Riegel v. Medtronic – U.S. Supreme Court Expands Pre-Emption Defense in Medical Device Context

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In Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008), the United States Supreme Court held that the pre-emption clause contained in the Medical Device Amendments (21 U.S.C. Section 360, et seq.) to the Food, Drug, and Cosmetic Act (21 U.S.C. Section 301, et seq.) bars common-law claims challenging the safety of a medical device that was granted premarket approval by the Food and Drug Administration (FDA). The following is an analysis of the Supreme Court’s decision.

Background

Plaintiff Charles Riegel sustained injuries when an Evergreen balloon catheter marketed by the defendant, Medtronic, Inc., ruptured while his doctor inserted it into his coronary artery. 128 S.Ct. at 1005. Thereafter, Riegel and his wife commenced an action in the United States District Court for the Northern District of New York to recover damages. They alleged claims premised upon negligence, strict liability and breach of warranty theories. Id. The District Court dismissed their action on the ground that the Medical Device Amendments (MDA) pre-empted the Riegels’ claims. Id., at 1005-06. The United States Court of Appeals for the Second Circuit affirmed. Id., at 1006.

Regulation of Medical Devices Under the MDA

The MDA established three levels of oversight for medical devices depending upon the risks that they present. Class I devices, which include, among other things, elastic bandages, are subject to the lowest level of oversight. Class II devices, which include items such as powered wheelchairs, are subject to additional “special controls.” Id., at 1003. Class III devices, which include the catheter at issue in Riegel, receive the most federal oversight. Id.

New Class III devices must undergo a “rigorous regime of premarket approval.” Id., at 1004. Moreover, once a device has received premarket approval, Section 360e(d)(6)(A)(i) of the MDA forbids the manufacturer to make, without FDA permission, changes in the design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. Id., at 1005. Lastly, after the FDA grants premarket approval, the device remains subject to reporting requirements. Id. For example, pursuant to 21 CFR Section 814.84(b)(2), the FDA must be informed of new clinical investigations or scientific studies concerning the device that the applicant is aware of or reasonably should be aware of, and it must report incidents in which the device may have caused or contributed to death or serious injury.
Unlike the rigorous premarket approval process pursuant to which new Class III devices are subject, existing Class III devices can receive “grandfathered” approval. For example, pursuant to 21 USC Section 360c(f)(1)(A), devices sold before the MDA’s effective date may remain on the market until the FDA issues a regulation requiring premarket approval. Moreover, even “[a] new device need not undergo premarket approval if the FDA finds it is ‘substantially equivalent’ to another device exempt from premarket ap-

The FDA must be informed of new clinical investigations or scientific studies concerning the device that the applicant is aware of or reasonably should be aware of, and it must report incidents in which the device may have caused or contributed to death or serious injury.” Id., at 1004 (citing 21 U.S.C. § 360(c)(f)(1)(A)). The FDA’s review of devices for substantial equivalence is known as the Section 510(k) process, which refers to the section of the MDA describing the review. Id.

Pre-Emption Under the MDA
Section 360(k) of the MDA includes a pre-emption provi-
sion which states:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any re-
quirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.


The Supreme Court’s Analysis
The Supreme Court’s analysis addressed the following, two questions:

1) whether the federal government established require-
ments applicable to Medtronic’s catheter; and if so,

2) whether the plaintiffs’ common-law claims are based upon New York requirements with respect to the catheter that are “different from, or in addition to,” the federal ones and that relate to safety and effectiveness.

Id., at 1006.

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Holland & Knight lawyers are available to make presentations on a wide variety of product liability law issues.
The effect of the Supreme Court’s decision could be ephemeral, as certain members of Congress have suggested that they might seek legislation which nullifies Riegel.

Whether the Federal Government Established “Requirements” That Apply to the Catheter

The Supreme Court answered the first question in the affirmative. It specifically concluded that the rigorous premarket approval process is “specific to individual devices.” Id., at 1007. The Court contrasted a device, such as the catheter, which undergoes premarket approval, to a device, the approval of which is grandfathered, as was the case in Medtronic v. Lohr, 116 S.Ct. 2240 (1996). In Lohr, the Court found that the grandfathered approval process did not impose device-specific “requirements.” Riegel, 128 S. Ct. at 1007 (citing Medtronic v. Lohr, 126 S.Ct. at 2240). The Court noted:

[Pre]market approval is specific to individual devices. And it is in no sense an exemption from federal safety review – it is federal safety review. Thus, the attributes that Lohr found lacking in § 510(k) review are present here [i.e., in the case of a device which undergoes premarket approval] .... While devices that enter the market through § 510(k) have never been formally reviewed under the MDA for safety or efficacy, the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness.

Id. (internal citations omitted) (emphasis in the original).

Whether Plaintiffs’ Common-Law Claims Rely Upon Any “Requirements” That Are “Different From, or In Addition to” Federal Requirements and That “Relate[] to the Safety or Effectiveness” of the Catheter

The Court commenced its analysis of the second question by noting that “safety and effectiveness are the very subjects of the Riegels’ common-law claims,” and therefore, it focused its remaining inquiry on whether New York tort law constitutes “requirements” under the MDA. Id. Based upon prior Supreme Court precedent, the Court concluded that the plaintiffs’ claims, premised upon state common-law, constituted “requirements.” For example, the Court noted: “In Lohr, five Justices concluded that common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device.” Id. The Court’s decision noted similar holdings in Bates v. Dow Agrosciences LLC, 544 U.S. 431, 443 (2005) (common-law actions were pre-empted by the Federal Insecticide, Fungicide, and Rodenticide Act) and in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 523 (1992) (common-law actions were pre-empted by a provision of the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. Section 1334(b). Lastly, the Court noted that “excluding common-law duties from the scope of pre-emption would make little sense.” Id., at 1008.

Based on this analysis, the Riegel Court affirmed the dismissal of the plaintiffs’ complaint.

Conclusion

The Supreme Court’s decision in Riegel may act to deter the plaintiffs’ lawyers from filing claims involving devices that received premarket approval. However, the effect of the Court’s decision could be ephemeral, as certain members of Congress have suggested that they might seek legislation which nullifies Riegel. For example, Senator Edward Kennedy, who was the sole Senate sponsor of the MDA, responded to Riegel by noting: “In enacting legislation on medical devices, Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices .... Congress obviously needs to correct the court’s decision. Otherwise, FDA approval will become a green light for shoddy practices by manufacturers.” Linda Greenhouse, “U.S. Supreme Court Makes it Harder to Sue Makers of Medical Devices,” International Herald Tribune, Feb. 21, 2008 at 1. Similarly, U.S. Representative Henry Waxman, who was on the Congressional panel that approved the MDA in 1976, stated: “This isn’t what Congress intended and we’ll pass legislation as quickly as possible to fix this nonsensical situation.” Id.

Given the foregoing, the long-term impact of the Supreme Court’s decision is unclear.

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Plaintiffs often seek to expand the scope of admissible evidence far beyond that necessary to prove the elements of their case. They do so because proving the elements of a product liability claim can sometimes be more difficult than attempting to score jury points with evidence of retrofits, recalls, prior lawsuits, customer complaints and former employee expert testimony — evidence that is often more prejudicial than probative. Plaintiffs also use this type of evidence to pressure defendants, who prefer to avoid the public airing of dirty laundry and risk of negative media exposure, into settlement. Defendants must aggressively respond to these tactics. They can do so with motions in limine, Daubert motions or other motions challenging expert testimony and focused objections. And they can now use the recent Eighth Circuit decision in Ahlberg v. Chrysler Corp., 481 F.3d 630 (8th Cir. 2007), for support.

The facts of Ahlberg, a wrongful death action, deserve attention. After leaving a 28-month-old child in a 1999 Dodge Ram pickup truck with the engine running, the decedent was killed while trying to stop the truck from rolling downhill. Allegedly the boy was able to shift the gear out of park and into reverse. The estate and survivors sued Chrysler — the vehicle’s manufacturer — and alleged all of the typical product liability claims. But the crux of the claims was that the failure to equip the truck with a brake-shift interlock (BSI) device — either originally or through a retrofit program — was negligent. A BSI device requires the driver to step on the brake before shifting out of park to prevent accidental acceleration. The plaintiffs attempted to use evidence of retrofits, recalls, prior lawsuits, customer complaints and a former employee expert to prove their claims. The trial judge, however, excluded all of this evidence. The jury subsequently returned a verdict for Chrysler on all counts. On appeal, the Eighth Circuit affirmed.

Exclusion of Evidence of Retrofits, Recalls, Prior Lawsuits and Complaints

Two Federal Rules of Evidence serve as the gatekeepers against the entry of certain types of evidence. Rule 401 defines “relevant evidence” as evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” And, even if evidence is relevant, it may be excluded pursuant to Rule 403 “if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” Importantly, the application of these rules rests squarely within the trial court’s discretion, which will not be reversed absent a clear and prejudicial abuse of discretion. Id. at 632. And the analysis is fact intensive. Accordingly, it is crucial to win evidentiary battles before the trial judge because reversing an evidentiary ruling on appeal is very difficult (of course, as demonstrated in Ahlberg, it will be equally difficult for a plaintiff to challenge the exclusion of evidence.)

Exclusion of Retrofit Evidence

The plaintiffs in Ahlberg sought to admit evidence of retrofits performed by Chrysler on Jeep Cherokees in 1996 — even though their case involved a 1999 Dodge Ram pickup truck. The plaintiffs argued the retrofit evidence was admissible to prove numerous purported points, including notice, concealment, negligent design, dangerous condition and failure to warn. But the trial court excluded the retrofit evidence. It did so primarily because the evidence involved an entirely different vehicle. Moreover, the retrofit evidence was not relevant to prove feasibility of the retrofit, since Chrysler stipulated to feasibility. Thus, the retrofit evidence had limited probative value that was substantially outweighed by
the danger of unfairly prejudicing, confusing and misleading the jury. Accordingly, for this type of retrofit evidence to potentially be admissible it must concern the same or substantially similar model as the product at issue or be used to prove some other relevant element, like feasibility. To exclude this type evidence, consider limiting the issues through stipulation. By stipulating to a relatively innocuous fact (i.e., feasibility), potentially devastating evidence can be excluded. Notably, “retrofit” was used interchangeably with “recalls” in this case, so the same analysis should apply to recall evidence.

**Prior Lawsuits and Customer Complaints**
The plaintiffs also attempted to use evidence of prior lawsuits and customer complaints concerning accidents involving Chrysler vehicles that lacked BSI devices. The evidence was properly excluded because no showing of substantial similarity was made. Notably, the trial judge determined that for any prior accident to be substantially similar it had to involve (1) a Jeep or Dodge truck with an automatic transmission manufactured between 1990 and 1999, (2) with a key left in the ignition, and (3) a child under age four. This standard was affirmed.

**It is crucial to win evidentiary battles before the trial judge because reversing an evidentiary ruling on appeal is very difficult (of course, as demonstrated in Ahlberg, it will be equally difficult for a plaintiff to challenge the exclusion of evidence.)**

A party may offer evidence of prior accidents to show notice, causation, feasibility of correction, or magnitude of danger if a showing of substantial similarity is made. See, *Drabik v. Stanley-Bostitch*, 997 F.2d 496, 508 (8th Cir.1993). Even though the plaintiffs argued that the trial judge’s substantial similarity standard was too restrictive, the Eighth Circuit noted that it was broader than the standard used in other cases, because it permitted the introduction of accidents involving different trucks (by allowing Jeeps as well as Dodge trucks).

Examples of more restrictive substantial-similarity standards can be found in *Lovett v. Union Pacific Railroad*, 201 F.3d 1074 (8th Cir.2000), and *Lewy v. Remington Arms*, 836 F.2d 1104 (8th Cir.1988).

**• In Lovett, a train collided with a 1985 Jeep Cherokee at a railroad crossing, and the substantial similarity test applied there required that evidence of other accidents (1) involve a 1985 Cherokee, (2) in a collision with a locomotive, (3) at a railroad crossing, (4) resulting in the Cherokee rolling over, (5) in a similar topographical area, and (6) at similar speeds to satisfy the substantial similarity requirement.**

**• In Lewy, the Eighth Circuit reversed the trial court’s admission of prior accident evidence, because the other accidents did not involve the same model rifle as that at issue. Arguably, an equally narrow substantial similarity standard should be used when analyzing the admissibility of prior accident and complaint evidence.**

**Potential Discovery Application**
Discovery is limited to material relevant to any claim or defense and must be reasonably calculated to lead to the discovery of admissible evidence. Fed.R.Civ.P. 26(b)(1). Plaintiffs often seek discovery concerning retrofits/recalls, prior accidents and complaints. The *Ahlberg* decision can be used as persuasive authority to protect against discovery of these matters unless the requesting party can show that this evidence could reasonably be admissible at trial. This requires a showing of substantial similarity, which must be narrowly tailored. Furthermore, strategic stipulations should be considered – like stipulating to feasibility – which may render otherwise admissible evidence irrelevant.

**Exclusion of Former Employee “Expert” Testimony**
Federal Rule of Evidence 702 governs experts and provides that “a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” The factors to consider when making a determination under Rule 702 are whether the expert’s theory or technique (a) can be and has been tested, (b) has been subjected to peer review and publication, (c) has a known or potential rate of error, and (d) has gained general acceptance in the relevant community. *Daubert*, 509 U.S. at 592-93.

A common tactic was attempted by the plaintiffs in *Ahlberg* – the plaintiffs tried to use a former Chrysler employee as an expert. The plaintiffs had described the former employee “expert” as an engineer – despite the fact that he had no degree in engineering – because he had worked with and managed engineers and was familiar with technical issues. His purported “expertise” was in the management of safety
issues at Chrysler. And he claimed to have personally retrofitted Chrysler vehicles with BSI devices that he made himself. To bolster their expert, the plaintiffs asserted that the BSI device was not complicated and the only necessary qualification was to understand how it worked and the risk involved to a vehicle without one. The trial court, however, rejected the plaintiffs' attempts.

After a hearing, the expert was excluded, because the expert used no appreciable methodology as required by Daubert and its progeny. Moreover, the purported “peer review” conducted by the expert’s former coworkers was held to be insufficient. Otherwise, the court noted, any employee could arguably be considered an expert based on the fact that he worked with others. The plaintiffs argued that their expert’s opinions were generally accepted in the community, but this was unpersuasive to the court, because a particular methodology is required and not mere reliance on general engineering principles.

Therefore, prior employment within an industry alone is insufficient to qualify an individual as an expert. The expert must have sufficient education and practical experience to back up his claimed expertise. The expert must also utilize reliable methodology and techniques and outside peer review of that methodology is required. When a former employee is offered as an expert, a red flag is raised and the expert’s qualifications should be particularly scrutinized. And when a proposed expert’s sole qualification is his prior employment, a motion challenging the testimony should always be considered.

By broadly discovering and seeking to admit at trial information on retrofits/recalls, prior lawsuits, complaints and the testimony of defendants’ former employees as experts, plaintiffs raise the cost of litigation and seek to pressure defendants into settlement. To respond, defendants should, when appropriate, stipulate to certain undisputed facts and also seek to limit discovery of this prejudicial information and aggressively object to its use at trial. Ahlberg can be used as an important tool to do so.

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2 The plaintiffs’ complaint alleged causes of action for negligent design, manufacture, inspection, testing and distribution; failure to warn, both before and after the sale; fraudulent concealment of the dangerous defects; and sale in an unreasonably dangerous condition.
3 Note that customer complaints are also properly excluded as hearsay.

Federal Court Rejects “Expert for Hire”

Matt F. Singer

Most attorneys are familiar with the four-factor Daubert test for the admissibility of expert testimony. A recent U.S. District Court opinion, however, appears to have added a fifth factor aimed at ferreting out the “expert for hire.” In Hayes v. MTD Products, Inc., 518 F. Supp. 2d 898 (W.D. Ky. 2007), the District Court for the Western District of Kentucky conducted the following analysis in ruling on a defense motion seeking to bar the testimony of an expert for the plaintiffs:

…[W]hether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying because the former provides important, objective proof that the research comports with the dictates of good science.
Hayes, 518 F. Supp. at 899-900. Partially based upon an analysis of this fifth factor, first identified in *Smelser v. Norfolk South Railroad Co.*, 105 F.3d 299, 303 (6th Cir.1997), the court excluded plaintiffs’ expert. *Id.*

**While no federal court opinion ruling on a Daubert motion has yet cited Hayes, attorneys are wise to consider its implications.**

**Expert Witnesses Are Not Always Unbiased**

George Hayes died when a lawn mower he was riding rolled over and crushed him. *Id.* at 899. The plaintiffs filed a product liability suit against MTD Products, the manufacturer of the lawn mower. *Id.* They retained Stuart M. Statler, a former commissioner for the Consumer Product Safety Commission (CPSC), as an expert. *Id.* Statler opined that the lawn mower manufactured by MTD was defective since it did not include a rollover protection system/structure, which he claimed would have prevented Hayes’ death. *Id.* In turn, MTD filed a Daubert motion to exclude Statler’s testimony. *Id.*

Initially, the trial court conducted a traditional *Daubert* analysis, focusing on the four standard factors:

1. whether the expert’s theory can and has been tested; 2. whether the theory or technique has been subjected to peer review and publication; 3. the known or potential rate of error and the existence and maintenance of standards controlling the technique’s operations; and 4. the extent to which a known technique or theory has gained general acceptance within a relevant scientific community.

*Id.* The court noted that Statler’s testimony failed to satisfy some of these factors. Specifically, he did not conduct any independent testing of rollover protection systems for lawn mowers, nor did he subject his theories to peer review. *Id.* at 900. Both of these factors, the court noted, suggested excluding Statler. *Id.*

However, rather than ending its analysis there, the trial court expressed concern that “expert witnesses are not ... always unbiased scientists because they are paid by one side for their testimony.” *Id.* (citations omitted). The court further elaborated that, where proposed expert testimony fails to flow “naturally from an expert’s line of scientific research or technical work,” but instead was “prepared solely for ... purposes of litigation,” it should be viewed with caution. *Id.* (citations omitted). In such situations, when an expert resembles the “quintessential expert for hire,” the expert must have some “extensive familiarity” with the product in question. *Id.* at 901. (citations omitted).

**“Expert” Experience Should Be Specific**

Statler had years of experience gained from consulting work and employment with the CPSC. *Id.* at 901. But this experience, indeed his entire “expertise,” was general, rather than specific to the product in question. Plaintiffs failed to provide proof that Statler was an expert in riding lawn mower safety or rollover protection systems. *Id.* Instead, Statler readily admitted to being an expert only in “consumer product safety generally, manufacturer and seller responsibility, and the consideration of dangerous products by the CPSC.” *Id.* Because he did not have experience specific to the product in general and because of his deficiencies under the more traditional *Daubert* analysis, the trial court excluded Statler’s testimony.

In the wake of Hayes, attorneys must be more vigilante than ever in selecting an expert. While no federal court opinion ruling on a Daubert motion has yet cited Hayes, attorneys are wise to consider its implications. Attorneys should not presume that because a proposed expert worked for a company or governmental agency that deals with a type of product generally, that expert would satisfy *Daubert*. If a proposed expert’s experience is only general, and she or he does not have experience specific to the product in question, that expert may be susceptible to exclusion.

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2. The CPSC is a federal agency that works to ensure the safety of consumer products such as toys, cribs, power tools, cigarette lighters and household chemicals. [http://www.cpsc.gov/about/about.html](http://www.cpsc.gov/about/about.html)
New York Federal Court Rejects Product Liability Insurance Claim Made Against a General Liability Policy

Summer Sylva

The United States District Court for the Southern District of New York, applying the law of the state of New Hampshire, recently denied plaintiff Tradin Organics USA, Inc. (Tradin), an organic food distributor, recovery on a product liability claim filed with its insurer, defendant Maryland Casualty Company (Maryland), under a policy which provided commercial general liability coverage. Tradin Organics USA Inc. v. Maryland Cas. Co., 2008 WL 241081 (S.D.N.Y. 2008). The court held that a “your product” policy exclusion “unambiguously preclude[d] coverage for losses caused by contaminated or defective product[s] sold by the insured” – a view, according to the Tradin court, endorsed by numerous courts in various jurisdictions, including New York.

Policy Exclusions Are Key

Tradin filed suit after Maryland rejected its claim to recover settlement costs it incurred as a result of the Canadian government’s recall of Tradin’s contaminated food product, raspberry crumble. Crofters Food Ltd., a Canadian-based company, had contracted with Tradin for the purchase of a large quantity of raspberry crumble. Tradin’s subcontractor, a Serbian company, produced and shipped the contaminated product directly to Crofters. After agreeing to compensate Crofters for the contaminated product, Tradin filed a claim for reimbursement under the commercial general liability policy issued to it by Maryland. Issued to Tradin, a New Hampshire corporation, through a New Hampshire-based insurance broker, the policy contained no choice of law provision and numerous coverage exclusions.

The policy covered Tradin for “those sums that Tradin [became] legally obligated to pay as damages because of … ‘property damage’ to which this insurance apply[ed],” but excluded coverage for damages due to “your product” and damages caused by “your work.” The policy defined “your product” as “any goods or products … manufactured, sold, handled, distributed or disposed of by” Tradin. The “your work” provision excluded from coverage any work or operations performed by Tradin or on Tradin’s behalf as well as “materials, parts or equipment furnished in connection with such work or operations.” This latter exclusion did not apply, however, “if the damaged work or the work out of which the damage [arose]” was performed on Tradin’s behalf by a subcontractor.

Maryland denied coverage based on the “your product” exclusion. Tradin, arguing that it was entitled to coverage because the “your work” exclusion did not apply, filed suit to recover settlement costs under a breach of contract claim. Tradin also sought treble damages on the theory that Maryland’s coverage denial was made in bad faith. Both parties moved for summary judgment, which the court stated could be granted if the wording of the policy “convey[ed] a definite and precise meaning absent any ambiguity.” Seiden Assocs., Inc. v. ANC Holdings, Inc., 959 F.2d 425, 428 (2d Cir. 1992).

Because federal jurisdiction was based on diversity, the court applied the choice of law rules of New York, the forum state. White v. ABCO Eng’g. Corp., 221 F.3d 293, 201 (2d Cir. 2000). Various factors deemed relevant by New York courts in resolving insurance contract disputes were important considerations in the court’s analysis and included: (1) the place the contract was negotiated, signed and issued; (2) the place of performance; (3) the location of the contract’s subject matter; (4) the parties’ domicile, residence, nationality, place of incorporation and place of business; (5) the location of the insured risk; (6) the location of the insurance broker; and (7) the location where premiums would be paid. Based upon these factors, the court concluded that New Hampshire’s substantive law governed the policy, acknowledging New Hampshire’s significant role as the state

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in which Tradin was incorporated and maintained its only place of business, the location of the agent to whom Tradin's insurance policy was issued and delivered, and the only state from which Tradin could have paid its premiums. Contributing to this conclusion, even if only by default, was the policy's omission of a choice-of-law provision.

Subcontractor Exclusions to “Your Product” and “Your Work”
Notwithstanding its willingness to apply New Hampshire law, the court acknowledged that New Hampshire had yet to specifically interpret “your work” and “your product” coverage exclusions. Branded an “unsettled area” of New Hampshire law, the court presumed, as is permitted, that New Hampshire’s law likely resembled the law of New York. Rogers v. Grimaldi, 875 F.2d 994, 1003 (2d Cir. 1989).
Augmenting this presumption with an examination of New Hampshire’s contract law in construing insurance policies generally, as well as relevant decisions of other state courts, the New York court concluded that various jurisdictions, including New York, “have held that similarly defined ‘your product’ exclusions unambiguously preclude coverage for losses caused by a contaminated or defective product sold by the insured.”

Here, the court stated, there was no dispute that Tradin’s tainted product was contaminated and defective, nor was there any question that Tradin had sold that product to Crofters – conduct satisfying the express language of the “your product” coverage exclusion. The district court rejected Tradin’s argument that it was entitled to coverage because the order and delivery of the defective product by Tradin’s subcontractor satisfied the subcontractor exception to the “your work” exclusion, concluding that the policy “unambiguously allow[ed] [Maryland] to deny coverage if any one” of the policy’s coverage exclusions applied. With the court’s grant of Maryland’s summary judgment motion, Tradin’s breach of contract action was dismissed and the bad faith tort on which it hinged was eliminated. Lawton v. Great Southwest Fire Ins. Co., 118 N.H. 607, 613 (N.H. 1978).

With this decision the New York federal court concluded that under New Hampshire law, a similarly worded “your product” exclusion is a general commercial liability policy precludes coverage for losses caused by contaminated or defective products sold by the insured. Companies that manufacture and/or sell “products” are advised to have separate product liability coverage.

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