Products Liability Law Daily Wrap Up, TOP STORY—STATUTES OF LIMITATIONS AND REPOSE—6th Cir.: Trial court's dismissal of mesh claims on statute of limitations grounds reversed over discovery uncertainties, (Aug. 26, 2021)

Products Liability Law Daily Wrap Up

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By Nicholas Kaster, J.D.

However, the Sixth Circuit upheld the lower court's dismissal of the patient's failure to warn claim because her appeal relied on evidence not presented to the lower court.

Product liability, negligence, and loss of consortium claims brought against Ethicon, Inc., the manufacturer of a Prolift-brand pelvic mesh device, were not necessarily barred by Kentucky's one-year statute of limitations, the U.S. Court of Appeals for the Sixth Circuit has ruled in a decision designated as not recommended for publication. In reversing a federal district court in Kentucky, the Sixth Circuit held that the claims survived summary judgment because they could come within Kentucky's "discovery rule," under which the limitations period would apply on the date a latent injury is discovered or should have been discovered. Viewed in her favor, the court said, the record suggested that the injured patient received inconclusive and contradictory guidance on the cause of her symptoms from the multiple medical professionals she consulted. In light of the patient's testimony that she believed her body had rejected the Prolift device and the evidence that multiple medical professionals also did not attribute her symptoms to the Prolift mesh until the patient herself raised it with her doctor, the question of when she should have known that she had been wronged was a question of fact entrusted to the jury, the appellate court concluded (*Cutter v. Ethicon, Inc.*, August 25, 2021, Stranch, J.).

Background. In 2006, the patient underwent implantation of a Prolift brand pelvic mesh, manufactured by Ethicon, a subsidiary of Johnson & Johnson, to treat her pelvic prolapse and pelvic pain. Her symptoms soon returned, however. Over the course of the next several years, she sought relief from multiple doctors and underwent several revision surgeries. In May 2012, the patient came to believe that her problems were being caused by a defect in the Prolift itself. As a result, she and her husband brought suit against Ethicon, alleging negligence, loss of consortium, product liability, and failure to warn.

Ethicon moved for summary judgment, arguing in part that the claims were barred by Kentucky's one-year statute of limitations. The district court granted the motion in January 2020, holding that as a matter of law, the claimants' "injury" from the Prolift device arose no later than March 2011, more than one year before they filed suit [see *Products Liability Law Daily*'s January 14, 2020 analysis]. It also noted that the patient's failure to warn products liability claim failed for lack of proximate cause. The current appeal ensued.

The statute of limitations and the "discovery rule." Kentucky law provides that personal injury suits must be filed within one year after the cause of action accrued. However, under the "discovery rule," the limitations period in certain suits begins to run "on the date of the discovery of the injury, or from the date it should, in the exercise of ordinary care and diligence, have been discovered."

The knowledge required is two-pronged: the limitations period is triggered when the plaintiff knows or should know not only that she has been injured but also that her injury may have been caused by the defendant's conduct. The discovery rule originated in the medical malpractice context, but Kentucky courts have applied the discovery rule to a range of other causes of action as long as the injury is "latent"-when "the fact of injury or offending instrumentality is not immediately evident or discoverable with the exercise of reasonable diligence."

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In determining whether the discovery rule applies and if so, when the limitations period begins to run, Kentucky law distinguishes injury from harm. Harm is "the existence of loss or detriment in fact of any kind to a person resulting from any cause," while injury is "the invasion of any legally protected interest of another," or stated differently, the wrongdoing that caused the harm. Thus, regardless of when a plaintiff experienced "harm," a "legally recognizable injury does not exist until the plaintiff discovers the defendant's wrongful conduct" or the fact of the misconduct becomes "objectively ascertainable."

Evidence of discovery in the patient's case. The threshold question in the case at bar was whether the injury suffered by the patient was latent, such that the discovery rule applied. The appeals court noted that the Prolift mesh did not immediately cause the patient pain-her symptoms only returned at the end of 2007, a year and a half after implantation. The problems then came and went over the years, sometimes improving slightly with treatment or revision, and then later returning. The device, moreover, was inside her body; its relationship with her symptoms was not "immediately evident or discoverable."

The district court concluded that the limitations period began to run no later than March 2011, when, according to the patient's testimony, a doctor recommended she undergo a third revision surgery. In the trial court's view, that recommendation was sufficient to put the patient on notice of the device's potential defects and trigger her duty to investigate.

The patient, however, contended that when the limitations period began to run is a question for the jury, and that the triggering event occurred in June 2011, when she and the doctor first discussed the possibility that a defect in the mesh itself was causing her symptoms and proposed removing it altogether. Resolving the question of when the patient had the requisite knowledge of her injury and its instrumentality is guided by the summary judgment standard, the appellate court explained, which requires that all reasonable inferences be drawn in favor of the claimants. Further, in determining when a plaintiff had or should have had the knowledge required to trigger the limitations period under the discovery rule, "a court must give special consideration to the patient's perspective" because her lack of medical knowledge may impede her ability to discover her injury.

Viewed in her favor, the court said, the record suggested that the patient received inconclusive and contradictory guidance on the cause of her symptoms from the multiple medical professionals she consulted. A reasonable jury could conclude from the evidence that the patient, despite diligently investigating the harm she was suffering, reasonably believed until June 2011 that her symptoms were due to a problem with her body rather than with the manufacture of the mesh. In the appellate panel's assessment, the evidence from the patient's perspective supported a dispute of fact as to when she may have recognized the alleged wrongful conduct of the device manufacturer. The court considered that the patient did not graduate from high school, only later obtaining her GED; and that she was not a doctor and had no special medical knowledge. When she underwent the initial implant surgery, she believed the mesh was something "natural" rather than a "synthetic" product. In addition, "the surrounding circumstances made the alleged causal relationship" between the Prolift's defects and her symptoms far from "obvious to a lay person." Not only was the implant internal, but the patient had a history of pelvic pain due to multiple health conditions that might have obscured the cause of her pain. Also, she visited many doctors over multiple years to identify the source of her symptoms and obtain treatment for them. Viewing the record in her favor, the appellate court noted that none of the medical professionals attributed her pain to a defect in the Prolift. Rather, they explicitly suggested the cause was scar tissue or tissue separation.

Noting that a patient has a "right to rely on [her] physician's knowledge and skill," the appeals court found that a jury could find that the patient genuinely and reasonably believed that her problems were the fault of her own body. As such, the record contained evidence that the patient experienced pain but because of her doctors' advice, she was unaware that it was attributable to defects in the Prolift device. A jury could find these efforts to be reasonably diligent. Under Kentucky law, the statute of limitations for a cause of action based on a latent injury does not begin to run until a person knows or should know that she has been wronged, and this knowledge should not be presumed by one who possesses no medical knowledge, the appellate panel said.

Therefore, in light of the patient's testimony that she believed her body had rejected the Prolift device and of the evidence that multiple medical professionals did not attribute her symptoms to the Prolift mesh until she raised

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the issue with her doctor in June 2011, the question of when she should have known that she had been wronged was a question of fact for the jury, the court concluded.

Failure to warn claim. The district court also had concluded that even if it were timely, the strict liability failure to warn claim failed for lack of proximate cause. The Sixth Circuit panel agreed. To survive summary judgment on a failure to warn claim, a plaintiff must provide evidence showing that (1) the defendant manufacturer had a duty to warn, (2) any warnings given were inadequate, (3) and the inadequate warnings were the proximate cause of the injury. In addition, the learned intermediary doctrine provides that a manufacturer's duty to warn of the foreseeable risks of a medical device is satisfied if it gives adequate warnings to the patient's healthcare provider. The district court concluded that the manufacturers' warnings were not the proximate cause of the claimants' alleged injuries because the doctor relied solely on personal surgical experience and demonstrations to inform his knowledge of the potential risk.

On appeal, the claimants offered testimony by the doctor from 2019 in another case to show that additional information from the manufacturer would have made him "look at the device differently." However, the court noted that the claimants did not provide this evidence to the district court in the 2016 failure to warn briefing, nor did they seek reconsideration of that decision on the basis of newly discovered evidence. The Sixth Circuit stated that it reviewed "the case presented to the district court," and that a party "may not by-pass the fact finding process of the lower court and introduce new facts in its brief on appeal." Thus, it declined to consider the doctor's 2019 testimony for the first time on appeal, and so it affirmed the dismissal of the failure to warn claim.

Accordingly, the Sixth Circuit reversed the district court's dismissal of the claimants' negligence, gross negligence, strict liability defective product, strict liability design defect, and loss-of-consortium claims; and it affirmed the district court's dismissal of their strict liability failure to warn claim. The case was remanded for further proceedings consistent with the appellate opinion.

Dissent. In dissent, Judge Nalbandian noted that the "discovery rule" applies to three types of cases: "cases involving latent injuries, latent illnesses, or professional malpractice." It was not apparent that this case fell into one of these categories, the judge opined. Regardless of the discovery rule's application, the judge said, the claimants' case still was untimely because, under Kentucky Supreme Court precedent, knowledge of either an "injury" or an "offending instrumentality"- a product that causes harm-is "discovery" for limitations purposes in Kentucky. It should have been "apparent from the facts that the product"-the Prolift-"may have been a potential cause of" of the patient's pelvic pain more than a year before May 2012, the dissenting judge stated. Because the patient had notice of the potential "offending instrumentality" more than a year before she sued, the dissenting judge would have affirmed the district court.

This case is No. 20-6040.

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Companies: Ethicon, Inc.; Ethicon Women's Health and Urology; Gynecare; Johnson & Johnson

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