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1	EL DORADO CO. SUPERIOR CT.
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8	SUPERIOR COURT OF THE STATE OF CALIFORNIA
.9	COUNTY OF EL DORADO
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11	TERRI S. O'NEAL, individually and as successor-in-interest to the Estate of CASE NO.:   CASE NO.: 20060184
12	BENJAMIN L. BRATT; BARRY M. BRATT, ) individually
13	Plaintiffs, COMPLAINT
14	VS. DEMAND FOR JURY TRIAL
15	SMITHKLINE BEECHAM CORPORATION, )
16	D/B/A GLAXOSMITHKLINE, A Pennsylvania ) Corporation; McKESSON CORPORATION, )
17	A California Corporation; and DOES 1-50
18	Defendants. )
19	COMPLAINT
20	Now come the plaintiffs, Terri S. O'Neal, Individually and as Successor-In-Interest to the Estate
21	of Benjamin L. Bratt, and Barry M. Bratt, individually, and complaining against the defendants
23	SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE ("GSK"), and McKESSON
23	CORPORATION ("McKesson") state:
25	NATURE OF ACTION
26	1. This is a wrongful death products liability case arising out of the Paxil-induced suicide
27	by Benjamin Bratt on February 14, 1997 in Pollack Pines, California. At the time of this event
28	Benjamin was under the influence of a powerful, serotonergic, psychotropic drug called "Paxil" which

1 Complaint

is manufactured and marketed by defendant GSK.

#### JURISDICTION AND VENUE

- 2. Original subject matter jurisdiction in this Court is appropriate as an unlimited civil case pursuant to California Code of Civil Procedure section 88 because the amount in controversy between the parties exceeds \$25,000.
- 3. This Court may assert personal jurisdiction over defendants because defendants, and each of them, have substantial, continuous and systematic commercial activities ongoing in the State of California. Further, defendants, and each of them, have purposefully availed themselves of the privilege of conducting activities within California, plaintiff's injuries arise out of that purposeful availment, and the exercise of jurisdiction over defendants, and each of them, comports with fair play and substantial justice.
- 4. Venue is appropriate in this Court because the injury to plaintiffs and their son occurred in this county.

#### **PARTIES**

- 5. Plaintiff Terri S. O'Neal is a competent adult and the mother of the decedent, Benjamin L. Bratt ("Decedent"). She is a resident of the State of California, County of El Dorado. She brings this action individually and as Successor-in-Interest to the estate of Benjamin L. Bratt to recover damages for the wrongful death of her son, those damages that survived his death, and for her individual economic and non-economic damages resulting from her son's death.
- 6. Plaintiff Barry M. Bratt is a competent adult and the father of the decedent, Benjamin L. Bratt. He currently resides in Port Macquarie, New South Wales, Australia. He brings this action individually to recover damages, including his individual economic and non-economic damages resulting from his son's death.
- 7. On February 14, 1997 Benjamin hung himself. On February 15, 1997, Benjamin Bratt died as a result of his ingestion of the prescription drug Paxil in Placerville, California. Benjamin was 13 years old at the time of his death.
- 8. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter referred to as "GSK") was and still is a corporation duly existing under and by virtue of the laws of the State of

Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. At all times hereinafter mentioned, defendant GSK was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil (known generically as paroxetine), an antidepressant, throughout the State of California.

- 9. Defendant MCKESSON CORPORATION was, and still is, a corporation duly existing under and by virtue of the laws of the State of California with its principal place of business in San Francisco, California. At all times hereinafter mentioned, defendant McKesson was, and still is, a company involved in the distribution and sales of pharmaceutical products, including the drug Paxil, throughout the State of California. Plaintiff is informed and believes that McKesson was a distributor, supplier, and/or wholesaler of the Paxil that was sold to plaintiffs and their son.
- 10. Does 1-10 are wholesalers and/or distributors selling Paxil in the State of California whose identity is presently unknown to plaintiff. On information and belief, plaintiffs allege that Does 1-10 are jointly and severally liable for the injuries described herein.
- Does 11-20 are pharmacies and/or retail outlets selling Paxil in the State of California whose identity is presently unknown to plaintiff. On information and belief, plaintiffs allege that Does 11-20 are jointly and severally liable for the injuries described herein.
- 12. Does 21-50 are defendants whose identity is presently unknown to plaintiffs. On information and belief, plaintiffs allege that Does 11-20 are jointly and severally liable for the injuries described herein.

#### **GENERAL ALLEGATIONS**

- 13. The drug paroxetine, is manufactured, promoted, distributed, and marketed by GSK under the trade name Paxil, Paxil Oral Suspension, and Paxil CR, and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs."
- 14. Paxil was first approved for use in the United States in 1992 for the treatment of depression in adults. Since it was approved, the Food and Drug Administration ("FDA") has received numerous reports of adults, adolescents, and children committing suicide as a result of taking Paxil. Like the other SSRIs, Paxil has an association with violent and suicidal behavior for some of the patients

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who take the drug. Side effects associated with Paxil include an extremely dangerous condition called "akathisia" which in turn is associated with acts of self-harm and/or violence. Other side effects include mania, depersonalization, hypomania and psychosis.

- 15. During the clinical trials for Paxil, numerous patients experienced suicidal thoughts, engaged in suicidal behavior, and actually committed suicide. GSK coded these suicide events that occurred during the clinical trials of paroxetine as "emotional lability." Many of them were determined by the clinical investigator to be related to Paxil and they occurred at a significantly more frequent rate than with patients taking placebo.
- Notwithstanding an abundance of evidence regarding the association between Paxil and 16. suicidality, GSK failed to provide the public and the healthcare community with a warning about this deadly side effect associated with Paxil. From 1992 until 2005, GSK provided doctors with the following information about suicide in Paxil's label:

The possibility of a suicide attempt is inherent in depression and may persist until Suicide: significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Paxil should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

The potential for violence and suicide is a class-wide effect of SSRI drugs—such as 17. Paxil—which purport to "selectively" inhibit the reuptake of serotonin by blocking serotonin receptor sites. In two peer-reviewed scientific articles by Pfizer's Dr. Roger Lane, the association and risk of violence and suicide for all SSRI drugs, including Paxil, is thoroughly discussed. SSRI-Induced extrapyramidal side-effects and akathisia: implications for treatment, Journal of Psychopharmacology, 12(2)(1998), pp. 192-214; Lane and Baldwin, Selective Serotonin Reuptake Inhibitor-Induced Serotonin Syndrome: Review, Journal of Clinical Psychopharmacology, 17(3)(1997), pp. 208-22. As Dr. Lane writes, these conditions are sometimes hard to detect and diagnose, although not so hard to treat. E.g. "SSRI-induced akathisia is a relatively rare event but is frequently unrecognized when it does occur." For this reason, is it imperative that both physicians and their patients be forewarned and alerted. However, GSK did not warn the public and the healthcare community of the risk of akathisia or suicide before Decedent's suicide.

- 18. Paxil has never been approved by the FDA for use with pediatric patients. However, GSK has conducted a number of clinical trials involving the use of Paxil with pediatric patients for the treatment of various indications, such as depression and anxiety. Those clinical trials show that Paxil is ineffective in pediatric patients. In other words, the clinical trials clearly show that Paxil performed no better than placebo in treating the indications for which the clinical trials were designed to measure. GSK's own documents admit that the results of these clinical trials did not show a statistically significant benefit over placebo.
- 19. These same clinical trials showed at least a 2 times increase in the occurrence of suicidal events with Paxil than with placebo, with one trial showing as much as a 6 times increase. However, the FDA and the healthcare community had difficulty learning of these increased rates of suicidal behavior because, as with the adult data, GSK coded suicidal events as "emotional lability." GSK intentionally suppressed this data in an effort to maximize Paxil's sales.
- 20. In September of 2004, the FDA released its findings regarding the link between suicide-related events and antidepressants, such as Paxil. The FDA's findings demonstrated that there was a class-wide link between SSRI use in pediatric patients and suicide-related events. As a result, the FDA negotiated with GSK and other drug manufacturers to strengthen the labels for SSRIs. In early 2005, GSK updated Paxil's label to include a "black-box" warning, which is the strongest warning allowed for by FDA regulations. That warning states:

#### Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS and PRECAUTIONS -- Pediatric Use)

Pooled analysis of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant

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- During the entire time Paxil has been on the market in the United States, FDA regulations have required GSK to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and Paxil. The regulations specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed GSK to issue such a warning without prior FDA approval.
- Thus, prior to Benjamin Bratt's suicide, GSK had the knowledge, the means, and the duty to provide his doctor and the consuming public with a stronger warning regarding the association between Paxil and suicidality through all means necessary including but not limited to labeling, continuing education, symposiums, posters, sales calls, etc. GSK failed to do any of these things.
- 23. Plaintiffs filed this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of Decedent's death as described herein. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Decedent's death as described herein at an earlier time because at the time the death occurred, the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the cause of Decedent's death as described herein, or the tortious nature of the conduct causing the death, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that Paxil is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action.

## FIRST CAUSE OF ACTION Against Defendants GSK, McKesson and DOES 1-50 FOR NEGLIGENCE

- 24. Plaintiffs incorporate herein by reference Paragraphs 1 through 23 inclusive as though fully set forth at length.
- On or about February 6, 1997, Benjamin Bratt first began ingesting Paxil. The drug was prescribed for Benjamin by Dr. Reginald D. Rice and his nurse practitioner, Carol Herrlie. Benjamin ingested/consumed Paxil over an approximately 8-day period. During that time, Benjamin experienced and endured grievous pain and suffering from Paxil's side effects including, but not limited to, akathisia, out-of-the-ordinary behavior, anxiety, trembling, depersonalization, emotional blunting, agitation, withdrawal from family, and suicidal thinking. After being on Paxil for about 8 days, Benjamin, under the influence of Paxil, attempted to commit suicide by hanging himself from his bed. One day later, Benjamin died at a hospital in Placerville, California from injuries sustained during this suicide attempt.
- 26. Decedent's injuries and death described herein were caused by the negligence and misrepresentations of GSK through their agents, servants and/or employees acting within the course and scope of their employment including among other things:
  - (a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Paxil;
  - (b) Failing to properly and adequately test Paxil for its intended use for the treatment of depression;
  - (c) Failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions to Paxil;
  - (d) Being careless and negligent in that GSK knew or should have known that Paxil was a substance known to have an association with producing life-threatening effects upon certain users including but not limited to akathisia, acts of self-harm, and violent and manic episodes;
  - (e) Negligently and carelessly failing to adequately warn the medical community, the

# SECOND CAUSE OF ACTION Against Defendants GSK, McKesson, and DOES 1-50 FOR STRICT LIABILITY

- 30. Plaintiffs incorporate herein by reference Paragraphs 1 through 29 inclusive as though fully set forth at length.
- 31. At all times herein mentioned, Paxil was unsafe for some people who took it, and GSK knew or should have known that said product was unsafe.
- 32. At all times herein mentioned, Paxil produced serious and sometimes fatal side effects, and GSK knew or should have known that said product could be unsafe because of said side effects.
- 33. At all times hereinafter mentioned and before Decedent's ingestion of Paxil, neither members of the medical community nor members of the general public knew of the dangers existing with respect to Paxil's administration, side effects, or inadequate testing.
  - 34. Decedent used Paxil in the manner in which GSK intended it to be used.
- 35. Decedent used or otherwise ingested Paxil in the amounts and manner and for the purpose recommended by GSK.
- 36. At all times material hereto, U.S.-marketed Paxil was not accompanied by complete and proper warnings for safe, informed use; the labeling accompanying Paxil did not warn physicians in general and plaintiffs and Decedent in particular of the dangers inherent in its use, particularly of the drug's association with violence and self-harm. Further, the labeling failed to adequately inform physicians in general and plaintiffs and Decedent in particular that Paxil is ineffective for the treatment of pediatric patients, thus depriving physicians of necessary information needed to perform an adequate risk/benefit analysis.
- 37. GSK promoted and maintained Paxil on the market with the knowledge of Paxil's unreasonable risk to the public in general and specifically to plaintiffs' son.
- 38. Paxil as used by Decedent was defective and unreasonably dangerous when sold by GSK, who is strictly liable for the injuries arising from its manufacture and Decedent's use.
- 39. As a supplier and seller of Paxil, McKesson Corporation is jointly and severally liable for Paxil's defects.

- 40. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs have sustained pecuniary loss resulting from the loss of their decedent's society, companionship, comfort, attention, protection, care, love, affection, advice, services, moral support, economic support, and general damages in a sum in excess of the jurisdictional minimum of this Court. As a further proximate result of GSK's conduct, plaintiffs have incurred expenses for funeral, burial, and other costs pertaining to their decedents' deaths in amounts to be ascertained.
- 41. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

#### III.

## THIRD CAUSE OF ACTION Against Defendants GSK, McKesson and DOES 1-50 FOR BREACH OF EXPRESS WARRANTY

- 42. Plaintiffs incorporate herein by reference Paragraphs 1 through 41 inclusive as though fully set forth at length.
- 43. At all times herein mentioned, GSK utilized packaging, journal articles, advertising media, and an outside sales force to urge the use, purchase, and utilization of Paxil and expressly warranted to physicians, plaintiffs and Decedent, and other members of the general public that Paxil was effective, safe, and proper for use in pediatric patients.
- 44. GSK represented to the consumer who would use Paxil and to the physicians who would prescribe it—without a complete disclosure of Paxil's side effects—that Paxil was safe and efficacious for children and adolescents suffering from depression, which amounted to an express warranty of Paxil's safety and efficacy.
- 45. GSK knew or in the exercise of reasonable diligence should have known that Paxil had the serious side effects set forth herein and was not efficacious for the treatment of pediatric patients.
- 46. Plaintiffs, Decedent and Decedent's doctor(s) relied on GSK's express warranty representations in the use of Paxil, but Paxil was not effective, safe, and proper for its intended use as warranted in that Paxil failed and was dangerous when put to its intended use.
- 47. As a direct and proximate result of the aforesaid conduct of GSK, plaintiffs have sustained pecuniary loss resulting from the loss of their Decedent's society, companionship, comfort,

attention, protection, care, love, affection, advice, services, moral support, economic support, and general damages in a sum in excess of the jurisdictional minimum of this Court. As a further proximate result of GSK's conduct, plaintiffs have incurred expenses for funeral, burial, and other costs pertaining to their Decedents' deaths in amounts to be ascertained.

48. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

IV.

# FOURTH CAUSE OF ACTION Against Defendants GSK, McKesson and DOES 1-50 FOR FRAUD

- 49. Plaintiffs incorporate herein by reference Paragraphs 1 through 48 inclusive as though fully set forth at length.
- 50. In deciding whether to prescribe a drug, doctors do a risk/benefit assessment in determining which drug to prescribe. In doing so doctors, such as Decedent's doctor(s) and healthcare providers, rely on the information received about Paxil from various sources, such as journal articles, company literature and discussions with GSK sales people. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician, such as Decedent's doctor(s) and healthcare providers, cannot accurately assess the crucial risk/benefit balance for the patient or exercise professional judgment that is independent. Consequently, the physician, including Decedent's doctor(s) and healthcare providers, cannot act in accordance with the professional and fiduciary obligations owed to the patient nor can the patient, or in this instance plaintiffs and their son, give informed consent to the treatment.
- 51. Concealing adverse information and providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's professional judgment, as what happened with Decedent and his doctor(s) and healthcare providers. This misleading information, along with omissions of material facts related to Paxil's safety and effectiveness, cause health care providers, patients and the general public to be misled about Paxil's risks and benefits and deprive doctors from making a proper risk/benefit assessment as to the use of Paxil. In internal, unpublished documents, which have been kept from public and regulatory scrutiny via the

stratagem of over-broad "confidentiality" designations, GSK has made numerous admissions about Paxil's associated harmful side effects and lack of effectiveness in children and adolescents. Notwithstanding these admissions, in flagrant and conscious disregard and indifference, GSK has denied publicly that such nexus exists, and has failed utterly to take any measures whatsoever to alert the public, the prescribing physicians, and the patients who take it, of the incipient dangers associated with Paxil.

- 52. Additionally, GSK has defrauded the medical profession (including Decedent's doctor(s) and healthcare providers), the Paxil patient population (including plaintiffs and their son), and the general public (including, but not limited to Decedent's friends and family) in that it, among other acts:
  - (a) Fraudulently mischaracterized and miscoded adverse events involving self-harm with the term "emotional lability" so as to reduce the number of occurrences and hide their existence from the public and regulators;
  - (b) Failed to inform the medical and research communities that a significant number of pediatric patients taking Paxil during clinical trials attempted acts of self-harm at a rate that was at least twice that for pediatric patients who took placebo;
  - (c) Fraudulently claimed that Paxil's characteristic side effects of insomnia, agitation and anxiety were of little or no concern when in fact these effects are known to be among the most critical and deadly of the short-term risk factors for self-harm;
  - (d) Fraudulently denied Paxil's association with serious or deadly thoughts or acts of self-harm when its own investigators informed GSK (and GSK determined itself) that Paxil was associated with such conditions;
  - (e) Allowed the use of concomitant medications in clinical trials to lessen side effects in order to avoid the reporting of treatment-emergent adverse events, such as akathisia;
- 53. When said representations and/or omissions were made by GSK, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by GSK with the intent of defrauding and deceiving the public in general and the medical

27<sup>°</sup>  community and with the intent of inducing the public to take Paxil and the medical community to recommend, prescribe, and dispense Paxil for use with pediatric patients.

- 54. At the time the aforesaid representations and/or omissions were made by GSK, and at the time that Decedent ingested Paxil, both he, plaintiffs, his family/friends and his medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on GSK's assertions, promulgated through its aggressive sales force to his medical providers as set forth herein, that the drug was safe and effective when, in fact, it was neither.
- 55. In reliance upon said representations and/or omissions, Decedent's medical providers did prescribe Paxil and plaintiffs and their son were induced to and did allow Decedent to take Paxil. Had Decedent or his parents known of the actual dangers of Paxil and its lack of effectiveness, through his medical providers or otherwise, he would not have ingested Paxil, or he would have ceased taking it or otherwise sought help once its side effects (which were clearly known to GSK, but not fully disclosed to such providers or the public) became apparent.
- 56. GSK's motive in failing to advise physicians and the public of the adverse reactions that can increase the risk of suicide and suicidality (and that it knew a percentage of users of the drug inevitably would experience) was for financial gain and its fear that if GSK provided proper and adequate information, Paxil would lose its share of the SSRI market.
- 57. At all times herein mentioned, the actions of GSK, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Decedent in particular and to the general public in that GSK did wilfully and knowingly place the dangerous and defective drug Paxil on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use indicating that Paxil is not safe and effective for use with pediatric patients.
- 58. At all times relevant herein, GSK's conduct was malicious, fraudulent, and oppressive toward Decedent in particular and the public generally, and GSK conducted itself in a willful, wanton, and reckless manner. Despite GSK's specific knowledge as set forth above, GSK deliberately recommended, manufactured, produced, marketed, sold, distributed, merchandized, labeled, promoted,

and advertised the dangerous and defective drug Paxil. All of the foregoing constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public. Thus GSK is guilty of reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of Decedent and others which proximately caused the injuries described herein. Therefore, Plaintiffs request punitive and exemplary damages in an amount to be determined at trial to deter GSK from continuing its conscious disregard of the rights and safety of the public at large and to set an example so GSK—as well as other similarly situated drug manufacturers—will refrain from acting in a manner that is wanton, malicious, and in utter, conscious disregard of the rights of a large segment of the public.

- 59. As a proximate result of GSK's fraudulent and deceitful conduct, representations and omissions, plaintiffs have sustained pecuniary loss resulting from the loss of their Decedent's society, companionship, comfort, attention, protection, care, love, affection, advice, services, moral support, economic support, and general damages in a sum in excess of the jurisdictional minimum of this Court. As a further proximate result of GSK's conduct, plaintiffs have incurred expenses for funeral, burial, and other costs pertaining to their Decedents' deaths in amounts to be ascertained.
- 60. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

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## FIFTH CAUSE OF ACTION Against Defendants GSK, McKesson and DOES 1-50 FOR NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

- Plaintiff incorporates herein by reference Paragraphs 1 through 60 inclusive as though fully set forth at length.
- 62. As a direct and proximate result of the wrongful and negligent conduct of Defendants as described herein, plaintiffs were present at the scene of their son's suicide attempt and resultant death. As a result, plaintiffs suffered serious emotional distress.

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### **PRAYER** 1 WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows: 2 1. For general damages in a sum exceeding this court's jurisdictional minimum; 3 2. For reasonable funeral, burial, and related expenses according to proof; 3. For all damages as allowed by law; 5 For punitive and exemplary damages according to proof; 4. 6 For prejudgment interest and post-judgment interest as allowed by law; 5. For the costs of suit herein incurred; and 6: 8 For such other and further relief as this Court may deem just and proper. 7. 10 BAUM • HEDLUND, A Professional Corporation DATED: April 13, 2006 11 12 By: 13 14 Attorneys for Plaintiffs 15 16 17 18 19 20 21 22 23 24 25 26 27 28