IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

WINSTON MENDEZ MONTES DE OCA, et al.,

Plaintiffs,

v.

ADVENTIS PHARMA, et al.,

Defendants.

CIVIL NO. 02-2608 (RLA)

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant AVENTIS PHARMACEUTICALS, INC. ("AVENTIS") has moved the court to enter summary judgment on its behalf dismissing the instant suit. The court having reviewed the arguments presented by the parties as well as the extensive documentation submitted for review hereby finds dismissal is warranted.

BACKGROUND

This action was originally instituted on October 28, 2002, by WINSTON MENDEZ MONTES DE OCA, his wife, NORMA SILVAGNOLI COLLAZO, and their children asserting negligence claims and products liability pursuant to art. 1802 of the Puerto Rico Civil Code, Laws of P.R. Ann. tit. 31, § 5141 (1990). The suit was based on a cancerous tumor developed by MR. MENDEZ purportedly caused by his use of Lantus®, an insulin product manufactured by the defendant.

MR. MENDEZ subsequently died on May 5, 2003, as a consequence of his cancer and his children, as heirs to his personal cause of

action, substituted him in these proceedings pursuant to Rule 25 Fed. R. Civ. P.

In their complaint[1] plaintiffs allege that AVENTIS failed to directly warn the consumer of the purported hazards and risks associated with the use of Lantus®. Plaintiffs further allege that MR. MENDEZ's use of the Lantus® insulin in his left thigh was the direct and proximate cause of his cancerous tumor.

AVENTIS argues that (1) plaintiffs' claims are barred by the learned intermediary doctrine; (2) plaintiffs have failed to establish the necessary causal relationship between the use of Lantus® and decedent's cancer; (3) the expert evidence shows that, based on the size and location of the tumor and the fact that it appeared within a few months of a single injection of the product, it is biologically implausible for the tumor to have been caused by the use of Lantus®, and (4) the claims are time-barred.

Because we find that AVENTIS is entitled to the immunity provided by the learned intermediary defense we need not address the other arguments raised by defendant in support of its summary judgment request.

SUMMARY JUDGMENT STANDARD

Rule 56(c) Fed. R. Civ. P., which sets forth the standard for ruling on summary judgment motions, in pertinent part provides that

[1] The original complaint was amended twice. See First Amended Complaint (docket No. 23) and Second Amended Complaint (docket No. 38).

they shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Sands v. Ridefilm Corp., 212 F.3d 657, 660-61 (1st Cir. 2000); Barreto-Rivera v. Medina-Vargas, 168 F.3d 42, 45 (1st Cir. 1999). The party seeking summary judgment must first demonstrate the absence of a genuine issue of material fact in the record. DeNovellis v. Shalala, 124 F.3d 298, 306 (1st Cir. 1997). A genuine issue exists if there is sufficient evidence supporting the claimed factual disputes to require a trial. Morris v. Gov't Dev. Bank of Puerto Rico, 27 F.3d 746, 748 (1st Cir. 1994); LeBlanc v. Great Am. Ins. Co., 6 F.3d 836, 841 (1st Cir. 1993), *cert. denied*, 511 U.S. 1018, 114 S.Ct. 1398, 128 L.Ed.2d 72 (1994). A fact is material if it might affect the outcome of a lawsuit under the governing law. Morrissey v. Boston Five Cents Sav. Bank, 54 F.3d 27, 31 (1st Cir. 1995).

"In ruling on a motion for summary judgment, the court must view 'the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.'" Poulis-Minott v. Smith, 388 F.3d 354, 361 (1st Cir. 2004) (citing Barbour v. Dynamics Research Corp., 63 F.3d 32, 36 (1st Cir.1995)).

Credibility issues fall outside the scope of summary judgment. "'Credibility determinations, the weighing of the evidence, and the

drawing of legitimate inferences from the facts are jury functions, not those of a judge.'" Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). *See also*, Dominguez-Cruz v. Suttle Caribe, Inc., 202 F.3d 424, 432 (1st Cir. 2000) ("court should not engage in credibility assessments."); Simas v. First Citizens' Fed. Credit Union, 170 F.3d 37, 49 (1st Cir. 1999) ("credibility determinations are for the factfinder at trial, not for the court at summary judgment."); Perez-Trujillo v. Volvo Car Corp., 137 F.3d 50, 54 (1st Cir. 1998) (credibility issues not proper on summary judgment); Molina Quintero v. Caribe G.E. Power Breakers, Inc., 234 F.Supp.2d 108, 113 (D.P.R. 2002). "There is no room for credibility determinations, no room for the measured weighing of conflicting evidence such as the trial process entails, and no room for the judge to superimpose his own ideas of probability and likelihood. In fact, only if the record, viewed in this manner and without regard to credibility determinations, reveals no genuine issue as to any material fact may the court enter summary judgment." Cruz-Baez v. Negron-Irizarry, 360 F.Supp.2d 326, 332 (D.P.R. 2005) (internal citations, brackets and quotation marks omitted).

In cases where the non-movant party bears the ultimate burden of proof, he must present definite and competent evidence to rebut a motion for summary judgment, Anderson v. Liberty Lobby, Inc., 477

U.S. at 256-257, 106 S.Ct. 2505, 91 L.Ed.2d 202; Navarro v. Pfizer Corp., 261 F.3d 90, 94 (1st Cir. 2000); Grant's Dairy v. Comm'r of Maine Dep't of Agric., 232 F.3d 8, 14 (1st Cir. 2000), and cannot rely upon "conclusory allegations, improbable inferences, and unsupported speculation". Lopez-Carrasquillo v. Rubianes, 230 F.3d 409, 412 (1st Cir. 2000); Maldonado-Denis v. Castillo-Rodríguez, 23 F.3d 576, 581 (1st Cir. 1994); Medina-Muñoz v. R.J. Reynolds Tobacco Co., 896 F.2d 5, 8 (1st Cir. 1990).

THE FACTS

AVENTIS and its predecessor at all relevant times developed, manufactured and sold a prescription drug product known as Lantus®.

Lantus® is a synthetic human insulin product approved by the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") for the treatment of Type I and Type II diabetes.

Lantus® was designed for once per day administration, to alleviate the inconvenience to patients of twice-daily administration and to provide more stable blood sugar levels.

Pursuant to its Investigational New Drug Application for Lantus®, No. 49,078, AVENTIS conducted two-year carcinogenicity studies in both rats and mice. A statistically significant increased incidence of malignant fibrous histiocytoma ("MFH") tumors occurred in male rats. The results of these studies were notified to the FDA.

New Drug Application 21-081 was submitted to the FDA on April 9, 1999, seeking approval of the Lantus® drug.

The FDA approved Lantus® as safe and effective for the treatment of Type I and Type II diabetes on April 20, 2000.

The FDA-approved prescribing information for Lantus®, which is included in the package insert, reads as follows:

> Carcinogenesis, Mutagenesis, Impairment of Fertility: In mice and rats, standard two-year carcinogenicity studies with insulin glargine were performed at doses up to 0.455 mg/kg, which is for the rat approximately 10 times and for the mouse approximately 5 times the recommended human subcutaneous stating dose of 10 IU (0.008 mg/kg/day), based on mg/m^2. The findings in female mice were not conclusive due to excessive mortality in all dose groups during the study. Histiocytomas were found at injection sites in male rats (statistically significant) and male mice (not statistically significant) in acid vehicle containing groups. These tumors were not found in female animals, in saline control, or insulin comparator groups using a different vehicle. The relevance of these findings to human is unknown.

MR. MENDEZ was diagnosed with diabetes in 1983.

On January 20, 1995, MR. MENDEZ began taking Humulin Insulin injections to treat his diabetes. Prior to initiation with Lantus®,

MR. MENDEZ administered twice daily injections of Humulin, sometimes in the abdomen and sometimes in the thigh.

Concerned that the insulin medication he was taking at the time, i.e., Humulin 70/30, might be discontinued, MR. MENDEZ went to see his endocrinologist, DR. CESAR TRABANCO, on July 5, 2001. DR. TRABANCO informed MR. MENDEZ and his wife, who was also present, that there was a new insulin product on the market, Lantus®, which had the advantage of only having to be injected once a day.

MR. MENDEZ was given two samples of Lantus® by DR. TRABANCO on July 5, 2001. Decedent only used those sample vials and never purchased Lantus®.

Included within the Lantus® packaging given to decedent was the product information/package insert for Lantus®.

MR. MENDEZ used Lantus® for approximately one to two months.[2]

In early August 2001, MR. MENDEZ injected the Lantus® a single time in his upper left thigh. Within a few days thereafter the injected area became painful and hard and started to bother decedent.

On October 17, 2001, an MRI showed a large mass in decedent's left thigh.

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[2] According to defendant decedent discontinued using the product in late August 2001 whereas plaintiffs contend that he used it through the end of September 2001. However, this time difference does not affect our ruling.

A biopsy of the tumor was performed on October 26, 2001, which was diagnosed as "Fibrous Malignant Histiocytoma, Giant Cells Variant, Invasive, High Grade."

MR. MENDEZ died on May 5, 2003, of Sarcoma stage 4.

The FDA-approved language contained in the product's Package Insert fully disclosed the carcinogenic potential of Lantus® to physicians. This Package Insert was included in the packaging of the Lantus® samples provided to MR. MENDEZ.

THE LEARNED INTERMEDIARY DOCTRINE

Plaintiffs allege that AVENTIS is liable due to its failure to warn the consumers directly of the purported hazards and risks posed by the use of Lantus®.

Pursuant to art. 1802, there are three elements required for proving negligence claims: (1) a duty, (2) negligent breach of that duty and (3) a damage flowing from the negligent act or omission. Cruz-Vargas v. R.J. Reynolds Tobacco, Co., 348 F.3d 271, 275-76 (1st Cir. 2001).

The Puerto Rico Supreme Court has adopted a strict liability approach for claims arising from damages resulting from defective products. In Mendoza v. Cerveceria Corona, Inc., 97 P.R.R. 487, 499 (1969) the Supreme Court noted that "the most equitable rule and the one of greatest congruence with the public policy is that of establishing the manufacturer's strict liability to the consumer." *See also*, Aponte-Rivera v. Sears Roebuck de P.R., Inc., 144 D.P.R.

830, 838 (1998) ("The doctrine of strict liability of the manufacturer or seller for the damages caused by defective or dangerous products applies in our jurisdiction."); Rivera-Santana v. Superior Packaging, Inc., 132 D.P.R. 115, 125 (1992) ("In an effort to meet Puerto Rico's social needs, by judicial act, and as a question of public policy, we have laid down and adopted the manufacturer's strict liability rule for defective products.")

There are three types of defects which trigger application of strict liability principles. These are: manufacturing defects, design defects and defective warnings. Aponte-Rivera, 144 D.P.R. at 839-40; Rivera-Santana, 132 D.P.R. at 128; Montero-Saldaña v. Am. Motors, Corp., 107 D.P.R. 452, 462 (1978); Collazo-Santiago v. Toyota Motor Corp., 149 F.3d 23, 25 (1st Cir. 1998); Caraballo-Rodriguez v. Clark Equip. Co., Inc., 147 F.Supp.2d 66, 71-72 (D.P.R. 2001).

In order to prove their failure to warn claim plaintiffs must establish that: "'(1) the manufacturer knew, or should have known the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury.'" Cruz-Vargas v. R.J. Reynolds Tobacco, Co., 348 F.3d 271, 276 (1st Cir. 2001) (citing Aponte-Rivera, 144 D.P.R. at 840).

The Doctrine

In strict liability cases involving prescription drugs the legal approach in the failure to warn context has been *sui generis*. "In a typical strict products liability case, the manufacturer's duty to warn extends to the consumer of the product. Where the product is a prescription drug, however, it is widely accepted that the manufacturer's duty to warn runs to the physician rather than the patient." Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992).

This rule is known as the "learned intermediary doctrine" whereby a prescription drug manufacturer has no duty to warn consumers directly of dangers or risks posed by the use of its product. Rather, this duty extends exclusively to the prescribing physicians. "Under the learned intermediary doctrine, manufacturers of prescription drugs escape liability for failure to instruct and warn consumers so long as they adequately instruct and warn physicians responsible for prescribing the medication." In re Meridia Prods. Liab. Litig., 328 F.Supp.2d 791, 811 (N.D. Ohio 2004).

The doctrine does not exempt manufacturers from providing adequate warnings of the risks of each product it sells. The difference is that the warnings are directed at the physician and not the patient who is the ultimate consumer. The manufacturer's duty is fulfilled once it adequately warns the physician. Garside, 976 F.2d at 80. "[W]here prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing

physician of any potential dangers that may result from the drug's use." Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir. 1974).

This doctrine seems to be widely accepted, *see* Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 852 (10th Cir. 2003) (adopted in forty-four jurisdictions); some states have enacted statutes incorporating variations thereof,[3] and has been applied in Puerto Rico. *See i.e.*, Guevara v. Dorsey Lab. Div. of Sandoz, Inc., 845 F.2d 364, 366 (1st Cir. 1988) ("prescription drug manufacturer has a duty to adequately warn prescribing physicians of hazards posed by the use of its drugs... The warning is directed not to the ultimate user but to the doctor prescribing the drug"); Pierluisi v. E.R. Squibb & Sons, Inc., 440 F.Supp. 691, 694 (D.P.R. 1977) ("It is the prevailing general rule that the duty of adequate warning by the manufacturer of an ethical drug is discharged by its warning of hazards to doctors.")

Rationale

The reasoning behind this theory is that the prescribing physician is in a better position to decide, from a medical standpoint, whether or not the drug is appropriate for a patient under his care.

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the

[3] North Carolina General Statutes §99B-5(c); Ohio Revised Code § 2307.76(C); New Jersey Statutes § 2A:58C-4, and Mississippi Code § 11-1-63(c)(2).

> propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer.

Reyes v. Wyeth Lab., 498 F.2d at 1276.

"[I]t is for the prescribing physician to consider warning labels supplied by the drug manufacturer, as well as other medical literature and sources and the personal medical history of his or her patient, in coming to an independent medical judgment whether to prescribe the medication in question." Colacicco v. Apothex, Inc., 432 F.Supp.2d 514, 545 (E.D.Pa. 2006). "The underlying premise of this doctrine is that patients rely on their doctors' expert judgment - not any materials included on the label or in the drug packaging - when deciding which drugs to use and how to use them." In re Meridia, 328 F.Supp.2d at 811.

Because the warning is directed at the prescribing physician, its adequacy is assessed with reference to the physician, not the

patient. That is, the information provided must allow the physician the opportunity to render adequate professional advise regarding the use of a particular course of treatment. "Thus, for drugs available only by prescription, warning labels are targeted at doctors, not individual users." Colacicco, 432 F.Supp.2d at 545.

The protection offered by the doctrine vanishes if the warnings to the physicians are found to be inadequate. "[T]he doctrine only applies if the facts support the conclusion that a drug manufacturer adequately warns doctors of a drug's dangers; it does not shield drug manufacturers from liability if the warnings they provided to physicians would not permit the physicians to adequately advise their patients." *Id.* at 546; In re Meridia, 328 F.Supp.2d at 811.

Exceptions

Some exceptions to the learned intermediary doctrine have arisen in response to particular situations where the underlying factors justifying the rule have been altered.

One exception pertains to mass immunizations which the courts have exempted because the underlying physician-patient is lacking. *See, i.e.*, Reyes v. Wyeth Lab. (polio vaccine administered at clinic by nurse); Davis v. Wyeth Lab., 399 F.2d 121, 131 (9th Cir. 1968) (even though vaccine "denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved.")

Another instance where prescription drugs have been taken out of the scope of this doctrine are oral contraceptives. The court reasoned that "[w]hereas a patient's involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use 'the pill,' as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role." MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 136-37, 465 N.E.2d 65 (Mass. Sup. Ct. 1985). *See also*, Odgers v. Ortho Pharm. Corp., 609 F.Supp. 867, 878 (E.D. Mich. 1985) (grounds for applying learned intermediary doctrine inapposite in oral contraceptive situations because "patient does not rely on the physician to nearly the same degree when it comes to choosing a method of contraception as in a decision regarding a therapeutic drug.") *But see*, Gurski v. Wyeth-Ayerst Div. Of Am. Home Prods. Corp., 953 F.Supp 412, 416 (D.Mass. 1997) (quaere if exception applies when birth control drug used solely for therapeutic reasons).

It has also been suggested that in cases of direct to consumer advertisement by the drug manufacturing companies the learned intermediary rule should not apply.

In Perez v. Wyeth Lab., Inc., 161 N.J. 1, 734 A.2d 1245, 1255-56 (N.J. Sup. Ct. 1999) the court extensively discussed the rationale behind the learned intermediary doctrine and found it lacking in

cases of direct marketing of contraceptive capsules surgically inserted in a female patient. The court reasoned that for this particular product there was an active participation of the patients in deciding which drug or device to use; there was no real concern that the patient-physician relationship would be affected, and the users relied on the FDA-approved warnings.

However, this approach has not been widely accepted. *See*, Colacicco, 432 F.Supp. 547 n.30 and cases cited therein (declining to apply the DTC exception "because, in the eight years since *Perez*, the New Jersey Supreme Court case making an exception to the [learned intermediary doctrine] for direct-to-consumer advertising, was decided, no state has joined New Jersey."); *See also*, Beale v. Biomet, Inc., 492 F.Supp.2d 1360, 1376 (S.D.Fla. 2007) ("While *Perez* court found that the law should be changing in response to changes in the marketing strategies by drug manufacturers, New Jersey is the only state to have done so."); In re Meridia, 328 F.Supp.2d at 812 n.19 (rejecting its application as widely unaccepted).

The Evidence

It is uncontested that the warnings and instructions accompanying the insert of the Lantus® product which were provided to decedent[4] were legally adequate with respect to decedent's physicians

[4] Plaintiffs admit that the insert accompanied the vials but argue that decedent was not proficient in English and that MRS. SILVAGNOLI only read the part dealing with its administration.

and in compliance with the applicable governmental regulations and requirements.

DR. ESAM DAJANI, plaintiffs' expert witness, opined in his report that the "professional product labeling of LANTUS provided to physicians fully disclosed the carcinogenicity potential of the product". He noted, however, that the "product labeling **provided to patients** did not disclose this important issue." (Emphasis ours).

During his deposition DR. DAJANI confirmed this conclusion when specifically asked regarding this point:

> Q. You think the FDA and Aventis did a good job with the end result of the labeling that went to physicians?
>
> A. Correct.
>
> Q. Your criticism is with respect to the information that went to patients, is that correct:
>
> A. Correct.

Depo. Tr. 206 lines 4-11.

In support of their direct to consumer advertising argument plaintiffs submitted various documents, internet material and TV news clips purportedly published by the defendant as part of its advertising campaign for Lantus®. Defendant argues that this evidence does not qualify as direct to consumer advertising because it was either directed to medical professionals or was not prepared by AVENTIS. Given today's ruling, there is no need for us to address these arguments.

At the outset, we must inescapably conclude that Lantus® does not even remotely fall within the limited type of prescription drugs that courts have exempted from the application of the learned intermediary doctrine. Further, plaintiffs have failed to explain why the circumstances surrounding this particular product should trump the reasons for the rule to the effect that "the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly." Garside, 976 F.2d at 80.

Further, as part of a plaintiff's need to establish the necessary causal connection between the alleged direct to consumer advertising and his or her injuries, it is imperative that evidence of having responded to the advertising be introduced precisely to obviate the underlying rationale of the doctrine. *See*, In re Norplant Contraceptive Prods. Lit., 165 F.3d 374, 379 (5th Cir. 1999) (declined to exempt from learned intermediary rule absent evidence that plaintiffs "actually saw, let alone relied, on any marketing materials issued [by the manufacturer.")

Even assuming that Lantus® is amenable to the direct to consumer advertising exception, the record in this case is devoid of any evidence intimating that decedent even saw informational material regarding Lantus® prior to his visit to DR. TRABANCO on July 5, 2001. Rather, the evidence points to the physician initially suggesting

that MR. MENDEZ try the new product and provided him the two sample vials.[5]

At no point do any of the plaintiffs specifically indicate, as part of their summary judgment burden, that decedent was swayed by advertising promoted by AVENTIS to the general public which promotion lead MR. MENDEZ to request the product from his physician.

According to plaintiffs, "Norma Sivagnoli saw advertisements **when her husband was taking Lantus®**".[6] Decedent's children also mentioned having seen promotional material, advertisements, brochures and a journal of Lantus® as well as TV advertisements. However, none indicate that decedent was privy to this informational material prior

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[5] Plaintiffs admitted the following defendant's Statement of Uncontested Material Facts (docket No. 169) which read as follows:

> 24. Concerned that the insulin medication he was taking at the time, Humulin 70/30, might be discontinued, Mr. Mendez went to see his endocrinologist Dr. Cesar Trabanco [on July 5, 2001]... **Dr. Trabanco informed Mr. Mendez and his wife, Norma Iris Silvagnoli collazo, who was also present, that there was a new insulin product on the market, Lantus®,** that had the advantage of only having to be injected once a day.
>
> 25. Mr. Mendez was given two samples of Lantus® by Dr. Trabanco on July 5, 2001.

(Emphasis ours). See also, NORMA IRIS SILVAGNOLI COLLAZO 12/7/05 Depo. Tr. 7-8.

[6] Plaintiffs' Counterstatement of Uncontested Material Facts (docket No. 180) ¶ 26 (emphasis ours). In her deposition MRS. SILVAGNOLI specifically testified that she could not remember whether she had seen Lantus® TV adds "before or after" her husband had started using the medication. NORMA IRIS SILVAGNOLI COLLAZO 12/7/05 Depo. Tr. 31.

to July 5, 2001.[7] Plaintiffs merely argue, in a conclusory fashion, that defendant conducted direct to consumer advertising. This allegation, without more, is not sufficient to defeat defendant's learned intermediary defense.

Faced with this factual scenario, we find that plaintiffs have failed to adequately meet their burden in opposing defendant's well-grounded summary judgment request.

CONCLUSION

Based on the foregoing, the Motion for Summary Judgment filed by AVENTIS (docket No. **169**)[8] is **GRANTED.**

Accordingly, the Second Amended Complaint is **DISMISSED** based on the learned intermediary defense. Judgment shall be entered accordingly.

IT IS SO ORDERED.

San Juan, Puerto Rico, this 30th day of September, 2008.

S/Raymond L. Acosta
RAYMOND L. ACOSTA
United States District Judge

[7] Plaintiffs' Counterstatement of Uncontested Material Facts (docket No. 180) ¶¶ 27-29.

[8] See Plaintiffs' Opposition (docket No. **182**); Defendant's Reply (docket No. **199**) and Plaintiffs' Sur-Reply (docket No. **209**).