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LITIGATING TOXIC SHOCK SYNDROME: LESSONS TO BE LEARNED

MARC STEVEN COLEN

Kern & Wooley, 10920 Wilshire Blvd., Suite 1500, Los Angeles, California 90024 (U.S.A.)

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Summary

An analysis of *West versus Johnson & Johnson Products, Inc.*, an important case involving toxic shock syndrome, was performed in order to determine if any lessons could be learned that would be applicable to toxic tort litigation in general. A detailed analysis of the facts of the case as well as background on toxic shock syndrome is presented. A number of important conclusions were drawn, concerning (1) manufacturer liability arising out of a design effect theory involving a product which is, by itself, relatively sterile and chemically inert, (2) defective warning (as distinct from failure to warn), and (3) punitive damage liability arising from inadequate testing. These conclusions should assist certain manufacturers to minimize their exposure in toxic tort litigation, particularly to punitive damages. The failure to introduce proper defense theories during trial is also discussed.

Introduction

The case of *West vs Johnson & Johnson Products, Inc.*, 174 Cal. App. 3d, cert denied 107 S.Ct.96 (1985), provides excellent insight into considerations in a toxic tort case involving a consumer product. In this case, the plaintiff, West, allegedly contracted toxic shock syndrome (TSS) while using a vaginal tampon manufactured by the defendant, Johnson & Johnson Products, Inc. (JJP). The action was based upon a strict products liability theory.[1] Her specific allegations were as follows:

1. the tampons were defective in design;
2. the instructions provided with the product were defective; and
3. JJP was negligent in its testing of the product.

The jury found for West and awarded $500,000 in compensatory damages

*The views expressed in this paper are those of the author and are not necessarily those of this firm.

[1]This type of theory is available in most, but not all, states. For a discussion of the strict liability theory in the context of toxic tort litigation, see M.S. Colen, Causation and the Defense of Toxic Tort Litigation, J. Hazardous Materials, 15 (1987) 57.

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and a staggering $10,000,000 in punitive damages. JJP moved for a new trial and a new trial was ordered unless West agreed to accept a reduction in compensatory damages to $100,000 and a reduction in punitive damages to $1,000,000. The Court of Appeal confirmed the decision.

Several interesting issues arose in this case, which issues are potentially highly significant to any company subject to toxic tort litigation. First, West proceeded on a design defect theory, which is somewhat unusual in toxic tort litigation.

Secondly, the Court of Appeal affirmed the trial court's determination that punitive damages, albeit reduced, were appropriate in this case based upon the evidence that JJP failed to adequately test the product.

Thirdly, the "consumer expectation" test was used to determine design defect rather than the risk-benefit analysis which JJP stated they desired, but only during the appeal.

Crucial to an understanding of the above delineated issues in the context of this case is a detailed analysis of the factual material presented to the fact determining body, the jury, during the trial. That factual analysis, including background information concerning toxic shock syndrome, will be presented first. This is followed by discussions of the three primary issues.

Toxic shock syndrome

Toxic shock syndrome (TSS) was first identified in 1978 by Dr. James K. Todd of the University of Colorado. Later retrospective studies indicated that the syndrome had been around for many years but had simply not been recognized as such.

Early in 1980 the federal Center for Disease Control in Atlanta, Georgia (CDC), began receiving reports from physicians and from state health departments about a purportedly new disease. The CDC was astounded to learn that approximately 97% of the cases reported involved menstruating women. According to these reports, typical symptoms were as follows:

1. fever with temperatures to 107 degrees fahrenheit (41.7°C);
2. shock;
3. extremely low blood pressure;
4. skin rashes;
5. liver abnormalities; and
6. kidney abnormalities.

Because the prevelance of the phenomenon was increasing, the CDC organized a task force to investigate and study it. By May 1980, approximately 55 cases had been reported and, of these, approximately 10% resulted in death.

The CDC task force began its work by drafting a restrictive definition of the new disease, refining the above delineated symptoms. The following factors were included in the profile:

1. temperature of at least 102 degrees fahrenheit (38.9°C);
2. sunburn-like rash, usually all over the body;
3. desquamation[2] occurring 7 to 10 days after the malady subsided;
4. abnormally low blood pressure;
5. diarrhea;
6. vomiting;
7. muscle pain;
8. liver abnormalities; and
9. kidney abnormalities.

On May 23, 1980, the CDC published a report which indicated that there was a strong correlation between this new disease and menstruation. On June 27, 1980, the CDC published a second report which stated that there was a close relationship between the disease and tampon use.

Prior to the second report, in the middle of June, the CDC invited tampon manufacturers to Atlanta, Georgia, to learn of its findings. Since the CDC knew very little at the time about tampons, it asked the manufacturers for information concerning the following:

1. how tampons were manufactured;
2. how tampons were marketed;
3. data on vaginal physiology; and
4. data on vaginal microbiology.

The manufacturers, including JJP, offered little.

The CDC then undertook its own microbiological studies. In only three to four weeks, it was determined that the symptoms of TSS are caused by a toxin secreted by *Staphylococcus aureus*. It had been known for at least fifty years before that *Staphylococcus aureus* commonly occurs in the vaginas of a certain but small percentage of women.

The CDC went on to recommend that those women that wished to avoid the risk of menstrually associated TSS[3] should stop using tampons. For women that continued to use them, the CDC recommendation was that they be used only part of the time. Last, the CDC recommended that warnings be placed on tampon packages concerning the risk of TSS.

Relevant facts of the instant case

West's injury

In February 1980 (prior to the CDC reports), West was a 20-year-old student living with her parents. During the weekend of February 23 and 24, her regular menstrual cycle began. As was her custom, she used "o.b. tampons" manufac-

[2]Desquamation is peeling of the skin.

[3]There are other causes of TSS. Studies have shown that the syndrome affects adult men and women as well as children.

tured by JJP. On the evening of February 26, 1980, West had a date to go to a concert. She prepared for the date and inserted a fresh o.b. tampon. She was asymptomatic through dinner and the first part of the concert.

During the latter part of the concert she became "very hot and very light headed, and just started feeling kind of faint — very drained." She walked around the hall, got a drink of water and then returned to her seat. The symptoms returned and her date brought her home.

The next day, West was worse and decided to stay home in bed. She thought that she had the flu. West continued to use tampons throughout this time, although at trial she was unable to testify as to whether she changed tampons that day. In the evening she began to vomit and to lose control of her bowels.

On the morning of the next day, February 27, West collapsed on the floor and was unable to move. Her parents carried her to their car and brought her to a local hospital emergency room. Initial examination revealed the following:

1. abnormally low blood pressure;
2. a temperature of 104.4 degrees fahrenheit (40.2°C);
3. chills;
4. vomiting;
5. pronounced reddening of the skin;
6. accelerated heartbeat; and
7. swollen tonsils with exudate.

A throat culture revealed the presence of beta-hymolytic streptococcus in West's throat but both the vaginal and rectal cultures produced negative results.

West was transferred to the hospital intensive care unit and given intravenous fluids and antibiotics, including penicillan. On the morning of February 29, her blood pressure began to rise. However, her creatinine level continued to rise, indicating renal malfunction. Over the next few days her condition stabilized and on March 4 she was discharged.

Shortly thereafter, the skin on the palms of her hands and soles of her feet began to peel in large chunks, but this soon subsided. She stayed home about one week then resumed attending school, although her full strength and endurance allegedly did not come back until several months later.

At the time of discharge, there was no definitive diagnosis. She was seen again at the hospital on March 27 and on June 30. By that time West appeared to have no residual damage as the result of her illness.

It was only some months later that her physicians read reports published by the CDC which led them to conclude that West had suffered from TSS. West was told of this belated diagnosis. This litigation resulted.

The product in suit

The o.b. tampon was originally designed in Germany and marketed through Western Europe since the late 1940s by the Carl Hahn Company, a German

firm and a wholly owned subsidiary of JJP's parent corporation, Johnson & Johnson, Inc.

The product was composed of 70% rayon and 30% cotton, with a small amount of surfactant added to prevent buildup of static electricity in the fibers. The tampon fibers themselves were intertwined, rolled, and compressed to maximize their natural capillary capabilities. The resulting tampon was highly absorbent. As it absorbed menstrual fluid, the o.b. tampon expanded radially and pushed against the user's vaginal walls. Unique among tampons, the o.b. tampon had no applicator or inserter. The user inserted it with her fingers alone.

In 1974 o.b. tampons were imported into the United States and test marketed. In 1977 JJP began manufacturing o.b. tampons in the United States and marketing them nationwide.

Premarket scientific investigation and testing

In 1971 through 1973, prior to importation of the o.b. tampon to the United States, several studies were conducted by the microbiology department of another Johnson & Johnson, Inc. subsidiary in order to explore and define the numbers and types of bacteria present in the vagina both before and during the menstrual period.

These studies disclosed, among other things, that the interior of a normal healthy adult vagina is a slightly acidic environment in which most pathogenic bacteria will not grow. With the onset of menses, the interior of the vagina ceases to be acidic and becomes neutral or even slightly alkaline. When that happens, the bacteria in the vagina flourish, including staphylococci. Some of the bacteria are pathogenic. The menstrual fluid was found to provide a rich nutrient medium for the bacteria. When the menstrual flow ceases, the interior of the vagina returns to its normal slightly acidic state and the bacterial level diminishes. The studies also revealed that about six percent of the women tested had *Staphylococcus aureus* in their vaginas.

During 1975 and 1976, the same Johnson & Johnson, Inc. subsidiary conducted additional tests using experimental o.b. tampons produced by the Carl Hahn Company which had an additive which was intended to maintain the acid balance in the vagina during menstruation and thus reduce the bacteria level. The project was dropped because the preliminary results did not indicate a significant difference in results when using the new tampon.

However, the studies did reveal two significant things. First, the total bacteria level in the vagina dropped markedly during the first days of menstruation when an o.b. tampon (untreated or treated) was in place. This indicates that the tampon absorbs bacteria. Secondly, sloughing by the o.b. tampon occurs such that small fibers are left behind in the vagina.

JJP went forward and prepared for the manufacture in the United States of the o.b. tampon by attempting to duplicate the German product. Domestic

cotton and rayon of the same grade as the German product were selected. Certain tests were performed, although the precise nature of all of these was not brought out at trial. However, we know that one of these tests was a patch test to see if there was any allergic reaction to skin contact.

Up to the time of trial JJP had not conducted any studies to ascertain whether the use of tampons was in any way related to vaginal infection.

Consumer complaints

JJP began receiving complaints about o.b. tampons from consumers and physicians in 1975, most of which consisted of complaints related to adverse reactions experienced in the use of the product. JJP attempted to communicate with the complaining party and, if communication and cooperation were established, JJP would typically ask for the return of the remaining portion of the box of tampons. These were tested for manufacturing defects, that is, discrepencies from the manufacturing specifications for size, shape and durability. Depending on the consumer's preference, JJP would send either a refund or a coupon for more o.b. tampons or other JJP products. The complaints did not, however, induce JJP to do any further testing.

The defect in design issue

The trial in this matter took place in November and December of 1982. At that time, the precise mechanism by which tampons contributed to menstrually related TSS had not yet been proven. JJP argued that,

1. West did not have TSS. JJP argued that *S. aureus* is resistant to penicillin and the other antibiotics given to West while streptococcus is not. JJP also stated that the symptoms were consistent with the alternative diagnosis of streptococcal scarlet fever.
2. The tampons by themselves did not cause TSS.
3. The o.b. tampons were not defective in any way.

West's experts testified to the contrary and particularly as to how the o.b. tampon was defective in design and how those defects contributed to the incidence of TSS. Their testimony was to the effect that,

1. A tampon (any type) is essentially a body foreign to the vagina and as such decreases the effectiveness of the white blood cells in attacking pathogenic bacteria. As a result, bacteria flourish and additional toxins are secreted.
2. The highly absorbent quality of the o.b. tampon is, in and of itself, a defect, exacerbated by the addition of the surfactant which increases the ability of the tampon to absorb fluid. With the increased quantity of fluid in the tampon comes a concommitant increase in pathogenic bacteria, since the fluid in the tampon is an excellent culture medium.
3. The radial expansion is a defect since it fully occludes the vaginal canal

and becomes a plug which is analogous to an abscess. The expansion also contributes to the sloughing phenomena discussed above. The fibers left in the vagina become breeding sites for pathogenic bacteria.

4. The mesh-like network of fibers in the o.b. tampon is a further defect since that network serves to inhibit white blood cells from attacking pathogenic bacteria inside of the tampon.
5. The fact that an o.b. tampon is inserted by hand is yet another defect inasmuch as any pathogenic bacteria on the hand of the user will be inserted into the vagina.
6. The manufacturer's instructions, which recommended leaving the o.b. tampon in until it is nearly saturated, induces the user to leave the tampon in longer than is safe.
7. Causation was addressed by the several experts in varying ways, but all concluded that the tampon *was* a critical factor in West's injuries.

The jury clearly believed West's experts and not JPP's. Neither the trial court judge nor the Court of Appeal found their judgement to be baseless.

It is very interesting that a product which is by itself relatively sterile (at least as packaged) and relatively chemically inert was found to be defective in design in a toxic tort case. Clearly, a manufacturer must give very serious consideration to the potential interaction between its product and any other substances with which it may foreseeably come in contact.

Note that the warning issue was identified as a design defect, rather than as the more conventional failure to warn. Just as failure to warn may lead to liability for a manufacturer, weaknesses or errors in the wording of the warning will similarly do so. Great care must be given to warnings; all warnings should be analyzed for the worst case situation where they are read to a jury (or other trier of fact) after someone has been injured and it is possible that the injury could have been prevented by the use of a different warning.

Punitive damages issue

It is on the basis of conscious disregard for public safety that punitive damages were awarded. JJP's and West's experts of course disagreed as to whether menstrually related TSS could have been discovered prior to June 1980 and as to whether additional testing of o.b. tampons would have revealed an association between their use and the occurrence of TSS.

JJP's experts testified as follows:

1. menstrually caused TSS is caused by a "newly emergent" strain of *S. aureus* which appeared in the 1970s;
2. the toxin produced by that strain was not isolated until 1980;
3. there was no way, prior to February 1970 that anyone could have predicted the connection between TSS and tampons;

4. the o.b. tampon had been adequately tested prior to its introduction in the United States; and
5. the consumer complaints did not justify further testing.

West's experts testified otherwise, as follows:

1. the strain of *S. aureus* involved, although rare, had been around for a long time (indeed, they testified that cases of menstrually related TSS incidents occurred as far back as 1947);
2. had appropriate testing been done, then TSS would have been recognized much earlier than 1980;
3. examination of JJP files revealed that JJP had never done any significant preliminary studies on the basic microbiology of the human vagina;
4. when faced with numerous complaints, further testing should have been initiated to ascertain whether o.b. tampons contributed to or caused vaginal infections; and
5. the 1975–1976 studies done by the Johnson & Johnson, Inc. were insufficient inasmuch as they used an inadequate sample size, improper sample selection and ignored crucial areas that should have been investigated.

On this issue as well, the jury found for West, believing her experts over those of JJP.

The lessons to be learned here are threefold. First, extensive testing (preferably *in vitro* or in human subjects rather than the arguably irrelevant animal testing[4]) is vital to minimize the probability of punitive damages liability, which may run into millions of dollars. Secondly, excuses such as that an analysis could not be done is somewhat less than convincing when, as here, someone else succeeds in performing the analysis in only a few weeks! Thirdly, consumer complaints should be carefully scrutinized in order to ascertain the necessity of further testing.

Consumer expectation test rather than risk-benefit analysis

At the request of West, the trial court presented the following instruction to the jury:

> "The manufacturer of a product is liable for injuries a proximate cause of which was a defect in its design which existed when it left possession of the defendant provided that the injury resulted from a use of the product that was reasonably foreseeable.
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> "A product is defective in design if the product failed to perform as safely as an ordinary consumer of the product would expect when used in a manner reasonably foreseeable by the defendant."[5]

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[4]See, e.g., Sackett, The Diagnosis of Causation, at. p. 107, in Epidemiological Issues in Reported Drug Induced Illnesses, McMaster University Press, 1978; Oser, The Rat as a Model for Human Toxicological Evaluation, J. Toxicol. Environ. Health, (October 1981) 521–522; Higginson, Chronic Toxicology: An Epidemiologists Approach to the Problem of Carcinogenicity, in Essays Toxicol., 7 (1976) 32.

[5]This is a modification of California standard jury instruction BAJI No. 9.00.5.

The trial court further instructed the jury that West had the burden of proving that the o.b. tampon,

> "was defective in that it failed to perform as safely as an ordinary consumer would expect."

These instructions were based upon one of the two tests for determining whether a product is defective in design that were presented in the seminal case of *Barker vs Lull Engineering Co.*, 20 Cal.3d 413 (1978).

JJP claimed on appeal that the trial court had erred in giving the above instruction and should have given the alternative instructions based upon the risk-benefit test.

Under the risk-benefit theory, for the plaintiff to prevail, the plaintiff must prove that the product's design proximately caused his injury and the *defendant* must have *failed* to prove that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such a design.

It is clear why JJP would want the risk–benefit theory to apply. The specific factors that would have to be considered under this *Barker vs Lull* test include the following:

1. whether a safer alternative design existed;
2. whether the cost of the alternate design was prohibitive; and
3. whether there would have been adverse consequences to the product and to the consumer from the alternative design.

JJP could have made arguments regarding all of these.[6]

However, JJP made what may have been two fatal errors during the trial. First, it appears that JJP did not even request that a risk-benefit instruction be given. It is up to the litigants to delineate all of the instructions that they desire that the court provide to the jury.

Second, JJP failed to produce *any* evidence regarding the above delineated factors that would have had to have been presented in order for them to have prevailed under the risk–benefit test, even if risk–benefit instructions had been given to the jury instead of the consumer expectation test instructions.

This lesson is one for the attorneys rather than for the manufacturer. While hindsight after a jury verdict and/or appellate decision is infinitely better in assessing what arguments should have been made, all possible methods of defense must be considered.[7] JJP believed, at least at the appellate level, that had the risk–benefit test been used, the result would have been different. If they had introduced the correct evidence, it is possible that the result would, indeed, have been different.

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[6]The author is not stating that such was indeed the case, but merely that an argument to that effect could be made.

[7]For a general discussion of techniques of defense of the causation aspect of toxic tort litigation, see Colen, *op. cit.*

Conclusion

The analysis of *West vs Johnson & Johnson* has permitted a number of important conclusions to be drawn to any manufacturer who may find itself involved in toxic tort litigation. One of the discoveries was that even a product which is itself relatively sterile and chemically inert could be found to be defective in design in a toxic tort case. This leads to the requirement that a manufacturer give very serious consideration to the potential interaction between its product and any other substances with which it may foreseeably come in contact, even if the product itself appears to be innocuous.

It has also been shown that it is vitally important for a manufacturer to carefully scrutinize the wording of any product warnings. Improper or otherwise defective warnings may result in the same liability in a design defect allegation as results from the more conventional allegation of failure to warn.

The punitive damage issue revealed three points concerning testing of products. First, extensive and proper testing is vital to minimize the probability of punitive damages liability, which may run into many million of dollars. Secondly, excuses such as that an analysis could not be done is less than convincing when, as in the instant case, someone else succeeds in performing the analysis in only a few weeks. Thirdly, consumer complaints should be carefully reviewed in order to ascertain if further testing is appropriate.

Lastly, there is a lesson for the attorneys taking this type of case to trial. All possible methods of defense must be considered. If JJP had introduced the correct risk–benefit evidence, it is indeed possible that, as JJP argued on appeal, the result would have been different.