Products Liability NEWSLETTER

OSB Products Liability Section

A section newsletter of the Oregon State Bar

Fall 2012 Volume XX, Number 1

TABLE OF CONTENTS

Notes from the Chair

Deanna Wray, Bodyfelt Mount

Fall CLE – October 5, 2012

This year the Products Liability Section is joining forces with the Litigation and Aviation Sections to present "Oregon Trial Practice: Emerging Trends and Multi-Jurisdictional Disputes."

The program features national and local attorneys and judges, tackling Spoliation, Jurisdiction, Conflicts of Law, Admissibility of Government Reports, and MDL Proceedings. Mark your calendars now for October 5, at the Hotel Monaco in downtown Portland. The CLE starts off with a light lunch and socializing at noon and ends at 3:30 pm.

In this Issue

Last year we published an article by Andrew Lee on the "unavoidably unsafe" and "learned intermediary" defenses in pharmaceutical cases: Comment k – Implications and Applications. Travis Eiva now shares a contrary view on the scope and application of Comment k, along with counterpoints to the defense perspective.

In this issue, we also highlight two interesting products cases. The first a jury verdict for plaintiffs in a Multnomah County trial involving blueberry fertilizer, the second a landmark ruling from the Supreme Court on a state's jurisdiction over a British manufacturer.

The Newsletter depends on volunteers to author or submit articles of interest to our section. If you have an idea, or if you run across something you think others would want to read, let us hear from you.

Electronic Versus Paper – Which Do You Prefer?

Some sections of the Bar have switched to circulation of the section's newsletter via e-mail only. Perhaps the paper newsletter has become novel, and you don't want one more e-mail clogging up your inbox. That's my take, but what is yours? If you think the Products Liability Newsletter should move to electronic publication, or not, send me an e-mail (wray@bodyfeltmount.com). The Executive Committee will consider the issue and make a decision before the next Newsletter is published.

Supreme Court Limits State's Jurisdiction Over Foreign Defendants

Patrick Angel is an attorney at the law firm of Angel Law PC in Portland, Oregon. Patrick practices with a focus on injury litigation, including defective medical devices and other product liability claims. Patrick is a member of the American Association for Justice, the Oregon Trial Lawyers Association and sits on the executive committee of the Oregon State Bar Products Liability Section.

Last summer the Supreme Court issued its decision in *J. McIntyre Machinery, Ltd. v. Nicastro* which shifted the direction of the law in the United States regarding a state's jurisdiction over non-resident or foreign companies. In short, the *Nicastro* decision seems to swing the pendulum back, in favor of defendant product manufacturers over consumers injured by product defects.

Robert Nicastro severely injured his hand at work on a machine manufactured by J. McIntyre Machinery, a British company. Nicastro subsequently filed a lawsuit in the state of New Jersey alleging the product was unreasonably dangerous as designed. J. McIntyre argued in return that the state court of New Jersey lacked jurisdiction over it because it was a foreign company and it had no facilities in New Jersey, paid no New Jersey taxes, did not advertise in New Jersey and had no employees in the state. The Supreme Court of New Jersey ruled that New Jersey courts *did* have the power to adjudicate J. McIntyre's legal obligations and liabilities since the minimum contacts test in *Asahi*[1] had been satisfied. New Jersey's highest court concluded that since J. McIntyre had hired a U.S. distributor that had sold the product to a New Jersey company, J. McIntyre knew or should have known that it's products were being distributed nationwide and might reach any of the fifty states.

The Supreme Court of the United States reviewed the decision of New Jersey's highest court and reversed that ruling, holding 6 to 3 that J. McIntyre had not "purposely availed" itself of doing business in New Jersey because they had not intentionally placed products specifically into New Jersey's stream of commerce with the expectation that they would be purchased by consumers within the jurisdiction. Justice Kennedy who wrote the plurality opinion argued that J. McIntyre had not purposely availed itself of the privileges of doing business in New Jersey because there was no evidence that it had advertised in New Jersey, shipped goods there or otherwise targeted the state. Justice Kennedy concluded that defendant had not "manifested an intent" to submit to the power of a sovereign, writing, "it is not enough that the defendant might have predicted that its goods will reach the forum State."[2]

The Due Process Clause requires that before a state may exercise personal jurisdiction, a nonresident or foreign defendant must have sufficient "minimum contacts" with the forum state. Historically, the minimum contacts requirement ensured that a state did not overreach its authority "as [a] co-equal sovereign in a federal system."[3] However, with the expansion of commerce and markets by the end of the twentieth century, considerations of sovereignty seemed to give way to a "reasonable and fairness" analysis which seemed to favor resident claimants when determining questions of a state's personal jurisdiction over foreign defendants.

In 1987 the Supreme Court considered in *Asahi Metal Industry Co. v. Superior Court*[4] whether placing a product into the stream of commerce was sufficient in and of itself to satisfy the minimum contacts requirement triggering a state's personal jurisdiction over a non-resident defendant. In *Asahi*, the Court expanded the state's jurisdictional authority in a unanimous decision, but generated two concurring and but competing opinions. Justice O'Connor writing for four justices and advancing a "stream of commerce plus" theory, would have held that a manufacturer had to do something more than merely placing a product into the stream of commerce to trigger minimum contacts with a forum state. Justice Brennan wrote a concurring opinion for four other Justices which would have held that placing a product into the stream of commerce was enough by itself as long as the manufacturer was aware that the product may be purchased in the forum state.

In *Nicastro*, the injury occurred in New Jersey to a New Jersey resident. J. McIntyre had hired a U.S. distributor to sell its machinery in the United States, McIntyre's distributor sold and shipped a machine to a New Jersey company, Nicastro's employer, and McIntyre wanted its U.S. distributor to sell machines to anyone in America who wanted to purchase them. Yet the plurality concluded that McIntyre had done nothing significant to specifically target the state of New Jersey and avail itself of its laws and protections. Thus, placing a product in the stream of commerce was not enough without evidence of defendant's intent to purposefully directed its conduct at the State of New Jersey.

As a practical consideration the *Nicastro* decision illustrates a shift that may persuade a plaintiff in future products liability cases against foreign defendants to consider the United States as a better forum if there is any question regarding the defendant's purposefully availing itself of a specific state's laws, protection or markets.

1 *Asahi Metal Industry Co., v. Superior Court*, 480 U.S. 102 (1987).

2 *J. McIntyre Machinery, Ltd., v. Nicastro*, 131 S. Ct. 2780 (2011) at 2787.

3 *Asahi*, 480 U.S. 102 (1987).

4 *Id.*

Jury Rules in Favor of Washington Blueberry Nursery in Defective Fertilizer Products Liability Case

By Patrick Angel

In February of 2012, a Multnomah County jury awarded two plant nursery owners in a products liability suit nearly $40 million to compensate them for the loss of millions of plants killed by what the jury concluded was a defective fertilizer.

Jagjit Aujla and his wife owned and operated J.R.T. Nurseries, which specialized in blueberry plants as well as some ornamental plants including azaleas and rhododendron. The business was thriving for more than 15 years, with an emphasis on selling blueberry plants to regional growers for resale to food chains, when a salesman for the nursery's supplier recommended a new fertilizer called "Multicote 15-9-12."

Aujla had been using Osmocote Plus 15-9-12 manufactured by Scotts, but the salesman for Multicote convinced him that his new fertilizer was the same as Osmocote Plus 15-9-12, and was less expensive.

Aujla applied defendant's Multicote to a portion of the JRT Nurseries' blueberry crop the first year, using Osmocote on the rest. The blueberry plants treated with the Multicote product died or were damaged, while the plants treated with Osmocote survived. Aujla didn't suspect the dead or damaged blueberry plants were the result of Multicote fertilizer because he was grieving over the sudden death of family member. He assumed the problems were the result of his inattention at managing the nursery.

The next year, at the salesman's suggestion, Aujla applied Multicote to all of JRT's Canadian blueberry crop, and to a portion of the U.S. crop. He also applied Multicote to many of his ornamental plants. Again, the plants treated with the Multicote product died or failed to thrive, while those treated with Scotts brand Osmocote did well. JRT Nurseries lost more than 4 million blueberry plants as a result of the defective fertilizer, incurring large debts and lost profits. They also lost the goodwill of many valuable customers, who turned to other suppliers. JRT Nurseries itself struggled to survive as a business as a result of the large scale destruction of its plant inventory and the loss of many customers.

DeZwaan Nurseries, Ltd., another Canadian nursery, also purchased Multicote fertilizer around the same time for use on its crop of Japanese maple trees. DeZwaan experienced a similar result as JRT. DeZwann's trees treated with Multicote died or failed to thrive, while those treated with a different fertilizer thrived. DeZwaan lost about 3,500 trees resulting in significant business losses.

JRT and DeZwaan sued the companies that designed and sold Multicote, Sun Gro Horticulture Distribution, Inc., the Woodburn Fertilizer Company, and the fertilizer's manufacturer, Wilbur-Ellis Co. The plaintiffs alleged that the fertilizer was defective and unreasonably dangerous because its untested formula of ingredients was toxic to nursery plants. Plaintiffs alleged that the manufacturers were negligent in using ingredients to make the fertilizer, which they knew or should have known were not recommended for use with horticulture crops and for failing to test those ingredients to ensure safe use of the product. The plaintiffs asserted in their lawsuit that the defendants negligently mixed an untested blend of ingredients in an attempt to gain market share from their main competitor, Scotts, which sold the Osmocote line of fertilizers.

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Plaintiffs also alleged that the defendants falsely represented that the fertilizer was a controlled-release product and that it was as good as Osmocote. Evidence at trial persuaded the jury that Multicote was not controlled-released.

JRT sought compensation claiming past economic losses of about $19 million and future estimated losses of about $20 million. DeZwaan claimed $251,000 in economic losses.

The defendants denied that Multicote was defective and argued, among other things, that the farmers should have tested Multicote before applying it to such a large number of plants. Defendants also claimed that Aujla was negligent because he reapplied the product for a second year after he knew plants had been damaged the year prior.

The Multnomah County jury found after 22 days of trial that Multicote 15-9-12 was a defective product. The jury further found Multicote was unreasonably dangerous, the defendants were negligent and had breached express warranties, and the fertilizer damaged the plaintiffs' crops. As to the JRT nurseries, the jury allocated fault at 77% to defendant Sun Gro, 13% to Wilbur Ellis, and 10% of the fault to the plaintiff, JRT. As to DeZwaan, the jury allocated fault at 85% to Sun Gro and 15% to Wilbur-Ellis.

The jury awarded approximately $39.57 million to JRT Nurseries, including $12 million for direct economic losses, and $22.5 million for JRT's loss of customers, as well as nearly $5 million interest. DeZwaan recovered $241,060 for their direct economic losses.

Plaintiffs were represented by Lawrence Baron of Portland, Oregon, Robert Udziela of Portland Oregon, and Joseph Prodor of British Columbia, Canada. Defendants were represented by Everett Jack and Bill Earle of Portland, Oregon.

Understanding Comment k through the Lens of Oregon Statutes

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In the Winter 2011 Products Liability Newsletter, Andrew Lee provided a thoughtful discussion about the scope, application, and interplay of the "unavoidably unsafe" and "learned intermediary" defenses in pharmaceutical drug product liability claims. *See* Andrew Lee, *Comment k – Implications and Applications*, Vol XIX-1 OSB Product Liability Newsletter 4, (Winter 2011). This article respectfully disagrees with the suggested scope and application of Comment k and, in turn, highlights Oregon statutory and case authority that may be raised to respond to some of Mr. Lee's points.

Comment k - the Unavoidably Unsafe Defense

Unlike most states, product liability law in Oregon is not left to evolve as common law. Its scope and application is defined by statutes. *See* ORS 30.900 *et seq*. However, the Oregon Legislature expressly imported a limited number of common law concepts into that statutory framework. Specifically, ORS 30.920(3) provides:

> It is the intent of the Legislative Assembly that the rule stated in * * * this section shall be construed in accordance with the Restatement (Second) of Torts sec. 402A, Comments a to m (1965).

The unavoidably unsafe defense highlighted in Mr. Lee's article is one of those imported common law concepts as it derives from Comment k of sec. 402A. That comment describes the defense as follows:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation

> calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

As Mr. Lee points out in his article, Comment k derives from a simple principle:

> Some products are necessary regardless of the risks involved to the user. The alternative would be that a product, essential to sustain the life of some individuals, would not be available – thus resulting in greater harm to the individual than that risked through use of the product.

Lee, XIX-1 OSB Product Liability Newsletter at 4 (quoting the Washington Supreme Court).

Comment k Likely Does Not Provide Blanket Immunity for All FDA-Approved (Prescription) Drugs in Oregon

Mr. Lee's article points to other jurisdictions to suggest that the unavoidably unsafe defense may provide a blanket protection for all FDA-approved pharmaceuticals. Lee, XIX-1 OSB Product Liability Newsletter at 4-5. So in effect, Comment k not only could provide immunity for the rabies vaccine as expressly discussed in the comment, but also for a drug prescribed for cosmetic purposes such as minocycline (one of the many prescription drugs to treat acne).

As an initial matter, an Oregon court has never announced such a blanket protection for all prescription drugs. Moreover, there is a substantial statutory barrier to such blanket protection if a court ever had to address the matter. In particular, when an Oregon court looks at the scope of the unavoidably unsafe defense, it is commanded by statute to construe the scope of that defense "in accordance with the *Restatement (Second) of Torts* sec. 402A, Comments a to m (1965)." ORS 30.920(3). In other words, an Oregon court may not construe that defense to be broader than what was contemplated by the 1965 version of Comment k.

The drafters of the Restatement expressly considered whether the unavoidably unsafe defense (Comment k) would provide a blanket exception to all prescription drugs. *American Legal Institute Discussion of the Restatement of the Law, Second, Torts*, 38 A.L.I. Proc 19, 90-98 (1961). Such an exception was proposed at the American Law Institute meeting where Comment k was adopted, but that proposal was expressly rejected. Id. (drafters of Comment k, including Dean Prosser, rejecting a proposal that the unavoidably unsafe defense should apply to all prescription drugs). Moreover, the plain text of Comment k suggests that only exceptional drug products should be excluded from the strict liability provisions. The rabies example given in the Comment vaccine example suggests that only certain drugs, those that fill an exceptional social need or provide a unique life-saving benefit, fall within the purview of Comment k. The 1965 version of Comment k was never intended to reach non-vital prescription drugs, such as drugs for cosmetic, sexual or lifestyle enhancement, or ordinary pain relief. Because the 1965 version of Comment k does not contemplate this expanded view of the unavoidably unsafe defense, ORS 30.920(3) may very well prohibit Oregon courts from construing the defense to provide such a blanket immunity for all approved drugs.

Some courts in other jurisdictions, in the evolution of their own state common law, have held that the protection of Comment k applies to all prescription drugs or FDA-approved drugs. But again, those courts were interpreting product liability law as a matter of common law rather than statute, and they were merely exercising their judicial policy-making authority to alter and expand the common law. The Utah Supreme Court in *Grundberg v. Upjohn Co.*, 813 P2d 89, 90 (Utah 1991) expressed as much:

> We acknowledge that by characterizing all FDA-approved prescription medications as 'unavoidably unsafe' we are expanding the literal interpretation of Comment k.

Oregon courts have no such common law authority to expand the interpretation of Comment k. ORS 30.920(3) (courts must construe Oregon product liability law in accord with the 1965 version of Comment a through m); *See also Griffith v. Blatt*, 334 Or 456, 466, 51 P3d 1256 (2002) (recognizing that ORS 30.920(3) expressly requires that the 1965 version of Comments a to m of *Restatement (Second) Torts*, Section 402A controls the affirmative defenses available in strict product liability claims).

Whether Comment k Applies is a Jury Question

Mr. Lee suggests that if blanket immunity for FDA drugs is not available, whether a particular defendant can receive Comment k immunity should be determined as a matter of law in a special evidentiary hearing at the trial court. No Oregon statute or rule of procedure provides that this specific affirmative defense should command the attention of a special hearing and fact finding status removed from the jury. Mr. Lee's article correctly identifies that the Oregon Supreme Court mentions an "evidentiary hearing" in reference to the unavoidably unsafe defense in footnote 4 *dicta* of *Senn v. Merrell-Dow Pharmaceuticals*,

Inc., 305 Or 256, 751 P2d 215 (1988). However, in that *dicta* footnote, the Oregon Supreme Court was merely acknowledging the soundness of the Idaho Supreme Court's refusal to review whether the defense would apply when there was not a "full evidentiary hearing" at the trial court. The footnote makes no mention as to whether that evidentiary hearing is before a judge or jury, whether it is a decision of fact or law, or whether Oregon would follow the same procedure. In the end, the note is *dicta*, and a jury trial is the quintessential "full evidentiary hearing." So this note referring to a statement by the Idaho Supreme Court may not provide any authority to remove this defense from the purview of the jury.

The fundamental question as to whether the unavoidably unsafe defense applies rests upon whether the unique benefits of the product's use are so great that serious risks associated with the product are nonetheless acceptable. The evidence necessary to answer this question is strikingly similar, if not identical, to the risk-utility evidence that the jury weighs when determining whether a product is dangerously defective under the consumer expectations test. *McCathern v. Toyota Motor Corp.*, 332 OR 59, 77-79, 23 P3d 320 (2001) (recognizing that the consumer expectations test of ORS 30.920 may be satisfied by evidence to the jury that a product's risk outweighs its utility). If the jury is capable of weighing such evidence in answering whether the consumer expectations test is satisfied, why would Oregon not allow the jury to weigh such evidence in determining whether the unavoidably unsafe affirmative defense is satisfied?

Removal of this fact determination from the jury has not been specifically sanctioned or contemplated by the statutes, the rules of procedure or evidence, Comments a to m of sec. 402A of the *Restatement (Second) of Torts*, or an Oregon appellate court. Under those circumstances, a trial judge may have little to no authority to take such a factual determination away from the jury, create a new and separate evidentiary hearing in which he or she finds facts, and determine as a matter of law whether a jury can weigh whether the drug's risks outstrip its utility.

The Application of Comment k Does Not Alter a Drug Manufacturer's Duty to Warn Consumers About a Drug's Risk

Mr. Lee's article also discusses the learned intermediary defense and its potential interplay with Comment k. Under the defense, a manufacturer of a pharmaceutical drug satisfies its duty to warn the consumer of the risks associated with the use of that product if it communicates adequate warnings to the prescribing physician. *Griffith v. Blatt*, 158 Or App 204 *rev'd* by 334 Or 456 (2001) (discussing the nature of the defense). In *Griffith*, 334 Or at 466-67, the Oregon Supreme Court reviewed whether Oregon law allows the defense to be invoked against a failure to warn product liability claim. The court recognized the commands of ORS 30.920(3) (Oregon product liability law is construed in accordance with Comments a to m of sec. 402A) and held that the learned intermediary defense does not apply in failure to warn product liability claims. In particular, the court saw no reference to the defense in the applicable Comments of sec. 402A, and the court pointed out that Comments j and h of sec. 402A commanded the contrary position that all product sellers have a duty to warn *the consumer* of the product risks. *Griffith*, 334 Or at 466-67.

Mr. Lee suggests that *Griffith's* rejection of the learned intermediary defense may be limited to its facts, and that a drug manufacturer may nonetheless fail to warn a consumer when there is a "true intermediary" between it and the consumer, such as a physician. Lee, XIX-1 OSB Product Liability Newsletter at 6. The phrase "true intermediary" is not a term found in Comments a to m of Sec. 402A, and it is not clear how it is distinguished from the "learned intermediary," which, as *Griffith* explained could not absolve a drug seller of its duty to warn the patient of the risks of the drug. Indeed, it is unclear how a "true intermediary" defense can persist under the "strict" liability aspect of Oregon product liability law outlined in ORS 30.920(1)(b) and (2)(b). Those provisions provide that all sellers of the product in the distribution chain (even if they did not sell the product directly to the consumer) are liable for defective warnings as long as the product "reach[ed] the * * * consumer without substantial change in the condition in which" the seller sold it. *See also* Comment Sec. 402A, Comment f ("The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor").

Presumably, Mr. Lee's suggestion that "Comment k * * * obviates the need for a trial court to decide the scope of *Griffith*." is based on the idea that if a drug manufacturer shows that it is entitled to Comment k immunity (either through a blanket protection for all FDA-approved drugs or through the separate evidentiary hearing before the court), then the manufacturer is released from the litigation and there is no need to ever get to the question whether the learned intermediary defense may apply as well. However, to suggest that the availability of the unavoidably unsafe defense in a case could preclude issues involving the learned intermediary defense may not account for the statutory commands that those defenses arise under separate and distinct claims

in product liability litigation. The unavoidably unsafe defense is a defense to a claim that the intended design of a product is dangerously defective because the importance of the design outstrips the risks. The learned intermediary defense is a defense to a claim that the defendant failed to adequately warn about the harms that the product can cause, notwithstanding the utility of the product.

The distinction between these claims is recognized in ORS 30.900. That statute sets forth that a product liability action in Oregon arises when an injury arises out of one or more of the following:

> (1) Any design, inspection, testing, manufacturing or other defect in a product;
>
> (2) Any failure to warn regarding a product; or
>
> (3) Any failure to properly instruct in the use of a product.

Even if a defendant proves that a drug is unavoidably unsafe under Comment k, the only protection that defense could provide is to a claim that the drug's ***intended design*** under ORS 30.900(1) is dangerously defective based on the nature of the harm it caused. The affirmative defense provides no immunity for a claim based on a drug seller's failure to warn the patient about the risks associated with the drug's use under ORS 30.900(2-3) or the drug seller's failure to properly inspect or prepare the drug so no *unintended* risks occur under ORS 30.900(1)[1].

Comment k expressly contemplates that "unavoidably unsafe" products may still be subject to claims under those other theories. The Comment provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs * * *. Such a product, ***properly prepared, and accompanied by proper directions and warning***, is not defective, nor is it unreasonably dangerous.

On the other hand, the learned intermediary defense is a defense to a claim that a drug ***was not accompanied by adequate warnings or instructions*** under ORS 30.900(2-3). That is, the defense provides that the drug seller does not have to warn or instruct the patient, because it has provided that information to a doctor (the learned intermediary) who in turn discusses the risks with the patient. Unlike the unavoidably unsafe defense, the learned intermediary is not part of a claim as to whether the product's ***intended design*** is dangerously defective under ORS 30.900(1).

The two defenses apply to different and distinct claims for liability. If a defendant drug manufacturer is successful in showing that the unavoidably unsafe defense applies to its product, it is not absolved of having to defend itself against claims that it nonetheless failed to adequately warn the consumer about the product risks. Accordingly, this writer disagrees that the success of a Comment k defense in a case would "obviate the need for a trial court to decide the scope of *Griffith*."

Post-*Griffith*, a learned intermediary defense no longer appears to be available to drug manufacturers as a means to avoid claims that they failed to warn a consumer about a drug's risks. And, even if there are continuing questions about the availability of that defense, a trial court's review of those questions likely are not precluded by any role that Comment k may play in the litigation.

The product liability section attempts to speak with one voice in its publications, but occasionally our members "agree to disagree." Thanks to Andy Lee and Travis Eiva for presenting the defense and plaintiff's perspective on this complex issue.

1 For example, a flaw in the manufacturer's preparation process causes an erroneous chemical combination in the drug and that erroneous combination – as opposed to the intended design – causes the harm to the consumer.

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