

Kingdom and Canada provided the factual basis for Count II of its complaint. Although the United States Court of Appeals for the Federal Circuit subsequently held that the dissemination of such data outside the FDA process and the data's use for fund raising and other business purposes was either an exempt use under section 271(e)(1) or did not constitute an infringing use under section 271(a), see Telectronics, 982 F.2d at 1523, when Pfizer filed its complaint this remained an open issue. As a result, we find that the allegations of Count II of Pfizer's complaint adequately set out a sufficient causal connection between advertising activities and the advertising injury of patent infringement. 15

<sup>15</sup> We reject Wausau's argument that an insured cannot show the required causal connection between the advertising injury of patent infringement and its advertising activity unless the plaintiff's complaint alleges that the advertising itself infringes the patent. Although such a restriction has some appeal in the context of copyright or trademark infringement, both commonly found advertising injury clauses, see Advance Watch Co. v. Kemper Nat'l Ins. Co., 99 F.3d 975, 806-07 (6th Cir. 1994), it is difficult to comprehend how an advertisement could ever infringe a patent. e.g., Bradshaw v. Igloo Prod. Corp., 912 F. Supp. 1088, 1100-01 (N.D. Ill.) (advertising an infringing product does not constitute an infringing use), aff'd in relevant part, 101 F.3d 716 (Fed. Cir. 1996). But see Union Ins. Co. v. Land and Sky, Inc., 247 Neb. 696, 777-78 529 N.W.2d 773, (1995)703, (suggesting advertisement that advocated infringement of a patented device might support liability for inducing patent infringement under 35 U.S.C. § 271(b)). Advertising techniques are not patentable and,

Finally, we note that the district court correctly determined that the patent infringement charged in Count II of Pfizer's complaint took place within the time and place restrictions described in Wausau's policies. As explained above, the 1989 filing of the NDA gave rise to the allegations of Count I, but the record shows that the commercialization of Nifelan that gave rise to Count II took place during the policies' coverage period of April 1992 to April 1993. Similarly, Count II of Pfizer's complaint alleges that Elan commercialized Nifelan in the United States, which falls within the

even if an insured gave away free samples of an infringing product as part of a promotion, the patent infringement would arise out of its manufacture of the product, not the advertising activity. Wausau's argument, therefore, asks us to construe the contract in a way that makes the enumeration of patent infringement as an advertising injury an illusory benefit. Cf. National Union Fire Ins. Co. v. Siliconix, Inc., 729 F. Supp. 77, 80 (N.D. Cal. 1989); see also Schafer Properties v. Tara State Bank, 220 Ga. App. 378, 381, 469 S.E.2d 743, 746 (1996) ("the favored construction will be that which gives meaning and effect to all the terms of the contract over that which nullifies and renders meaningless part of the document.").

<sup>&</sup>lt;sup>16</sup> Significantly, although Wausau contests the characterization of these efforts as "advertising activities," it does not contest EPRC's assertions that it promoted Nifelan at conferences in April, May, and June of 1992 or that EPRC published articles regarding Nifelan in the trade press during the same time period.

coverage territory of Wausau's policies.<sup>17</sup> Pfizer, in an interrogatory response, also explained that Elan's advertising of its product in the United Kingdom and Canada gave rise to Count II of the complaint. Although coverage for advertising injuries in the United Kingdom requires a sale or activity traceable to the broader coverage territory, that limitation does not apply to Canada, which falls within the policies' primary coverage territory. We conclude that Count II of Pfizer's complaint against Elan gave rise to an arguable or potential claim against Wausau's commercial liability policies and, therefore, obligated Wausau to provide EPRC a defense. Accordingly, we

<sup>17</sup> As defined in the Wausau policies:

<sup>4. &</sup>quot;Coverage territory" means:

The United States of America . . . ,
 Puerto Rico and Canada.

c. All parts of the world if:

<sup>(1)</sup> The injury or damage arises out of:

<sup>(</sup>a) Goods or products made or sold by you in the territory described in a. above; or

<sup>(</sup>b) The activities of a person whose home is in the territory described in a. above but is away for a short time on your business; . . . .

affirm the district court's decision to grant summary judgment against Wausau on this question.

#### II Wausau's Liability for Pre-Tender Litigation Expenses

Elan contends that the district court erred by granting summary judgment to Wausau on the question of pre-tender litigation expenses. The parties agree that Pfizer filed its complaint against Elan on July 9, 1992 and that EPRC did not notify Wausau of the lawsuit until September 11, 1992. During that two-month period, Elan retained counsel and began to defend the lawsuit, incurring \$519,682.05 in defense expenses. The district court held that Wausau was not liable for these pre-tender expenses as a matter of Georgia law. Elan does not argue that the district court neglected a material issue of contested fact, but rather contends that the district court misapplied the law to the uncontested facts. We disagree.

The only Georgia case that addresses the issue of an insurer's liability for the costs of a legal defense incurred before the insured

tenders notice of the lawsuit is O'Brien Family Trust v. Glen Falls Ins. Co., 218 Ga. App. 379, 461 S.E.2d 311 (1995). In that case, an insured trust, without notifying the insurer, began to defend a lawsuit with its own counsel and at its own expense. After approximately four years, the trust gave the insurer written notice of the lawsuit and the insurer, without reserving its rights, opted to take over the suit and guickly settled it. The trust then sought to recover from the insurer the legal expenses it had incurred over the previous four years. The Georgia Court of Appeals noted that the insurance policy at issue required the trust to give the insurer written notice of a claim as soon as possible and immediately to forward to the insurer any papers filed in any lawsuit against the trust. Id. at 380, 461 S.E.2d at 313. The policy, however, was silent on the issue of pre-tender legal expenses. Id. at 380-81, 461 S.E.2d at 313. The court held that the policy did not permit the trust to recover its expenses from the insurer, explaining that:

Such a construction would render contractual terms necessary to trigger . . . [the insurer's] performance under the policy meaningless.

<u>Id.</u> at 381, 461 S.E.2d at 313.

Wausau's CGL and CUL policies contain language similar to the policy at issue in <u>O'Brien</u> in all salient respects. The policy is silent on the issue of pre-tender expenses but includes terms that require the insured to provide notice of potential claims "as soon as practicable" and to forward all papers connected with lawsuits "immediately." Elan argues that bad facts make bad law and valiantly attempts to distinguish <u>O'Brien</u> on the facts. The <u>O'Brien</u> court, however, did not rest its ruling on the admittedly extreme facts

<sup>18</sup> The CGL provides:

b. If a claim is made or "suit" is brought against any insured, you must:

<sup>(2)</sup> Notify us as soon as practicable.

You must see to it that we receive written notice of the claim or "suit" as soon as practicable.

c. You and any other involved insured must:

<sup>(1)</sup> Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the claim or "suit" . . . . CGL § IV(2).

before it, but rather announced a rule of general applicability. <sup>19</sup> Regardless of whether the <u>O'Brien</u> opinion might be criticized as bad law, as a federal court sitting in diversity, the district court had no choice but to apply it. <u>See Erie R.R. Co. v. Tompkins</u>, 304 U.S. 64, 58 S. Ct. 817, 82 L. Ed. 1188 (1938). Applying that rule to this case, we hold that EPRC did not trigger Wausau's duty to defend until it tendered notice of the Pfizer lawsuit on September 11, 1992 and that, as a result, Wausau is not liable for the litigation expenses Elan incurred before that date.

Our holding above that Wausau subsequently breached its duty to defend cannot serve to expand the scope of Wausau's liability.

See Colonial Oil Indus. v. Underwriters, 268 Ga. 561, 563, 491

S.E.2d 337, 339 (1997) ("when the insurer breaches the contract by

The unusual facts before the O'Brien court may account for the fact that no other court appears to have applied the rule announced in that case. In most cases where the insured fails to tender notice in a reasonable time the insurer will assert the late notification defense and avoid liability entirely. See e.g., Canadyne-Georgia Corp. v. Continental Ins. Co., 999 F.2d 1547 (11th Cir. 1993) (affirming summary judgment in insurer's favor on similar facts). It is only in cases such as the one sub judice, in which the insured's tender of notice is presumably not so late as to avoid the insurer's duty to defend, that the issue arises.

wrongfully refusing to provide a defense, the insured is entitled to receive only what it is owed under the contract—the cost of the defense."). Although the insurer in the O'Brien case honored its duty to defend without reservation despite the four year delay, there is no indication that the court based its ruling on that fact. The O'Brien court's legal decision that the provision of notice to the insurer triggers the duty to defend compels our conclusion that the obligation does not include expenses incurred before that notification. We affirm the district court's partial grant of summary judgment on this issue.

### III Wausau's Liability for Elan Plc's Defense Costs

Finally, we address the district court's ruling that Wausau is not liable for the costs of defending Plc in the Pfizer litigation. As noted above, EPRC purchased the CGL and CUL policies at issue in this case. An endorsement to the policies, however, includes coverage for EPRC's shareholders, as additional insureds, but only to the

extent of their liability as stockholders. The parties agree that Plc, as EPRC's sole shareholder, is an "additional insured" under the policies. The only question before us, then, is whether Pfizer's complaint sought damages from Plc by virtue of its status as a stockholder of EPRC.

Although Georgia's courts do not appear to have interpreted the precise coverage limitation at issue here, the parties have advanced persuasive authority on the point. In CertainTeed Corp. v. Federal Ins. Co., 913 F. Supp. 351, 354 (E.D. Pa. 1995), for example, a district court applying Pennsylvania and Minnesota law considered a parent company's claim for coverage under its subsidiary's insurance policy that contained the following language: "Your stockholders are also insureds but only with respect to their liability as stockholders." Although the court held that the parent company did not qualify as a stockholder under the facts of the case, the court also explained that the policy did not cover claims asserting liability based on the stockholder's conduct, either alone

or in concert with the insured. <u>Id.</u> at 357. Instead, the court explained that: "The policy language reflects coverage for a stockholder when its status as a stockholder–not its own conduct–makes it liable for conduct of the named insured." <u>Id.</u><sup>20</sup>

Although Pfizer's complaint did assert that EPRC is a whollyowned subsidiary of Plc, neither the complaint nor the facts supporting it laid out a claim that Plc's status as EPRC's sole stockholder was a basis for liability. Instead, the complaint alleged that EPRC or Plc engaged in conduct that infringed Pfizer's patent.

Although we have found no controlling Georgia authority on this question, the Georgia Supreme Court has strictly applied coverage limitations based on the insured's particular role under See Shelby Ins. Co. v. Ford, 265 Ga. 232, 454 corporate law. In Shelby, the insured had purchased a policy S.E.2d 464 (1995). that covered her individual liability "only with respect to the conduct of a business of which you are the sole owner." Id. at 232, 454 S.E.2d at 465. The insured was the sole owner of a corporation that ran a child-care business. When a child, injured on the premises of the child-care center, sued the corporation and the individual insured, the court deferred to the corporate form and held that the insurer owed neither the corporation nor the individual a defense. The court explained that the corporation was not a named insured under the policy and that because the corporation, not the individual insured, conducted the child-care business, the insurance policy did not cover liability that the individual incurred while employed in that business. Id. at 233-34, 454 S.E.2d at 465-66. The court, relying on Georgia corporate law and the precise language of the insurance policy, ignored the plain reality that the individual insured owned and operated both the corporation and the child-care business and, therefore, denied coverage.

As in the <u>CertainTeed</u> case described above, there is no allegation that Plc is liable for damages to Pfizer because of an alter ego relationship with EPRC or because of its status as EPRC's sole-shareholder.<sup>21</sup> As a result, we agree with the district court's conclusion that the costs of defending Elan, Plc in the Pfizer suit fall outside the coverage of Wausau's policies.

#### CONCLUSION

Elan asks us to reverse the district court's order of August 8, 1996, limiting Wausau's liability to the cost of defending EPRC in the Pfizer suit after September 11, 1992. Wausau asks us to reverse the district court's August 28, 1995 order finding that Wausau owed

Elan argues that Pfizer did assert a theory of alter ego liability against Plc as part of its arguments in support of the district court's personal jurisdiction over Plc, an Irish corporation. We need only note that Wausau's policies do not provide coverage for EPRC's stockholders to the extent that a plaintiff may establish jurisdiction in a particular forum by virtue of the shareholder relationship. The contract language clearly limits coverage to suits alleging that the stockholder's liability arises out of the relationship. Our review of Pfizer's arguments during this portion of the litigation reveals that, contrary to Elan's assertions, Pfizer made no argument that Plc's liability depended upon the shareholder relationship. Accordingly, we find Elan's argument on this point to be without merit.

Elan a duty to defend the Pfizer lawsuit. After comparing the language of Wausau's CGL and CUL policies to Pfizer's allegations against Elan, and examining the facts underlying Pfizer's complaint, we conclude that Wausau did owe a duty to defend EPRC against the lawsuit. We hold that Pfizer's allegations of patent infringement through the commercialization of clinical studies regarding Nifelan fell within the "advertising injury" coverage in the policies. We hold, however, that EPRC did not trigger Wausau's duty to defend until it tendered notice to Wausau on September 11, 1992, and that, as a result, Wausau is only liable for the costs of defending the lawsuit after that date. Finally, we hold that Wausau did not owe a duty to defend Plc in Pfizer's lawsuit because the complaint made no claim of shareholder liability against Plc. We AFFIRM the district court as to both its 1995 order granting summary judgment in EPRC's favor and its 1996 order granting partial summary judgment in Wausau's favor.