No. SC88890

IN THE SUPREME COURT OF MISSOURI

CORTEZ STRONG,

Respondent/Cross-Appellant,

v.

AMERICAN CYANAMID COMPANY,

Appellant/Cross-Respondent.

On Appeal From The Circuit Court Of The 22nd Judicial Circuit, City Of St. Louis
Hon. Michael B. Calvin, Circuit Judge
Cause No. 9920880

APPELLANT AMERICAN CYANAMID COMPANY'S SUBSTITUTE REPLY AND CROSS-RESPONDENT'S BRIEF

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INTRODUCTION

Cyanamid's opening brief demonstrated that, for two reasons, Strong's case should never have gone to the jury. *First*, his claims turned on testimony from an expert, Thomas Bozzo, that was based on a disputed interpretation of the FDA's vaccine regulations—testimony that was both improper (because the meaning of the regulations was a legal issue for the trial court) and substantively unsustainable (because it conflicts with the interpretation and implementation of the regulations by the FDA itself). *Second*, Strong failed to present a submissible case that the omission of the particular tests that he contends were required by law had any effect—or even *could* have had any effect—on the safety of the vaccine that he received.

In response, Strong argues that Bozzo testified only about "compliance" with the FDA's regulations, not about what they meant; that, in any event, the regulations meant what Bozzo said they meant, at least before 1991; and that the FDA's contrary interpretation is not entitled to deference. As to the lack of tests, Strong seems at times to accept that he must show that any omission made his vaccine more likely to cause injury than had the tests been done, but he then argues that mere proof that his injury was caused by his polio vaccine is sufficient standing alone or, if not, that Bozzo's testimony regarding the possibility of an increased risk of polio satisfies his burden. He also defends the jury's $8.5 million damages award as not excessive, and cross-appeals the denial of prejudgment interest. None of these arguments has merit.

I. POINT I: THE TRIAL COURT SHOULD HAVE RESOLVED THIS CASE AS A MATTER OF LAW, BECAUSE STRONG'S CLAIMS DEPENDED ENTIRELY ON BOZZO'S APPLICATION OF FDA REGULATIONS IN A WAY THAT CONFLICTS WITH THE AGENCY'S OWN GOVERNING INTERPRETATION.

Strong argues that material from each intermediate "tissue culture passage" used to create vaccine production seeds was itself a "seed" within the meaning of 21 C.F.R. § 630.10(b)(3) and (b)(4) and, therefore, subject to mandatory testing. (*E.g.*, Resp. Br. 54-56.[1/]) Cyanamid did not test these intermediate materials for neurovirulence, because neither the company nor the FDA has ever interpreted the regulations to treat them as "seeds." Strong does not dispute that the final production seeds used to create the vaccine that Strong received—as well as the three vaccine monopools made from those

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[1/] It is unclear from Strong's brief whether he argues any longer that "seed" includes original strain material or only "intermediate" materials produced from the strain material at a stage prior to the making of Cyanamid's production seeds. (*Compare, e.g.*, Resp. Br. 54, 62 *with id*. at 56, 68.) Bozzo testified that the original strain material was a "seed" for which the regulations required testing (*see id.* at 79), on the theory that any material used to make a new generation of attenuated poliovirus is a seed and must be tested as a seed. The trial court's error in allowing this testimony was the same, however, whether Strong focuses only on the intermediate materials or on those materials and the original strains.

production seeds, and indeed the final trivalent vaccine itself—*were* successfully tested and cleared by the FDA for use. (*See*, *e.g.*, *id.* at 62; Cyanamid Br. 33.) Thus, whether or not there was a regulatory violation—which is the sole basis for Strong's claims that his vaccine was in a defective condition, unreasonably dangerous, or negligently produced—turns solely on which side is correctly construing the regulations. That is a classic dispute of law that the trial court should have resolved, and it should have done so in Cyanamid's favor, rather than allowing Strong to take his case to a jury based on Bozzo's erroneous construction of the law.

A. Bozzo Testified About the Disputed Meaning of the Regulations, Not Simply About "Regulatory Compliance."

Strong seeks to deflect Cyanamid's main point by arguing that Bozzo testified only about the "fact of compliance" with regulations, not about their meaning. (Resp. Br. 73; *see id*. at 70-87.) That is clearly incorrect.

Strong himself cites three key points on which Bozzo cited a "lack of regulatory compliance" with respect to testing, each time specifying what regulatory provisions he deemed "'involved.'" (*Id.* at 79.) Because there was no factual dispute about what testing Cyanamid did and did not perform, Bozzo's testimony can only be understood as addressing, in his view, what the cited regulations required. Moreover, a few pages earlier in the transcript, Strong's lawyer expressly asked what the regulations required, and Bozzo answered:

> Q. Now, in regard to those regulations, what were—what is—*what do the regulations demand* of a vaccine manufacturer in regard to its seeds?

A. Okay. Well, I can tell you that—well, the seeds, the master of seeds and all of the seeds needs [sic] to be neurovirulence tested. *That's what the regulations say*. . . .

(Tr. 683 (emphasis added); *see also id.* at 689 (failure to test original strains violated 21 C.F.R. §§ 630.10 (b)(3)-(5) and 21 C.F.R. § 630.16(b)(1)); *id.* at 691 (failure to test intermediate materials violated 21 C.F.R. §§ 630.10 (b)(4)-(5) and 21 C.F.R. § 630.16(b)(1)).) Strong's contention that "[a]t no point on direct examination did Mr. Bozzo seek to inform the jury of the meaning of any regulation" (Resp. Br. 79) is inexplicable.

There also is no comparison between Bozzo's testimony and that described in *Wulfing v. Kansas City S. Indus., Inc.*, 842 S.W.2d 133, 153 (Mo. App. W.D. 1992), *overruled on other grounds by Exec. Bd. of the Mo. Baptist Conv. v. Carnahan*, 170 S.W.3d 437 (Mo. App. W.D. 2005). (*See* Resp. Br. 82-84.) *Wulfing* recognized that an expert in securities regulation could explain to the jury "the step-by-step practices ordinarily followed by lawyers and corporations in shepherding a registration statement through the SEC." *Wulfing*, 842 S.W.2d at 153 (quoting *Marx & Co. v. Diner's Club, Inc.*, 550 F.2d 505, 508 (2d Cir. 1977)). Bozzo's testimony, by contrast, was a far cry from a mere description of practices ordinarily followed by vaccine producers in shepherding their products through the FDA approval process. Indeed, he never provided any such description. Rather, Bozzo's sole function at trial was to review documents provided to him by counsel and to testify whether Cyanamid violated the FDA's regulations based on his opinion on the hotly contested *legal* issue of what the FDA's

regulations required. That was his *only* task in this case. (Tr. 603-04 ("Q: And in this litigation what did I ask you to review and for what purposes as you understood? A: You asked me to review a lot of records to determine if there was any noncompliance with FDA requirements[.]").)

Nor is this case anything like *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 380 (Mo. banc 1986), a design defect case in which an expert explained how aircraft parts could be wrongly installed and how the parts at issue were neither designed nor marked to minimize installation errors. (*See* Resp. Br. 84-86.) The FAA regulation mentioned by this expert served simply to underscore (and in effect to codify) the general standard of care in the industry, which, in contrast to Bozzo's testimony, was the subject of that expert's testimony.[2/] There also is no suggestion in *Nesselrode* that the parties disagreed as they do here about the regulation's meaning. *Nesselrode* thus does not stand for the proposition that experts commonly testify about the meaning of disputed regulatory requirements (as opposed to whether a particular design or process complies with an undisputed requirement), or that it would ever be proper if they did. The testimony about the FAA regulation in *Nesselrode* was simply not at issue.

[2/] "Each element of the flight control system must have design features or must be distinctly and permanently marked so as to minimize the possibility of incorrect assembly that could result in the malfunctioning of the control system." 14 C.F.R. § 23.685(d) (1981). *See Nesselrode,* 707 S.W.2d at 379.

In this case, Strong relies exclusively on the FDA's regulations as the only guide by which to measure the vaccine and Cyanamid's conduct in making it. And in contrast to *Nesselrode*, the parties' disagreement about the meaning of the regulations was central to the outcome of the case. To render an opinion that Cyanamid breached the regulations, Bozzo necessarily interpreted them in his own way. And by allowing that testimony, the trial court erroneously permitted a witness to give the jury an opinion on a disputed question of law.[3/]

[3/] Cyanamid repeatedly contested not only Strong's construction of the FDA's testing requirement, but also the propriety of offering expert testimony to the jury on that legal issue. (*See, e.g.*, Tr. 637-38 ("So we don't think he has the qualifications with respect to his telling the jury what the regulations mean or how they should be applied here. Those are questions of law for the Court, not for the witness."); *id*. at 667 ("If the witness wants to testify that before the seeds in 1979 could have been used we needed to do some other test . . . I think that's just an issue of law for the Court, not one in which this witness can opine because the regulations require what they require."); *id*. at 684 ("Your Honor, I object to the testimony. . . . [T]he regulation says what it says, not what Mr. Bozzo says it says.").) For that reason, nothing about Bozzo's testimony was "[i]nvited error." (Resp. Br. 87.) Once the court allowed Bozzo on direct examination to give his interpretation of the FDA regulations, and his consequent opinion that Cyanamid had violated them, Cyanamid was entitled to cross-examine him on the subject. *See, e.g.*,

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(continued . . .)

This case is much more like *Burrell ex rel. Schatz v. O'Reilly Auto., Inc.*, 175 S.W.3d 642 (Mo. App. S.D. 2005), in which a commercial pick-up truck struck a disabled individual who was driving a motorized scooter in a cross walk. The truck driver's employer wanted to introduce expert testimony that the plaintiff violated a statutory duty to wear a safety helmet while operating a "motortricycle." *Id*. at 651. The plaintiff maintained that his scooter was a "motorized wheelchair," which by statute is not a "vehicle" and thus cannot be a "motortricycle." *Id*. (quoting §§ 301.020.2 and 301.010(64) RSMo.). The employer argued that this classification issue was a question of fact for the jury. The Court of Appeals flatly rejected that argument:

> Although, the terms "motorized scooter" and "motorized cart" are not statutorily defined, neither is the term "motorized wheelchair." Deciding whether the legislature intended the phrase "motorized wheelchair" to include any assistive device "designed to increase the mobility of persons with disabilities" is purely a matter of statutory interpretation; consequently, *it is a question of law, not fact*.

(. . . continued.)

Pasternak v. Mashak, 392 S.W.2d 631, 639 (Mo. App. 1965) ("the [invited error doctrine] has no application when the party complaining did not invite the error and was forced to his position by the rulings of the court"), *overruled on other grounds by In re Estate of Mapes*, 738 S.W.2d 853 (Mo. banc 1987).

Id. at 652 (emphasis added, citations omitted).

Here, too, whether the undefined term "seed" in the FDA's regulations was intended to include any materials used to make a new generation of attenuated poliovirus, as Bozzo testified, or only the production seeds used to make the monopools that constituted the final vaccine, as Cyanamid and the FDA maintained, is "purely a matter of [regulatory] interpretation," and a "question of law, not fact." *Id*. *See also, e.g.*, *City of St. Louis v. Kisling*, 318 S.W.2d 221, 225-26 (Mo. 1958) (expert testimony that party could legally use land to access property under state easement rules inadmissible as "conclusion of domestic law"); *Mitchell v. Dir. of Revenue*, --- S.W.3d ---, 2008 WL 1735191, at *3 (Mo. App. S.D. Apr. 16, 2008) ("Whether a motorized device is classified as a motor vehicle for purposes of [statute authorizing driver's license suspension] is a question of law."); *Gladstone Special Rd. Dist. No. 3 of Clay County v. County of Clay*, 248 S.W.3d 60, 63 (Mo. App. W.D. 2008) ("This case . . . involves the interpretation of a statute, which is purely a question of law."); *see also* § 490.100 RSMo. (1996). It was error for the trial court to admit expert testimony on that question and to submit it to the jury. *See Young v. Wheelock*, 64 S.W.2d 950, 1008 (Mo. 1933) ("an expert's opinion

cannot be received if it amounts to a conclusion of law").[4/] The court should have determined the issue as a matter of law. *See, e.g.*, *Rice v. Bol*, 116 S.W.3d 599, 612 (Mo. App. W.D. 2003) ("[I]t is the responsibility of the trial court to determine and instruct the jury on the applicable law, which the jury is then to apply to the facts, which it determines in rendering its verdict.").

B. Because the Seed Testing Regulations Apply Only to Production Seeds, Not to Strains or Intermediate Materials, Judgment Should Have Been Directed in Cyanamid's Favor.

On the merits of the regulatory interpretation question, Strong argues that the FDA's interpretation of the term "seed" in 21 C.F.R. § 630.10(b) is not entitled to any deference (Resp. Br. 43-54) and that the term instead includes all materials used to make

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[4/] *See also*, *e.g.*, *State v. Kinder*, 942 S.W.2d 313, 334 (Mo. banc 1996) ("Expert testimony is not admissible on issues of law."); *Wulfing*, 842 S.W.2d at 153 ("It is the rule that the opinion of an expert on issues of law is not admissible."); *Turner v. Fuqua Homes, Inc.*, 742 S.W.2d 603, 614 (Mo. App. W.D. 1987) (expert testimony regarding federal regulations governing manufacture of mobile homes properly excluded as addressing "existence or application of the law"); *Burke v. Moyer*, 621 S.W.2d 75, 79 n.4 (Mo. App. W.D. 1981) ("interpretation of the meaning of legislative enactments is not a subject for expert testimony").

new generations of attenuated poliovirus (*id*. at 54-70). There is no support for either argument.

1. The FDA's Interpretation Is Entitled to Deference.

Strong first argues that no deference is appropriate, because the FDA's views were not properly before the trial court. (*Id.* at 43-44, 51-53.) That is not correct. To begin with, interpretation of the FDA's regulations—including the question of deference—is a matter of law. The question is not what evidentiary submissions were made to the jury. The regulations were at issue, and the court's role was to resolve disputes about their meaning.

Nor is there any basis for Strong's suggestion (*id.* at 52) that deference is appropriate only when an agency is itself "before the Court as a party in the case." *See, e.g.*, *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 317 (E.D. Pa. 2007) (deferring to interpretation expressed in regulatory preamble even though agency not party to case); *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 249-50 (D.D.C. 2002) (same); *see also Federal Express Corp. v. Holowecki*, --- U.S. ---, 128 S. Ct. 1147, 1155 (2008) (deferring to interpretation of regulations presented in *amicus* brief even though agency not party to case); *Auer v. Robbins*, 519 U.S. 452, 462 (1997) (same); *M. Fortunoff of Westbury Corp. v. Peerless Ins. Co.*, 432 F.3d 127, 129 (2d Cir. 2005) (same); *Oregon Paralyzed Veterans v. Regal Cinemas, Inc.*, 339 F.3d 1126, 1131 n.6 (9th Cir. 2003) (same).

Here, the FDA's views were clear from two sources at the trial court's disposal, and they have now been confirmed by a third. *First*, as Cyanamid's opening brief points

out (Cyanamid Br. 19), the record indisputably shows that when Cyanamid applied to the FDA for approval of its three production seeds, it included (in documents known as "protocols") each seed's lineage, including the fact that the production seeds were derived from strains by way of intermediate materials. (*See* Def.'s Exs. 39-41, 45-47, 113A, C, E.) These protocols identified what materials had been tested and the results. They did not show tests on either the original strain or intermediate materials, and the FDA knew that. (*See* Tr. 750-52, 754-58.) Had the FDA interpreted its regulations to require testing of those materials, it would have demanded further documentation at that point. It did not.[5/]

Second, in 1991, the FDA expressly confirmed its view that the regulations required testing only of production seeds, not of strain or intermediate materials. (Cyanamid Br. 19-20 (quoting 56 Fed. Reg. at 21,422 and 21 C.F.R. §§ 630.10, 630.16-17, as amended in 1991).) The 1991 agency statements and regulatory amendments did not, as Strong argues (Resp. Br. 43, 47-51), *change* the applicable testing rules. They only reiterated and clarified the agency's longstanding interpretation. *See* 56 Fed. Reg.

[5/] Dr. Ritchey never testified at trial "that full compliance with the regulations was unnecessary and that some of these requirements were specifically waived by the regulatory agency in which Mr. Bozzo served." (Resp. Br. 26 (citing Tr. 1608, 1708-09).) She testified about which tests were required and which were not. (Tr. 1607-10, 1612-13, 1706-08, 1713-15.)

21,422 (1991) ("New § 630.10(b)(4) has been added to embody [] longstanding agency interpretation.").

Nor have the agency's views ever conflicted with judicial interpretations of the specific regulations at issue here. (*See* Resp. Br. 44-47, 49-50, 56-64.) In *Berkovitz v. United States*, for example, the U.S. Supreme Court held only that the plaintiffs' complaint did not on its face implicate the discretionary function defense that the federal government enjoys under the Federal Tort Claims Act. 486 U.S. 531, 547-48 (1988). The case had nothing to do with the interpretation of the seed-testing regulation. Likewise, Strong's reliance on *In re Sabin Prods. Liab. Litig.*, 763 F. Supp. 811, 823 (D. Md. 1991), and related cases (*see* Resp. Br. 44-46, 62-63) is misplaced. In fact, the court in *Sabin* specifically rejected a claim that the Division of Biological Standards ("DBS"), a forerunner to the FDA's Center for Biologics Evaluation and Research, should have required Cyanamid to test original strain material as a "seed," sustaining the government's contrary construction of its regulations:

> [Plaintiffs] assert that DBS should have required SOM [the strain material] to be tested as a seed. DBS takes the position that this was unnecessary because SOM had been used in clinical field trials leading to the adoption of the [oral polio vaccine] program and was deemed to be a strain which had already been adequately tested. . . . Nothing which occurred at trial persuaded me that plaintiffs met their burden of demonstrating that DBS's interpretation of the regulations on this point was unreasonable. To the contrary, since Lederle [a division of Cyanamid] itself did not produce the

> SOM material and since the seeds and lots which were SOM's progeny were subjected to neurovirulence testing, DBS's interpretation of the regulations was entirely proper.

In re Sabin, 763 F. Supp. at 827. Notably, the court in *Sabin* could not have viewed intermediate materials—as opposed to production seeds and vaccine monopools—as "seeds and lots which were SOM's progeny," because it was indisputable (as here) that the only materials that were "subjected to neurovirulence testing" were the production seeds and monopools. *Id.* In short, there is no case that has interpreted the FDA's regulations at issue here, before or after 1991, to require testing on original strains or intermediate materials or that has failed to defer to the FDA's position on this dispositive issue.[6/]

Finally, in addition to the interpretive aids available to the trial court, this Court has the benefit of an *amicus* brief from the United States, forcefully reiterating the

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[6/] Strong also cites generally to *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987), *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1986), *Campagna v. Am. Cyanamid Co.*, 767 A.2d 996 (N.J. App. Div. 2001), and *Rivard v. Am. Home Prods.*, 917 A.2d 286 (N.J. App. Div. 2007), as cases interpreting 21 C.F.R. § 630.10 *et seq*. in accordance with Bozzo's testimony. (Resp. Br. 18 n.4.) None of these cases has anything to do with the interpretation of the FDA regulations (21 C.F.R. § 630.10(b)(3) and (b)(4)) at issue in this appeal.

agency's interpretation and confirming that its 1991 statements and amendments clarified, rather than changed, its construction of the regulations. (U.S. Amicus Br. 9-15.)

Given these sources, there was and is no question of how the FDA interpreted its own regulations in 1986 and continues to interpret them today. Under settled Missouri law, that interpretation was and is entitled to deference. (*See, e.g.*, Cyanamid Br. 20-22.)

2. Strong's Interpretation of "Seed" Is Incorrect.

Even apart from deference, the interpretation of the FDA's testing regulations proffered by Strong (Resp. Br. 54-70) cannot be sustained.

When the regulations are read as a whole and with a basic understanding of the vaccine production process, the term "seed" can only sensibly apply to production seeds—that is, the materials used to make monopools that constitute the final trivalent vaccine. (Cyanamid Br. 5.) Section 630.10(b)(4) states that "[n]o seed virus shall be used *for the manufacture of poliovirus vaccine*" unless satisfactory tests are conducted (emphasis added). The only seed viruses used to make *vaccine* are the production seeds, and if those seeds pass testing, then the regulations have been satisfied. (*Id.* at 33-34.)

That interpretation is confirmed by the text of Section 630.10(b)(5), which provides that "[s]ubsequent and identical neurovirulence tests shall be performed in monkeys . . . upon introduction of a new *production seed* lot . . . " (emphasis added). That is what occurred here when Cyanamid created the new production seeds that it used to make Strong's vaccine. Nothing in this provision refers to materials other than the new production seeds.

The meaning of "seed" in the testing regulations also is not affected, as Strong contends, by other uses in other places and contexts, such as internal Cyanamid documents and Cyanamid's initial license application. (*See* Resp. Br. 19-22, 30-31, 64-70.) The question is not whether the term can be used more loosely or broadly, but how the FDA used it in its regulations. Moreover, in making this argument, Strong misleadingly suggests that when the regulations were changed in 1996 to adopt Cyanamid's license application as the standard for making and testing oral polio vaccine, Cyanamid was required to test its master seeds for neurovirulence because it said that it would do so in its license. (*Id.* at 30-31 (citing to Cyanamid's initial license application in the early 1960s).) Cyanamid's license application had been corrected twenty years prior to 1996, however, to provide only that "[a]n intramuscular neurovirulence test is performed on each *production seed*." (*See* Def.'s Ex. 97B at 3 (emphasis added); *see also* Tr. 713-14.) That usage is consistent with the meaning of the regulations and with how both Cyanamid and the FDA conducted themselves here.

Finally, Strong gains no support from 21 C.F.R. § 630.13(a), which provides that "[v]irus in the final vaccine shall represent no more than five tissue culture passages from the original strain, each of which shall have met the criteria of acceptability prescribed in § 630.10(b)." (*See* Resp. Br. 55-56.) His argument seems to be that, under this regulation, each "tissue culture passage" had to undergo the same testing required for "seeds" under Sections 630.10(b).

Strong has never made this argument before. (*See generally, e.g.*, Tr. 689-94 (cataloguing "deviations from regulations," not including this one).) Under settled

principles, he cannot raise it for the first time now. *See Huter v. Birk*, 439 S.W.2d 741, 745 (Mo. 1969) ("We cannot affirm on a theory not covered by the pleadings and not actually presented to the trial court."); *Christian Health Care of Springfield W. Park, Inc. v. Little*, 145 S.W.3d 44, 53 (Mo. App. S.D. 2004) ("On appeal, a party is bound by the position she took in trial court, and we can only review the case upon those theories."). In any event, the argument lacks merit. In context, the regulation's requirement of acceptability under § 630.10(b) refers not to each tissue culture passage, but to each "original strain." Indeed, one of the criteria for strains mandated by § 630.10(b)(2) is that they be shown to be "free from harmful effect" in a clinical trial of at least one million susceptible individuals. If that requirement were applied to every "tissue culture passage" as Strong's new reading of § 630.13(a) would have it, then a manufacturer would have to subject every batch of final vaccine to a full-blown clinical trial of at least a million people before it could ever be used. That would be absurd. Moreover, even if § 630.13(a) called for the application of § 630.10(b) to each "tissue culture passage," that would not change the fact that the testing requirements in the latter provision, both on their face and as construed by the FDA, apply only to production seeds, not to intermediate materials. Even on Strong's reading of § 630.13(a), only those "tissue culture passages" that were also "seeds" would have to be tested—as was done here.

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Manufacturers of vaccines operate under intensive oversight by the FDA. Regulations govern every aspect of a vaccine's production, testing, and distribution. The FDA enforces those regulations, as it did here, on a lot-by-lot basis, conducting much of

its own testing and making decisions whether each batch of product complies with federal standards. Vaccine manufacturers must be allowed to rely on uniform standards as developed, interpreted, and enforced by the regulatory agency—not as interpreted by expert witnesses in tort cases or as determined by juries that are persuaded by witnesses hired by one party or another.

The only way to guarantee predictability and to avoid *ad hoc* determinations is to enforce the time-honored rule that the interpretation of regulations is always a legal issue for the courts, guided by appropriate deference to the promulgating agency. In this case, the trial judge's function was usurped by an expert witness, and the jury was allowed to determine what the regulations required. That was reversible error both as a procedural matter and because the expert's opinion was wrong as a matter of law. Strong's only theory of liability depends on establishing a violation of the FDA's seed-testing regulations, which is refuted by the undisputed facts showing that there was no such violation as a matter of law. The trial court's judgment should be reversed and the case remanded with instructions to enter judgment for Cyanamid.

II. POINT II: STRONG FAILED TO MAKE OUT A SUBMISSIBLE CASE THAT HE WAS INJURED BY AN UNREASONABLY DANGEROUS DEFECT ARISING FROM A BREACH OF FEDERAL REGULATIONS.

Even if he could show violations of the FDA's testing regulations, Strong could not prevail without proving that his injury either was proximately caused by Cyanamid's negligence in violating those regulations or was a "direct result" of Cyanamid's sale of a product that was, because of the testing failure, in a "defective condition, unreasonably

dangerous for its intended use." (Cyanamid Br. 23-27; *see also* Resp. Br. 90, 94, 95-97.) Cyanamid's opening brief showed that Strong did not—and, indeed, could not—submit evidence sufficient to allow the jury to find causation. (Cyanamid Br. 28-36.)

A. Cyanamid's Arguments Are Properly Presented, and Strong Was Required to Link His Injury to Cyanamid's Supposed Testing Violations.

Strong responds first that Cyanamid has waived its argument that Strong's evidence failed to tie any testing omission to Strong's injury, at least as to Strong's product liability claim. (Resp. Br. 95-99.) He evidently contends first that the jury could have found damage to Strong as a "direct result" of the "defective condition" of the vaccine that he received, even if he showed no connection between his injury and the testing failure that allegedly made the product "defective," and second that Cyanamid has waived any argument to the contrary by phrasing its point on appeal in terms of "causation." (*E.g.*, *id.* at 95 (instruction "does not require the jury to find any relationship between regulatory violations and Cortez Strong's polio"), 89-90, 98, 104 (only question is "did the polio vaccine cause Cortez Strong to contract polio"), 98 ("By limiting its assignment of error to *causation*, Cyanamid has abandoned any claim that Cortez Strong failed to make a submissible case for the 'defective condition, unreasonably dangerous' element of Instruction 7." (emphasis in original).) These arguments are wholly artificial.

Strong's injury was a "direct result" of a "defective condition" (or of Cyanamid's negligence) only if it was caused by the same problem that established the defect (or the negligence). "Defect" and "causation" are inextricably linked in this respect.[7/] Strong's contrary argument is no more sensible than arguing that a plaintiff could prevail in a car crash case merely by showing that there was a manufacturing defect affecting the car's brakes, without also showing that the car's bad brakes caused the crash. *See also Nesselrode*, 707 S.W.2d at 375 ("[T]he doctrine of strict tort liability is not, nor was it ever intended to be, an enveloping net of absolute liability."). The nature of Cyanamid's objection to Strong's case has never been in doubt. There has been no waiver.

Moreover, Strong's suggestion that there need be no connection between defect and injury cannot be squared with his own repeated, and accurate, restatement of the

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[7/] *See*, *e.g.*, *Coulter v. Michelin Tire Corp*., 622 S.W.2d 421, 425 (Mo. App. S.D. 1981) ("In order to recover under the doctrine of strict liability, a plaintiff must establish that: (1) the product was defective and dangerous when put to a use reasonably anticipated by the manufacturer; and (2) the plaintiff sustained injury or damage as a direct result of the defect."); § 537.760 RSMo. (2000); *Bluedorn v. Missouri Pac. Ry. Co.*, 25 S.W. 943, 947 (Mo. banc 1894) ("[R]ecovery cannot be had upon mere proof of injury and a defendant's breach of a statute or ordinance. The plaintiff must prove that the breach of regulation was the proximate cause of his injury."); *Tompkins v. Kusama*, 822 S.W.2d 463, 464 (Mo. App. E.D. 1991).

applicable rule: "liability attaches to a vaccine manufacturer when it can be shown that 'a polio vaccine violating these FDA regulations *was any more likely to cause injury than a fully compliant vaccine*.'" (Resp. Br. 90 (quoting *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 508 (6th Cir. 2003)) (emphasis added in part)); *see also, e.g., id.* at 94, 99 (quoting W. Keeton, *Prosser and Keeton on Torts* § 98 (5th ed. 1984) (products liability claims appropriate for "damaging events caused by defects *of a kind that made the product more dangerous than it would otherwise be*" (emphasis modified)), 114, 123-25.) At bottom, there is no disagreement about the applicable legal standard. The question is whether Strong introduced enough evidence to allow a jury to find that it had been met.

B. Strong's Evidence Did Not Make Out a Submissible Case.

Strong argues at some length that the testimony of Garrett Charles Burris was sufficient to support a finding that Strong's injury resulted from vaccine-associated polio. (*Id.* at 100-05.) That argument is irrelevant, because Cyanamid's appeal does not challenge the sufficiency of Strong's case on that point.

Furthermore, Burris's testimony alone cannot support liability based on some obscure distinction between "proof of defect" and "defective condition." (*See id.* at 115-21.) Strong points to circumstantial evidence cases in which an injured plaintiff was able to establish that a product was defective notwithstanding the inability to identify the precise nature of the problem. (*Id.* at 116-20 (citing *Rauscher v. GM Corp.*, 905 S.W.2d 158, 160-61 (Mo. App. E.D. 1995); *Uder v. Missouri Farmers Assoc., Inc.*, 668 S.W.2d 82, 93 (Mo. App. W.D. 1984); *Williams v. Deere and Co.*, 598 S.W.2d 609, 611-12 (Mo. App. S.D. 1980); *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 446 (8th Cir. 2008)).) In

such cases, it is sometimes permissible to infer the existence of a defect from the mere occurrence of an unanticipated and otherwise unexplained injury. *See, e.g.*, *Williams*, 598 S.W.2d at 612 ("Common experience tells us that some accidents do not ordinarily occur in the absence of a defect and in those situations the inference that a product is defective is permissible.").

This case, however, is not a circumstantial evidence case. Strong *has* identified what he claims to be the precise "defective condition"—namely, the failure to test certain intermediate materials as allegedly required by FDA regulations. (*See, e.g.*, Resp. Br. 116.) Furthermore, it is undisputed that oral polio vaccine that fully complies with the FDA's regulations nevertheless carries with it a well-known, inherent risk of causing the very type of injury that occurred here. The mere fact of injury cannot give rise to any inference of defect.[8/] In a case like this one, Strong cannot rely on the specific defect that

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[8/] This is not and never has been a "design defect" case in which the use of attenuated live virus in the vaccine's design is under attack. The risk of contracting polio from oral polio vaccine is well understood, fully disclosed in the product's labeling, and uncontested in this case. *See, e.g.*, Def.'s Ex. 106B (package insert stating "[p]aralytic disease following the ingestion of live poliovirus vaccines has been, on rare occasion, reported in individuals receiving the vaccine, and in persons who were in close contact with vaccinees"); *see also Graham*, 350 F.3d at 512 ("All vaccines produced from live viruses, as this one is, carry the paradoxical risk of inducing the very disease that the

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he alleges without also introducing expert testimony sufficient to support a finding that the failure to test in fact rendered his vaccine more dangerous than it otherwise would have been. *See United States v. St. Louis Univ.*, 336 F.3d 294, 303 (4th Cir. 2003) (evidence that regulatory violation proximately caused defendant's polio "must be in the form of expert testimony"); *Missouri Farmers Ass'n v. Kempker*, 726 S.W.2d 723, 727 (Mo. banc 1987); *Mueller v. Bauer*, 54 S.W.3d 652, 656 (Mo. App. E.D. 2001).

To establish that the alleged regulatory violation proximately caused Strong's polio, therefore, he can look only to testimony provided by Bozzo. (Resp. Br. 105-15.) By any measure, that testimony was insufficient. (*See id.* at 28-36.)

To begin with, Bozzo was never even proffered to link the regulatory failures that he alleged to Strong's injury. (Cyanamid Br. 23, 29-30; *see also* Resp. Br. 90.) Nor was he proffered to testify that any failure to test rendered Cyanamid's product "unreasonably dangerous," although Strong now claims that he did so. (Resp. Br. 90-91, 107-09.) The two types of proof are, of course, really the same. If a regulatory violation did not increase the risk that Strong would contract polio from Cyanamid's vaccine, then any "defective condition" caused by the regulatory violation cannot be said to have made the

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vaccine strives to prevent."). This is a manufacturing defect case in which Strong must prove that, had the defect not existed, he would not have contracted polio from the vaccine.

product "unreasonably dangerous" (*id.*; *see also* Resp. Br. 106-07), just as it cannot be said to have "direct[ly] result[ed]" in Strong's injury (*see* Resp. Br. 96 (quoting jury instruction)). From either perspective, Strong needed an expert who could give the jury a well-founded basis for concluding that the claimed testing violations actually created "a danger elevated beyond the normal risk" that is inherent in any oral polio vaccine. (Resp. Br. 106-07.)

As a matter of law, Bozzo's testimony fails in this regard. Strong relies on the brief passage in which Bozzo said that omitting "safety tests" in general could "raise the possibility of a product being unsafe" to "the general public," plus a few cross-examination responses in which Bozzo refused to concede that he could *not* testify to any increased risk, without ever actually asserting that (or explaining how) he *could*. (*Id.* at 107-09 (quoting Tr. 686).) The vague affirmative testimony about "possibilit[ies]" is insufficient for reasons set out in Cyanamid's opening brief. (Cyanamid Br. 31-33.[9/])

[9/] Strong argues incorrectly that Cyanamid did not object to this testimony at trial and cannot complain of it now. (Resp. Br. 109-10.) Cyanamid objected repeatedly to Bozzo's testimony, to no avail. (*See id.* at 849-54.) Moreover, Bozzo was ultimately permitted to testify as an expert only on issues of regulatory compliance, not on their consequences to Strong. (*See* Tr. 636-38; *see also id.* at 604.) Timely objections overruled by the trial court preserve claims of error as to subsequent evidence of the same type. *See State ex rel. State Highway Comm'n v. Offutt*, 488 S.W.2d 656, 661 (Mo. 1972).

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The unexplained cross-examination responses add nothing of substance and cannot be used to save Strong from his failure to make out his affirmative case. Indeed, in the most substantive of those responses, Bozzo referred back to his deposition testimony for the general proposition that "lack of vaccine safety testing increases the problem with the safety of the product." (Resp. Br. 109 (quoting Tr. 626).) But as Cyanamid has explained, in that same deposition testimony (which was admitted at trial), Bozzo actually conceded that, while there might be a "*potential* association" between the regulatory violations that he alleged and "the polio case of the plaintiff, . . . *I am not in a position to say that that's what occurred*." (Cyanamid Br. 32-33 (quoting Tr. 849) (emphasis added).) Liability cannot be predicated on the testimony of an expert who expressly disclaims any ability to link alleged regulatory violations to the injury actually suffered by the plaintiff. And while Cyanamid highlighted this testimony in its opening brief (*id*.), Strong has nothing whatsoever to say in response.

Nothing in Strong's brief comes close to filling this fundamental gap in his proof. That is not surprising, because, as Cyanamid has also explained, in this case causation is not only unproven, but it is also affirmatively *excluded* by the proof. (Cyanamid Br. 33-34.) Strong bases his claim on a failure to test intermediate materials, but those are not

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Most importantly, even if the evidence was otherwise admissible, it remains insufficient as a matter of law to sustain the jury's verdict on causation.

what he received when he was vaccinated. Rather, he received vaccine made from three monopools which in turn were made from three production seeds, and all of those materials *were* satisfactorily tested. (Tr. 765, 774; *see also* Def.'s Ex. 39-41, 45-50, 54-56, 105A-H; Tr. 1644-76.) Bozzo conceded that there were no problems with any of these tests. (Tr. 758-59, 762, 764-65, 771, 774.) And if the production seeds and monopools had satisfactory levels of neurovirulence, then any precursor materials *must* have had satisfactory levels, too. (Tr. 1611 (trial testimony of Dr. Mary Ritchey); *see also id.* at 1712-15 (testing earlier components is not necessary to ensure safety when production seeds and monopools are tested).[10/])

[10/] Strong quotes Dr. Ritchey's testimony to suggest that testing on precursor components was necessary to assure safety. (Resp. Br. 28-29, 110-11.) But, in the cited passage, Ritchey testified only that if an end product is deemed *un*safe, that does not necessarily mean the precursor materials were *un*safe. (*Id.* at 28-29; Tr. 1757-58.) That is consistent with her testimony (and the FDA's position) that attenuated virus may become *more*—not less—virulent as additional passages are made. (*See* Tr. 1610-11 (If "the seed is attenuated, well, then the prior passage before will [have been] attenuated."); *see also id.* at 1712-15 (testing earlier components is not necessary to ensure safety when production seeds and monopools are tested).) That is why safety testing is performed at the final two stages, not earlier.

No doubt recognizing the force of this argument, Strong offers a new, theoretical reason why testing at earlier stages might nonetheless have enhanced safety. (Resp. Br. 28-29, 110-12.) Evidently, the notion is that because any given test sample might miss a few neurovirulent particles dispersed elsewhere in the lot under test, "the more testing done, the more likely the tests are to reveal the presence of non-attenuated . . . polio virus." (*Id.* at 112.) Even a cursory examination reveals that this theory makes little sense as support for *earlier* testing: Because each successive passage can only get *more* virulent, if there were any problem with tests not revealing virus that had lost its attenuation (and there is no evidence whatsoever of that here), then the logical solution would be to perform more tests on the *final* samples, not to test earlier samples that could only be more attenuated and thus *safer*. Moreover, in the long history of this litigation, Strong's new theory appears for the very first time in his appellate brief. Apart from its apparent weakness, it is unsupported by anything in the record (or in the FDA's regulations), not sponsored by any expert witness, and untested by deposition, *voir dire*, cross-examination, or evaluation by an opposing expert. It cannot be considered here, and it certainly cannot support the verdict in this case. *See Huter*, 439 S.W.2d at 745; *Christian Health Care*, 145 S.W.3d at 53.

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At its core, the issue of causation is straightforward. Relying as he does on the FDA's regulations as the standard by which Cyanamid's vaccine must be made, Strong must prove that a violation of those regulations rendered his vaccine less safe than it otherwise would have been, thus causing him to contract polio when he would not have

been injured had the violation not occurred. The only regulatory violation that Strong has claimed is Cyanamid's failure to test strains and intermediate materials. Although Strong presented expert testimony that he suffers from vaccine-associated polio, he has no testimony that the lack of testing on the early components of his vaccine made his vaccine less safe and more likely to cause polio than a vaccine made from strains and intermediate materials that had been tested. Without this necessary link, there is no causation as a matter of law. The judgment should be reversed and the case remanded with instructions to enter judgment for Cyanamid.

III. POINT III: STRONG HAS FAILED TO JUSTIFY THE EXCESSIVE VERDICT AND DOES NOT EVEN ADDRESS THE LACK OF EVIDENCE TO SUPPORT THE AWARD FOR FUTURE ECONOMIC DAMAGES.

Cyanamid recognizes that juries have wide discretion when it comes to fixing the amount of damages (*see* Resp. Br. 128), but this discretion is not boundless. Remittitur exists to remedy situations like this, in which the jury's award "exceeds fair and reasonable compensation for plaintiff's injuries and damages." *Lay v. P & G Health Care, Inc.*, 37 S.W.3d 310, 332-33 (Mo. App. W.D. 2000). Because Strong lacks evidence of *any* future economic damages, and his total award is far out of line with other cases, remittitur is appropriate in the event that the judgment here is otherwise affirmed.

There clearly was no evidence of future economic loss. Strong argues that from the testimony of his vocational expert, James England, "the jury could infer that at a minimum, Cortez's earning capacity had diminished substantially over his expected 47 year lifetime of work." (Resp. Br. 131-32.) Even if that were true, Strong ignores the

rule that an award of future economic damages must be reasonably certain, cannot be speculative, and must be supported by evidence that provides a jury with a *reasonable estimate* of the amount of loss. (*See* Cyanamid Br. 37.) The evidence to which Strong points—that certain jobs "might" be unavailable to him and that, for reasons unrelated to his injury, it may be difficult for him to get into several colleges (Resp. Br. 131)—fails to provide any estimate of his future economic loss, much less a reasonable one. Jurors do not inherently know how much various vocations are likely to pay. The jury simply accepted the $2 million figure for future lost earnings that Strong's counsel argued—for the first and only time—in his summation. There was no actual *evidence* to support this aspect of damages.[11/]

[11/] Strong tries to pull together all numerical values mentioned in England's testimony in an attempt to show some kind of evidentiary support for the jury's award of $2 million for future lost earnings award. (*See* Resp. Br. 131.) These values are explicated in the brief as $6-8 in hourly wages for unskilled jobs currently available to Strong and $20 in the highest hourly wages that "might be available to him but for his disability." *Id.* Even when tallying these hypothetical values and accounting for the most generous $14 difference between the highest and lowest possible hourly wages, at 40 hours per week, 52 weeks per year (without accounting for vacations or holidays), over a 47-year career (the duration of work that Strong mentions for the first time in his post-trial briefs), the difference comes out to $1,368,640. While this figure is speculative, at

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The total $8.5 million award also is not in line with other cases, which, contrary to Strong's argument (*see id.* at 132-33 (comparable cases "are of little guidance")) are critical to this Court's review. *See, e.g.*, *Alcorn v. Union Pac. R.R. Co.*, 50 S.W.3d 226, 250 (Mo. banc 2001); *Redfield v. Beverly Health & Rehab. Servs., Inc.*, 42 S.W.3d 703, 713 (Mo. App. E.D. 2001). Strong attempts to address *Alcorn* and *McCormack v. Capital Elec. Constr. Co.*, 159 S.W.3d 387 (Mo. App. W.D. 2005), arguing that these cases support his $8.5 million verdict. (*See* Resp. Br. 132.) He is wrong. Alcorn's injuries—for which she received $25 million in noneconomic damages—are not comparable to Strong's. She had "over 20 broken bones, significant blood loss, and a traumatic head injury." *Alcorn*, 50 S.W.3d at 234. This led to cardiac arrest, and she spent 40 days in the hospital and lapsed into a coma for several days. *See id.* Moreover, her "vision ha[d] been diminished, she suffer[ed] from a permanent mood disorder and depression, she

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best, it does show that the jury's award of $2 million for future economic damages was not based on any numerical values mentioned during James England's expert testimony, nor any numbers that Strong's brief now discusses. Rather, $2 million was the precise figure Strong's counsel requested in his closing argument, without justification and without evidentiary basis. It is an award that can be explained only by the jury's sympathy for Strong combined with the prejudice Strong's counsel created against Cyanamid.

suffer[ed] from chronic pain, her cognitive abilities ha[d] decreased, and she [was] unable to care for herself." *Id.* None of this is true of Strong, and the award Alcorn received is not a legitimate comparison.

Likewise, Strong's injuries cannot be fairly compared to McCormack's. The latter was permanently disabled and unemployable, had no control of his bodily functions, and suffered brain damage and sexual dysfunction. *See McCormack*, 159 S.W.3d at 395-96. Strong is able to work, does not suffer from any of these profound ailments, and testified that, unless he tells people, they sometimes do not even realize that he has any disability. (*See*, *e.g.*, Tr. 1489-90, 1492, 1494-95.) Other than the fact that both McCormack and Strong received virtually identical awards (with Strong's being *larger*), the two cases are not comparable. While no one denies that Strong's weakness in one arm and slight weakness in his hands are real and significant injuries, they are simply not in the same category as McCormack's or Alcorn's injuries and do not reasonably warrant an award of $6.5 million in non-economic damages.

Finally, Strong ignores the cases that reflect far lower damage awards for injuries more comparable to Strong's. (*See* Cyanamid Br. 39-40.) Nor does Strong address Cyanamid's argument that the Court should order a new trial because of the repeated prejudicial evidence that was admitted, over Cyanamid's objections, leading to an

excessive verdict. (*See id.* at 41-44.[12/]) If this Court does not reverse the judgment in favor of Strong, it should at the very least remit the damages here or, in the alternative, order a new trial.

[12/] Rather, in the opening of his brief, Strong cites *Morrissey v. Welsh Co.*, 821 F.2d 1294 (8th Cir. 1987) (*see* Resp. Br. 127), without mentioning that the court in *Morrissey* remanded the case for a new trial on the issue of damages, specifically because of prejudicial evidence that led to the jury's presumably excessive award. *Id.* at 1302-03 ("[B]ecause we find prejudicial error in plaintiff's opening and closing statement, we find the sum awarded must be set aside and a new trial on damages must follow.").

RESPONSE TO STRONG'S CROSS-APPEAL

(RESPONDS TO RESPONDENT/CROSS APPELLANT'S POINT RELIED ON V.)

Strong claims that he is entitled to prejudgment interest because he invoked § 408.040 RSMo. (1991) in a letter to Cyanamid. The trial court denied Strong's motion for prejudgment interest. For several reasons, an award of prejudgment interest is improper here. In the event that the Court determines that Strong may be entitled to such interest, it should order that a hearing be held to determine whether to award it.

I. STATEMENT OF FACTS.

Strong filed his case in late 1999; it was tried five and a half years later. On July 7, 2001, Strong sent a letter to Cyanamid offering to settle the case for $1.4 million. This letter invoked § 408.040. In the four years following this offer, Strong made several subsequent demands, ultimately reducing his demand to $1.2 million. These subsequent demands were made orally and neither cited § 408.040 nor complied with it.

In the nearly four years between the first offer on July 7, 2001, and the entry of judgment on May 26, 2005, Cyanamid repeatedly sought to push the case forward. Strong, by contrast, let this case languish for months, through, among other things, a failure to schedule depositions, propound new discovery, and move to resolve purported "discovery disputes." On several occasions, Cyanamid filed motions to enter scheduling orders to force Strong either to complete discovery or to file motions with respect to any discovery issues that were still outstanding, to compel expert disclosures and expert depositions, and to set a firm trial date. (*See*, *e.g.*, LF XXIII:4136-38; LF II:207-13 (reiterating the history of Strong's delay and requesting a date certain for expert

depositions to commence).) On each occasion, Strong claimed that the case could not go forward until he received yet more discovery, after which Strong simply ignored the court-ordered schedules.[13/]

[13/] *See, e.g.*, LF XXIII:4152 (Letter from Cyanamid attorney Gregory S. Chernack to Strong attorney Stanley P. Kops (April 28, 2003) ("This case has been characterized by two things over the past two years: Defendants' efforts to move it forward, and Plaintiff's efforts to avoid expert discovery by complaining that you needed more fact discovery while doing *nothing* to pursue any such further discovery until we force the issue. Now, another two months has passed since the March 4 hearing, and Plaintiffs have done *nothing* to pursue the additional discovery that you claim was needed.")); LF XXIII:4155 (Letter from Chernack to Kops (Jan. 23, 2003) ("Your letter appears to be a continuation of your effort both to continue to postpone expert discovery in this case and to continue to use this case to obtain discovery of matters that have no possible relevance here for use in other litigation—a practice for which Judge Rea recently rebuked you in the Horwin case pending in California.")); LF XXIII:4157 (Letter from Chernack to Kops (Dec. 6, 2002) ("[Y]ou still have not offered any dates for Dr. Verzilli's deposition[.]")); LF II:219-24, 230 (Defendant's Motion to Quash Plaintiff's Notice of Deposition of Corporate Designee (reiterating the history of Plaintiff's delay)); LF XXIII:4183 (American Cyanamid Company's Opposition to Plaintiff's Motion to Compel (July 10, 2002) ("Plaintiff's motion, made at a time that the parties should be

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After judgment was entered in this case, Strong moved to amend the amount of the verdict to add prejudgment interest. (*See* LF XXIII:4092.) Cyanamid opposed this motion, arguing that § 408.040 should not apply here and that if prejudgment interest were to be awarded, then the court, consistent with basic principles of due process, would have to hold a hearing. (*See* LF XXIII:4129-32.) The court denied Strong's motion. (*See* LF XXIII:4195.)

II. THE PREJUDGMENT INTEREST STATUTE SHOULD NOT BE APPLIED IN THIS CASE.

This Court has observed that a settlement offer made pursuant to § 408.040 is "analogous to an offer in contract." *See Brown v. Donham*, 900 S.W.2d 630, 633 (Mo. banc 1995). Under basic principles of contract law, once a new offer is made, the original offer is revoked and superseded. *See*, *e.g.*, *Travis v. Nederland Life Ins. Co.*, 104 F. 486, 489 (8th Cir. 1900); *see also* 1 Richard A. Lord, Williston on Contracts § 5:8 at 668-69 (4th ed. 1990); 1 Joseph M. Perillo, Corbin on Contracts § 2.20 at 229 (rev. ed. 1993).

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engaging in expert discovery to bring this matter to a close, should be denied. It is meant to do nothing more than delay.")).

In this case, Strong made several offers subsequent to July 7, 2001, none invoking § 408.040 and none triggering that statute. Once Strong made a new offer, the prior one was revoked as a matter of law, and there was no reason for Cyanamid to deal with any portion of that prior offer. *See, e.g.*, *Wilson v. Wal-Mart Stores, Inc.*, 72 Cal. App. 4th 382, 389-90 (Cal. App. 1999) (holding that California's prejudgment interest statute, which is virtually identical to Missouri's, applied "the general contract principle that any new offer made prior to a valid acceptance of the prior offer, extinguished the prior one"). Strong could have complied with the statute when he made subsequent demands, but he did not do so.

Cyanamid recognizes that there is authority, cited by Strong, which holds that once a settlement demand is made pursuant to § 408.040.2, "it is immaterial whether plaintiff made any subsequent offers of settlement." *Lester v. Sayles*, 850 S.W.2d 858, 874 (Mo. banc 1993); *see also McCormack*, 159 S.W.3d at 402. However, neither of these decisions discussed the impact of a subsequent offer that fails to invoke the prejudgment interest statute. In *Lester*, the court did not characterize the subsequent settlement demands, 850 S.W.2d at 872-74, while *McCormack* addressed the unusual question whether prejudgment interest should be awarded when the settlement demand exceeds the jury's award after the first trial but not the award made in a retrial, 159 S.W.3d at 402-03. Extending the language of *Lester* to this case—where Strong has revoked his initial offer—would run counter to established principles of contract law. The Court should consider whether *Lester* should be read to cover the new offers of settlement made here.

III. THE LANGUAGE OF THE STATUTE DOES NOT SUPPORT THE AWARD OF PREJUDGMENT INTEREST ON FUTURE DAMAGES.

Section 408.040 serves two policies: "(1) it compensates claimants for the true cost of money damages they have incurred due to the delay of litigation; and (2) it promotes settlement and deters unfair benefit from the delay of litigation." *McCormack*, 159 S.W.3d at 402. There can, however, be no loss to a claimant and hence no benefit to a losing party from delay on an award of future damages, because the jury awards such damages based upon the value of the injury at the time it renders its verdict. To apply prejudgment interest to the entire award here would improperly overcompensate Strong. *See, e.g., Gonzalez v. Tounjian,* 665 N.W.2d 705, 719 (N.D. 2003) ("An award of prejudgment interest on future damages back to the date of injury ignores the underlying rationale for reducing such damages to present value and would constitute a windfall to the plaintiff. We conclude that interest on future damages should not be awarded in a tort case."); *John's Heating Serv. v. Lamb,* 46 P.3d 1024, 1041 (Ak. 2002) ("A jury award for future damages is discounted to present value as of the date of the verdict to reflect the fact that the damages are made part of a recovery before they would otherwise accrue. In this way, 'the financial impact of the passage of time [is] incorporated into the jury's damage award, [and] any award of prejudgment interest on this amount would therefore constitute a double recovery.'" (quoting *Sebring v. Colver,* 649 P.2d 932, 936 (Ak. 1982))); *Alvarado v. Rice,* 614 So. 2d 498, 499 (Fla. 1993) ("It is well settled that a plaintiff is entitled to prejudgment interest when it is determined that the plaintiff has suffered an actual, out-of-pocket loss at some date prior to the entry of judgment.").

Although the Court in *Lester* stated "that prejudgment interest shall be based 'on *all money due* upon any judgment or order,'" 850 S.W.2d at 874 (emphasis added), the Court was quoting from § 408.040.1, a section that specifically deals not with prejudgment interest, but rather with *post-judgment* interest. Section 408.040.2, the provision at issue here, does not contain that language. That the legislature used different words in these two provisions demonstrates that pre-judgment and post-judgment interest should be treated differently, particularly because, unlike with post-judgment interest, the purpose of the statute would not be served if prejudgment interest were available on the entire award. *See Thatcher v. Trans World Airlines*, 69 S.W.3d 533, 543 (Mo. App. W.D. 2002). Imposing prejudgment interest to cover future damages makes no logical sense and is inconsistent with the statute itself.

IV. AWARDING PREJUDGMENT INTEREST WITHOUT A HEARING TO DETERMINE WHETHER STRONG WAS AT FAULT FOR THE DELAY WOULD SUBVERT THE PURPOSES OF THE STATUTE AND RENDER IT CONSTITUTIONALLY INFIRM.

Section 408.040 seeks to ensure that prevailing parties are fully compensated while attempting to promote settlement by preventing a party from benefiting from its delay. *See McCormack*, 159 S.W.3d at 402. Awarding Strong millions of dollars in prejudgment interest would subvert both of these purposes while rewarding him for *his* delay and encouraging others to engage in the same dilatory tactics.

Notwithstanding Strong's claims that the prejudgment interest statute is mandatory, the Missouri Supreme Court has twice declined to decide whether a plaintiff's delay

should affect its application. *See Smith v. Shaw*, 159 S.W.3d 830, 835-36 (Mo. banc 2005); *Lester*, 850 S.W.2d at 873. Here, the issue is squarely before this Court. To further the purposes of the statute, a hearing should be required before Strong is awarded any prejudgment interest.[14/] If it were determined that Strong lengthened the life of this litigation, Strong's award would have to be reduced or eliminated based on any delay that

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[14/] Contrary to the ruling of the Court of Appeals, Cyanamid has not waived its constitutional right to a hearing on the question whether Strong's delays in this case should offset any award of prejudgment interest. Cyanamid requested a hearing at the first logical time that it could—when Strong filed his motion for pre-judgment interest after the jury verdict. Any request for a hearing prior to the time would have been premature. Likewise, the appellate court was incorrect when it stated that the issue has not been properly preserved for appeal because the trial court had not ruled on § 408.040's constitutionality. In *Missouri Highway and Transp. Comm'n v. Merritt*, 204 S.W.3d 278, 284 (Mo. App. E.D. 2006), the case that the Court of Appeals cites for this proposition, the constitutional challenge was brought for the first time in the Court of Appeals. Here, the issue was raised in the trial court in the first instance, but because the court denied Strong's motion for prejudgment interest, it had no reason to rule on the constitutional issue.

he caused.[15/] In the event that the Court concludes that the statute does not allow for a hearing, the statute should be deemed unconstitutional on the grounds that it denies Cyanamid its due process rights under Section 1 of the Fourteenth Amendment of the United States Constitution and Article I, Section 10 of the Missouri Constitution by depriving Cyanamid of its property without affording it a hearing. *See Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 437 (1982) (due process requires "an opportunity. . . granted at a meaningful time and in a meaningful manner for a hearing appropriate to the nature of the case" (quotation marks omitted)); *Belton v. Bd. of Police Comm'rs*, 708 S.W.2d 131, 137 (Mo. banc 1986) (a party is entitled to a hearing before being deprived of its property, as long as the property interest is not *de minimus*); *see also*

[15/] Strong has previously attempted to place blame for the delay on Cyanamid, citing three writs of prohibition that Cyanamid sought during the litigation. Unlike Strong's actions, which deliberately postponed discovery over a period of four years, Cyanamid's application for these writs sought legitimate, speedy relief from two specific orders of the trial court. One, seeking preclusion of an order that would require Cyanamid to produce, in violation of federal law, the names of persons who reported adverse reactions to its polio vaccine, was issued one month after its filing in October 2001. (*See* ED No. 80206 and Order.) The other two, seeking relief from an order denying summary judgment, were filed in April 2005—after completion of discovery—and were both answered within one month. (*See* ED 86097 and Order; SC 86749 and Order.)

Cox Health Sys. v. Div. of Workers' Comp., 190 S.W.3d 623, 629-30 (Mo. App. W.D. 2006).

CONCLUSION

The trial court's judgment against Cyanamid should be reversed, and the case should be remanded for entry of judgment in Cyanamid's favor. If the judgment against Cyanamid is affirmed, damages should be reduced, and the trial court's judgment denying prejudgment interest should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned counsel hereby certifies pursuant to Rule 84.06(c) that this Appellant's Substitute Reply and Cross-Respondent's Brief: (1) contains the information required by Rule 55.03; (2) complies with the limitations contained in Rule 84.04(g); and (3) contains 11,306 words, exclusive of the Sections exempted by Rule 84.06(b)(2) of the Missouri Rules of Civil Procedure based on the word count which is part of Microsoft Office Word 2003. Finally, the undersigned certifies that the diskette accompanying this Appellant's Substitute Reply and Cross-Respondent's Brief under Rule 84.05(a) has been scanned for viruses using Trend Microscan and is virus-free.

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I do hereby certify that I have on this 2nd day of July, 2008, caused a copy of the foregoing pleading to be served by first class mail, postage prepaid, on the following:

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APPELLANT AMERICAN CYANAMID COMPANY'S
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