EXHIBIT A

Exponent®

Leland Braund v. Guidant Corporation, *et al.*

Expert Report

Exponent
Failure Analysis Associates

Leland Braund v. Guidant Corporation, *et al.*

Expert Report

Prepared by

Dr. John E. Moalli
Exponent, Inc.
149 Commonwealth Drive
Menlo Park, CA 94025

June 1, 2007

Doc no. SF37892.000 A0T0 0607 JEM1

Contents

1 Qualifications and Other Information

I am a Principal Engineer and Group Vice-President at Exponent Failure Analysis Associates (Exponent), which is based in Menlo Park, California. I hold two academic degrees: 1) a Bachelor of Science degree in Civil Engineering from Northeastern University; and 2) a Doctor of Science degree in Polymers from the Massachusetts Institute of Technology. I have been practicing in the field of polymer science and engineering for more than 20 years. A true and correct copy of my curriculum vita is attached as Appendix 1, and a list of my testimony over the preceding four years is contained in Appendix 2. I provide consulting engineering services in all aspects of polymer science and engineering including, but not limited to, mechanical testing, material selection, product design and development, patent analysis, polymer chemistry, polymer physics, and polymer processing.

I am engaged in both large and small consulting projects and have at my disposal, and regularly consult with doctoral level scientists, engineers and physicians specializing in such areas as chemistry, medicine, biomechanics, and polymer science and testing.

I have specific experience in evaluation and testing of the mechanical and physical properties of polymers and also in the determination of the microstructural characteristics and chemistry that control these properties. I wrote my doctoral thesis at MIT on mechanical behavior of polymers, and I have published papers in peer-reviewed journals on this topic. I have personally tested thousands of polymers ranging from films used in medical devices, to rubbers used in hoses and tires, to composite structures used in aircraft.

I have performed research and analysis on the mechanical behavior of polymers used in the medical environment including implantable prosthetic materials, bone cements, and sutures. I have published a book chapter on the failure analysis and testing of polymeric medical devices. I have personally examined hundreds of explanted polymeric medical devices in efforts to study their mechanical behavior and interaction with the human body and other implanted materials. I have performed microscopy on hundreds of explanted medical devices (including Guidant Prizm 2's) and am familiar with the analysis of the morphology of explanted devices using microscopy.

I am familiar with the application of risk analysis in the analysis of polymeric materials and medical devices, and have published an award winning paper on simplified methods of risk analysis in polymeric products.

I am on the faculty at Stanford University, in the School of Engineering, where I teach an engineering design class. I dedicate one section of this class to the design and analysis of medical devices, and another section to risk analysis in the design process.

1.1 Material Considered

I have examined a wide variety of documents produced in this litigation including expert reports, deposition testimony and related exhibits, and internal company documents. The company documents include those related to design, manufacturing, and testing of Guidant medical devices, Guidant correspondence with the FDA, and polyimide testing. In addition, I may rely on literature or other material that I have reviewed as a normal part of my training and education. Finally, I have inspected 20 Prizm 2's of varying manufacturing dates as well as the Braund device.

1.2 Exhibits

I have not yet created any exhibits for purposes of trial.

1.3 Compensation

Exponent is being compensated at the rate of $525 per hour for my work in this matter.

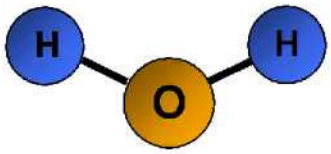
2 Analysis and Opinions

2.1 Review of Polymeric Materials and Engineering Design

2.1.1 Polymeric Materials

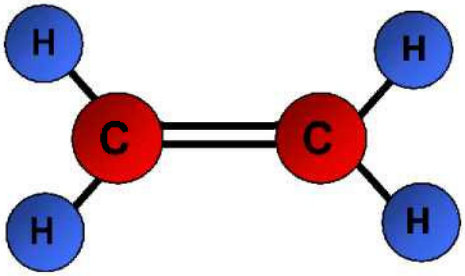
Polymers are common materials in today's society and are the basis of everything from plastics, to rubbers, to wood, to DNA. Synthetic polymers enjoy widespread use because they offer a unique balance of manufacturability, mechanical and physical properties, and are light-weight.

Polymers are made from molecules strung together to form long chains and other more complex structures. Most people are familiar with the water molecule, H_2O, as shown below:

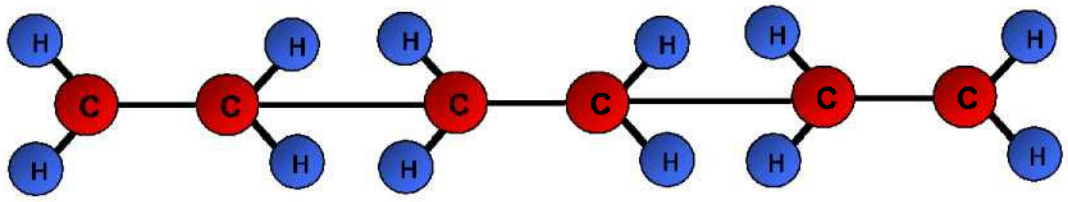


By their nature, water molecules cannot be linked together, and a large number of them in close proximity at room temperature create liquid water. If water molecules were able to be linked, they would create poly-water.

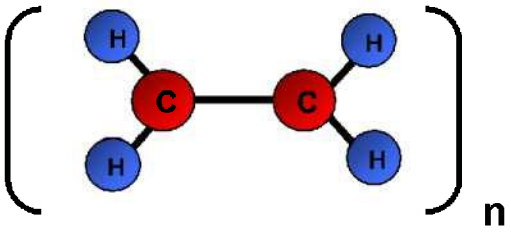
Another simple molecule is ethylene, which is based on 2 carbon atoms and 4 hydrogen atoms:



Unlike water, ethylene has a double bond that can be opened up and used to create links to other ethylene molecules:



This process can be repeated thousands of times to create poly-ethylene, a plastic commonly found in everyday items like plastic bags and pipes. Instead of drawing out each link in the polymer chain, the common nomenclature would be to show the repeat unit (or "mer") followed by a letter designating how many links are in the chain:

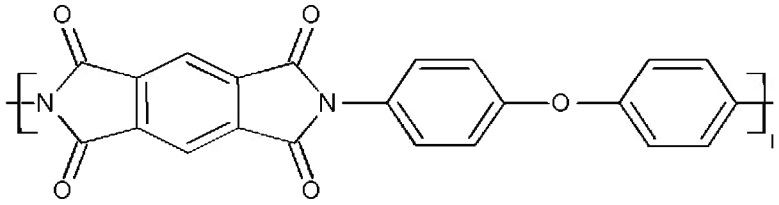


It is easy to see, then, how the name polymer comes about; many ("poly") mers are linked together to make a very long molecule. By tailoring the length of the molecular chain and the chemistry of the "mer" repeat unit, scientists and engineers are able to create polymers with a huge variety of strength, ductility, temperature resistance, and other properties. This ability to constantly vary the way a polymer behaves is what allows their use in everything from household goods, to structural materials in cars and aircraft, to medical devices. Even within a discipline such as medical devices, polymers can be engineered to provide a multitude of properties.

2.1.1.1 Polyimide

Polyimide is a type of synthetic polymer that enjoys widespread use in a variety of applications – from medical devices, to microelectronics, to aerospace applications. Polyimide is recognized as having a unique combination of electrical, thermal, chemical, and mechanical properties.

The ability to maintain mechanical properties over a broad spectrum of conditions is related to the imide mer:



Ring structures and double bonds along the backbone of the polyimide chain make it stiff and resistant to heat. One common use for polyimide is as an insulator.

As with any material, polyimides are not ideal for every application. For example, polyimides may degrade in aqueous environments, with reductions in tensile strength and elongation affected by temperature, duration, and pH.[1] The use of polyimide in demanding environments, including aqueous ones, has remained prevalent despite this characteristic because proper design and engineering can be used to account for diminished mechanical properties. A review of patent literature, for example, reveals that polyimides continue to be specified in medical devices in recent times despite the fact that more hydrolytically stable materials are available.

2.1.2 Product Design with Polymeric Materials

The basis of design with polymeric materials is similar to that of more traditional materials such as metal; a product is conceived, the concepts are formulated into a design, prototypes are tested and validated, and the product is launched into the market. Evaluation of field performance and consumer response is often utilized as a feedback mechanism for design enhancements and improvements; designs are often modified from first versions to increase usefulness and functionality.

In the absence of previous field or clinical experience, designs are often based on published or measured mechanical and physical properties from materials suppliers or specification sheets, and numerous standards exist for the evaluation of these parameters. Published guidelines and standards do not guarantee a problem free product,[2] nor do they always allow for innovation in areas where technology is rapidly changing. A better approach is incorporation of standards with historical data on material performance, testing and evaluation of products, and robust designs with appropriate redundancy.

2.1.3 Medical Device Design with Polymeric Materials

Standards also come into play in design of medical devices, and one interpretation of their function has been memorialized by the Global Harmonization Task Force (GHTF)

---

1 Delasi, R., Russell, J. "Aqueous Degradation of Polyimides," J. Applied Polymer Sci., 1971, 15, 2965.

2 Reitman, M.T., and Moalli, J.E., "Product Development and Standards Organizations: Listings and Certifications for Plastic Products," 8th Annual International Conference on Industrial Engineering Theory, Applications and Practice, Las Vegas NV, 2003.

in a document entitled "Role of Standards in the Assessment of Medical Devices." The published intent of this paper is "to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices ... " A review reveals that the GHTF believes that certain considerations should be kept in mind:

- Standards represent the opinion of experts from industry, regulators, users, and other interested parties.
- Standards are based on current scientific knowledge and experience.
- Innovation may present unanticipated challenges to experience.
- Rigid and mandatory application of standards may deter innovation.
- Operation of a quality system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health.
- Quality systems include provisions that address both innovation and experience.
- Such provisions include field experience, risk analysis and management, phased reviews, documentation and record keeping as well as the use of product and process standards.

Hence, as mentioned above in terms of product design in general, a well-accepted industry practice is to blend the use of appropriate standards with internal controls, quality systems, and risk analysis.

Basic product design dictates that various parameters be assessed during product development. Reliability, the ability of a device to perform consistently, is an output of design, and, although never 100 percent, can be enhanced through risk analysis based design. For example, a fault related to manufacturing tolerances or foreseeable misuse and identified in a failure modes and effects analysis, can be addressed by creating redundant or back-up components or functions.

2.2 The Guidant Ventak Prizm 2

2.2.1 History

The Guidant Ventak Prizm 2 DR Model 1861 (1861) is an implantable cardioverter defibrillator (ICD) that was first released to the market in 2000. The Prizm 2 was remarkable compared to previous devices as to its size; it was substantially smaller.

As with other ICDs, the Prizm 2 has several functions including pacing (sending energy to the heart in the event of a heartbeat that is too fast or too slow), cardioversion (sending a mild shock to the heart in order to stop a fast heartbeat), and defibrillation (sending a

stronger shock to the heart in the event that ventricular fibrillation is detected). Therapy is delivered through leads that run from the header of the device directly to the patient's heart. Wires within the header pass through to a metallic portion of the ICD called the can which contains electronic circuitry for the device. As an electronic device, the conductors in the 1861 were insulated to prevent contact with other conductors and related shorting. For example, the negative defibrillation (DF-) wire was insulated with a polyimide tubing shell, and could be routed in such a way as to not contact positively charged portions of the header. The space between the DF- wire and other components within the header was filled with a silicone medical adhesive (MA).

In February of 2002, an incident occurred in which an 1861 failed. Subsequent investigation and analysis revealed that the negative defibrillation wire (DF-) shorted to the metal backfill tube of the 1861. Initially, Guidant believed that nicks in the insulation created during the manufacturing process, or cold flow of the polyimide tubing, were likely causes of the short. Mr. Braund's device was manufactured and implanted prior to this event.

In April of 2002, a similar failure was induced in the laboratory during bench testing. A manufacturing change, initiated through an engineering change order (ECO) in April of 2002, applied medical adhesive which was allowed to cure to the backfill tube in order to prevent potential shorting to the DF- wire.

In May of 2002, an additional field occurrence was noted, a trend was opened, and the effectiveness of the first ECO was evaluated; the technical team agreed that further corrective action was warranted. In November of 2002, a design change was initiated through a second ECO, which called for addition of a polyimide tube around the metallic backfill tube to further reduce the likelihood of the DF- wire contacting it. To date, there has been a single failure in the post-April ECO population.

2.3 Design

It is my opinion that the 1861 is a reliable device and the header is not defective in design. It is clear that Guidant followed an appropriate risk-based design process and addressed potential failures by creating a system with appropriate redundant features.

As part of the 1861 design and development process, Guidant performed a Failure Modes Effects and Criticality Analysis (FMECA). Furthermore, a spacing analysis was performed. These analyses contemplated physical spacing, medical adhesive, and polyimide tubing insulation as a means for maintaining the electrical integrity of the wires in the header. In my experience, this type of redundancy is typical in a robust design that accounts for normal variations in assembly, manufacturing, and component failure; the presence of a single feature is sufficient to eliminate the failure mode.

The adequacy of the 1861 design is borne out in the actual field performance; the failure rate of the 1861 is not only similar to that of its peer products, it is also better than the reliability predicted by Guidant. The Guidant corporate reliability standard for

implantable defibrillators was 0.200% failures per month, or 93% survival at 3 years. While the predicted reliability for the 1861 was slightly better at 0.1443% failures per month, or almost 95% survival at 3 years, the actual reliability of the device is greater than 99% (this includes the known failures of the type alleged by plaintiffs). In comparison to peer ICDs manufactured by Medtronic and St. Jude, the Prizm 2 has similar or better reliability.

The overall reliability of the 1861 reflects the modifications to manufacturing described in the ECOs. Even prior to these changes the reliability of the device was still greater than the corporate requirement and the peer devices. This observation is critical in terms of assessing the initial safety of the device; although the changes may have enhanced performance, the 1861 was never unsafe to begin with. As is prudent with any engineered product, improvements to the initial design, as well as the manufacturing process, are reflective of a continuous product improvement process based on field performance and historical data and do not necessarily indicate design inadequacies.

I have personally examined more than a dozen explanted 1861 devices, both visually and microscopically. Although some of these devices exhibited cracked tubing on the DF-wire, and others indicated contact between the DF- wire and the backfill tube, they all functioned normally when tested (with the exception of a single device which had visibly arced). My observation of cracked tubing on functioning devices is consistent with the known high reliability of the 1861 in field use; it takes several concurrent events to create an arcing short. First, a crack must exist in the insulating polyimide tubing.[3] Second, there must be insufficient MA between the wire and the backfill tube. Third, the wire must be in contact with, or in very close proximity to, the backfill tube. Fourth, the crack must be in the region of the insulation that is in contact with the backfill tube; if the crack is too distant from the backfill tube, arcing cannot occur. Finally, the device must deliver therapy that would exceed the capacity of the insulation in the *in vivo* conditions.

2.4 Use of Polyimide

With the knowledge of the hydrolytic stability of polyimide in hand, it is instinctive to query the suitability of polyimide in implantable devices. To answer this question, it is necessary to examine some fundamental parameters of basic engineering design. First, is there an alternative polymer available that can meet the known design constraints (i.e., implantability, biocompatibility, resistivity)? Second, if the polyimide does in fact degrade, is the loss in a specific property greater than the residual property desired? Third, if the polyimide does in fact degrade, is the performance of the system compromised, or are there redundancies in the design to account for changes in the polyimide?

---

[3] There are a number of variables that affect the propensity of the polyimide insulation to crack, including stress level (bend radius), moisture level, and time of exposure. This variability is also born out in the field data as not all polyimide insulation is cracked.

In terms of the 1861 design, it is clear that the use of polyimide to insulate the DF- wire was appropriate. During the design phase of the 1861, polyimide was the best available candidate in terms of implantable polymeric insulating tubing. Silicone was also a candidate, but the investigations and allegations surrounding its use as an implantable material in mammary prostheses and small joint orthopedics certainly diminished its desirability as an engineering material. Furthermore, these issues made availability of silicone questionable. Poly(ether ether ketone) (PEEK) was not available as small diameter tube in an implantable grade.

The published data concerning hydrolytic degradation of polyimide also do not eliminate its viability as an implantable material. As indicated previously, the number of patents granted for the use of polyimide in medical devices showed a steady increase from the mid-1980s through the design period of the 1861. If design practitioners were leery of the use of polyimide *in vivo* because of potential degradation, it is doubtful that the patent literature would be so full of new applications.

The header design of the 1861 contemplated potential component failure and operator variability, and was not defective. Guidant evaluated the polyimide tubing on the component level, tested its performance as a system in acute *in vivo* testing, and finally Guidant had ample clinical history that demonstrated the efficacy of polyimide as an insulating material in this application.

2.5 The Braund Device

I have inspected the Braund 1861 visually and using an optical stereo microscope and was able to make several important observations. First, there was no evidence that arcing had ever occurred in the DF- wire. Second, there were no visible cracks on the polyimide insulation on the DF- wire. Third, the location of greatest bend (highest stress) on the wire was sufficiently remote from the backfill tube that it is highly unlikely that if cracking did exist that any short or arc would occur. Finally, there was space, filled with MA, between the backfill tube and the DF- wire insulation, making the likelihood of an arcing event extremely remote. In my opinion, the Braund device had no manufacturing defects. I have attached a typical photograph of the Braund device in Appendix 4.

2.6 Rebuttal

If called upon at trial, I will offer rebuttal testimony related to the opinions of plaintiff's experts.

Appendix 1

CV of Dr. John E. Moalli

John E. Moalli, Sc.D.

Group Vice President and Principal Engineer

Professional Profile

Dr. John Moalli is Group Vice President of Exponent Failure Analysis Associates. He addresses issues related to polymers (plastics), composite materials, rubbers, adhesives, and general materials science. His specialties include product design and development, analysis of fracture surfaces, combustion behavior, experimental mechanical property evaluation, development of constitutive relations, fracture behavior, patent analysis, and risk analysis in polymer and polymer composite systems. He is familiar with issues related to government recalls. His current areas of research pertain to the evaluation of polymers in medical, automotive, construction, recreational, and other environments.

Prior to joining Exponent, Dr. Moalli held the position of Research Associate at the Massachusetts Institute of Technology and was an independent materials science consultant.

Credentials and Professional Honors

Sc.D., Polymers, Massachusetts Institute of Technology, 1992

B.S., Civil Engineering, Northeastern University (with high honors), 1987

Tau Beta Pi; Sigma Xi; Chi Epsilon; Wullf Award; Society for the Plastics Industry Best Paper Award (2); Joseph P. Lawler Award; Percy J. Hill Award

Editorial Advisory Board, Medical Plastics and Biomaterials (member); Society for the Plastics Industry (member); Society for Plastics Engineers (senior member)

FAA Private Pilot, Airplane Single and Multi-Engine Land, Airplane Single Engine Sea, Instrument Airplane

Publications

"Polymeric Coatings for Medical Devices," Medical Device and Manufacturing Technology, Touch Briefings, pp. 28-30, 2006 (with M. Rietman)

"Failure Analysis of Nitrile Radiant Heating Tubing," Proceedings of ANTEC 2006, Society of Plastic Engineers, Charlotte, NC, May 2006 (with C.D. Moore, C. Robertson, and M. Reitman).

"Postmortem Analysis of Anastomotic Suture Line Disruption Following Carotid Endarterectomy," Journal of Forensic Science, Vol. 49, No.5, 2004.

"Determination of In-Service Exposure Temperature of Thermoformed PVC via TMA," Proceedings, 31st Annual North American Thermal Analysis Society Conference, Williamsburg, VA, 2004 (with J. McPeak and M. Reitman).

"Failure Analysis of a Large Diameter Floating Marine Hose," Proceedings, Society of Plastic Engineers, ANTEC 2002 (with S. Coakley and J. Pye)

"Practical Risk Analysis as a Tool for Minimizing Plastic Product Failures," Proceedings, Society of Plastics Engineers, ANTEC 2000 (with S. Medhekar and R. Caligiuri).

"Avoiding the GIGO Syndrome—Combining the Real and Virtual Worlds in the Analysis of Polymer Product Failures," Society of Plastics Engineers, ANTEC 2000 (with S. Kurtz, R. Sire, S. Srivastav, and M. Wu)

"Translating Failure Into Success—Lessons Learned From Product Failure Analysis," Society of Plastics Engineers, ANTEC, 1999.

"Failure Analysis of Polymeric Medical Devices," *Medical Plastics & Biomaterials*, Vol. I, No. 2, 1994 (with S. P. James).

"Ceramic Coated Rigid Rod Polymer Fibers," *SAMPE Quarterly*, Vol. 23, No. 4, July 1992.

"Ceramic Coated Rigid Rod Polymer Fibers," Proceedings, 47th Annual Society for the Plastics Industry Conference, Cincinnati, OH, 1992 (with F.J. McGarry).

"New Single Fiber Test Methods," Proceedings, 46th Annual Society for the Plastics Industry Conference, Washington, DC, 1991 (with F.J. McGarry).

Mechanical Behavior of Rigid Rod Polymer Fibers; I. Measurement of Axial Compressive and Transverse Tensile Strengths," *Polymer*, Vol. 32, No. 10, 1991 (with F.J. McGarry).

"Mechanical Behavior of Rigid Rod Polymer Fibers; II. Improvement of Compressive Strengths," *Polymer*, Vol. 32, No. 10, 1991 (with F.J. McGarry).

Presentations

"Product Development and Standards Organizations: Listings and Certifications for Plastic Products," 8th Annual International Conference on Industrial Engineering Theory, Applications and Practice, Las Vegas NV, 2003.

"The True Ultimate Stresses and Fracture Morphology of Ultra-High Molecular Weight Polyethylene Upon Tensile Failure," Transactions of the ASME Summer Bioengineering Conference, June 1997 (with S.M. Kurtz, C.W. Jewett, R.M. Vogt, and A.A. Edidin).

"Adhesion of Condensing Pluggers and Composite Placement," Proceedings, International Association of Dental Research Conference, Rio de Janeiro, Brazil, 1991 (with P.L. Millstein and E. Risciotti).

Book Chapters

"Failure Causes," *ASM Handbook, Volume 21 Composites*, pp. 951–952, ASM International, Material Park, OH, 2001

"Failure Analysis of Polymeric Medical Devices," *Medical Plastics—Degradation Resistance and Failure Analysis*, R.C. Portnoy (ed.), PDL, Norwich, NY, pp. 13–20, 1998.

Books

J. Moalli (ed.). Plastics Failure Analysis and Prevention, 1st Edition, William Andrew Publishing, Norwich, NY, 2001.

Academic Appointments

- Lecturer, Stanford University Department of Chemical Engineering (2005–present)

Appendix 2

List of Testimony
(Proceeding 4 Years)

Trial Testimony

1. Limestone County Water and Sewer Authority, *et al.* v. Shell Oil Co., AL
2. Bates, *et al.* v. Goodyear Tire & Rubber Co., NM
3. Sumerel, *et al.* v. Goodyear Tire & Rubber Co., CO
4. XL Insurance v. Celanese, Inc., London, England
5. Loughridge, *et al.* v. Goodyear Tire & Rubber Co., CO
6. Six Flags v. Canyon Manufacturing, Inc., TX
7. Holmes v. Goodyear Tire & Rubber Co., CO
8. Phillips, *et al.* v. Sumitomo Bakelite
9. Cross Mountain Ranch v. Goodyear Tire & Rubber Co., CO
10. Nature Guard Cases, Modesto, CA

Deposition Testimony (in addition to above-mentioned cases)

1. White v. Mack Truck, SC
2. Arrowhead Brass v. Real Seal, Inc., Orange County, CA
3. Venenberg v. Six Flags, TX
4. Virginia Consolidated Plaintiffs v. Ap.P. Green, *et al.*, VA
5. Gee v. Ethicon, Inc., OK
6. Kenney v. Dalloz Fall Protection, FL
7. Tillotson Corporation v. High Five Products, *et al.*, Inc., GA
8. Fujitsu LTD v. Sumitomo Bakelite, *et al.*, San Jose, CA
9. Hoffmaster v. Sand Point, Los Angeles, CA
10. Devine v. Ford Motor Company, Phoenix, AZ
11. Malcom v. Evenflo, MT
12. Che Rotramble v. Yamaha Motor Corp., TX
13. Chamblee v. Union Carbide Corp., *et al.*, Baltimore, MD
14. Lyon v. Kholer, TX
15. TW Heyenga Construction v. Paul Anthony Kopacz, *et al.*
16. Barous v. Randell Manufacturing, San Francisco, CA
17. Fortini v. 3M Company, *et al.*, Los Angeles, CA
18. Smith and Nephew, Inc., *et al.* v. Arthrex, Inc., OR
19. Ocean Terrace Condominium Trust v. General Electric Company, MA
20. Cabinets 2000 v. Frazee, *et al.*, San Diego, CA
21. Rincon v. V.W.R. International, Inc. *et al.*, San Francisco, CA
22. Lathrop v. A.W. Chesterton, *et al.*, San Francisco, CA
23. Piazza v. Advocate Mines, *et al.*, San Francisco, CA
24. Garrett v. Union Carbide, *et al.*, Portsmouth, VA
25. Rutherford v. Texas Industries, *et al.*, Dallas, TX
26. Duron v. Guidant, Minneapolis, MN

Appendix 3

Photographs

Figure 1. Photograph showing the DF- wire in the Braund device. No cracking is evident in the wire insulation, the point of maximum bend is not in contact with the backfill tube, and MA filled space exists between the backfill tube and the DF- wire insulation.