UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Robert W. Hasel, and ABCO Research, LLC,
Plaintiffs,
v.
Pulpdent Corporation, a Massachusetts corporation,
Defendant.

Civil File No. 01-2008 DSD/FLN

EXPERT REPORT OF RICHARD J. SIMONSEN, D.D.S., M.S.

I. Introduction

I, Richard Simonsen, have been asked to prepare this expert report for plaintiffs Robert Hasel and ABCO Research. This report relates to the Hasel patents-in-suit: U.S. Patent Nos. 5,944,527 (the '527 patent) and 6,315,567 (the '567 patent). This report and its attached exhibits are to be read as a whole.

II. Qualifications

I am Associate Dean for Preclinical Affairs and Research, and Professor of Restorative Dentistry, at the Arizona School of Dentistry & Oral Health, Mesa, Arizona. My work in the field of dentistry has included the full-time practice of dentistry in community, private and HMO clinics, and teaching/administrative positions at the University of Minnesota, New York University, the University of Connecticut and as Professor and Chair of the Department of General Dentistry at the University of Tennessee, Memphis. I also spent ten years in the dental industry as Global Professional Services Manager for 3M Company, Dental Products Division. From 1984-1986, I was Editor-in-Chief of *Quintessence International*, an international peer-reviewed dental journal based in Berlin, Germany. I am presently part of a small team creating a new dental school in Arizona.

I have authored or co-authored a number of publications that are directed to materials and methods used to restore defects in teeth. My first book, *Clinical Applications of the Acid Etch Technique*, was published in 1978. Since then, I have lectured extensively in the United States and around the world on the acid etch technique and composite resin systems. These and the remainder of my qualifications are set forth in my Curriculum Vitae, which is attached to my report as Exhibit A. My Curriculum Vitae includes a list of all publications authored or coauthored by me.

III. Compensation

My rate of compensation in connection with my undertaking in this case is $300.00 per hour. I have not testified as an expert at trial or by deposition within the preceding four years.

IV. Information Considered in Forming Opinions

In preparing this report, I relied on my review of the materials listed in Exhibit B. I reserve the right to supplement, modify, or expand my opinions and supporting exhibits in response to the reports of Pulpdent's experts. I expect to supplement my opinions if Pulpdent provides answers to Plaintiffs' outstanding discovery requests.

V. My Understanding of the Legal Principles Involved

My analysis and opinions are based on my understanding of a number of legal principles having to do with infringement. First, patent claims are made up of elements or limitations. These elements or limitations contain terms of art that have to be construed. Their construction is based on the claims themselves, the patent specification, the patent file history, and possibly the way in which those skilled in the field of dentistry understand the terms. The preamble of a claim is not a claim element or limitation if it merely states an intended use for a structurally complete invention found in the body of the claim.

Second, I understand that when one determines whether a claim is infringed, one looks at each and every element of the claim and compares the claim elements to corresponding elements in the allegedly infringing product or method. If each and every element of a claim is found in an allegedly infringing product or method, then the claim is literally infringed.

However, even if a claim is not literally infringed, a claim may be infringed under the doctrine of equivalents. A claim element not found literally in an allegedly infringing product or method is found under the doctrine of equivalents if any differences between the claim element and the corresponding element in the allegedly infringing product or method are insubstantial. One test used to determine whether the differences are insubstantial is the function-way-result test. Under this test, a determination is made for each claim element not found literally in the allegedly infringing product or method as to whether the allegedly infringing product or method includes an element which performs substantially the same function as the claim element in substantially the same way to obtain substantially the same result.

Finally, I understand that a person induces infringement by actively and knowingly aiding another's direct infringement.

VI. Opinions

A. Background

I expect at trial to offer a primer on dental restorations. I also expect to testify at trial regarding the evolution of restorative compositions and their method of application.

B. Development of the State of the Art Relating to the Subject Matter of the Present Suit

Dentistry was revolutionized with the development of the acid etch technique by the late Dr. Michael Buonocore. His discovery, first published in 1955, documented a technique that

allowed dentists to bond preventive and restorative materials to teeth. This technique has blossomed into use in almost every area of dentistry from simple fillings to orthodontics, where brackets are now routinely bonded to teeth.

In the early 1970's, about the time I graduated from dental school, Buonocore's 1955 paper had been supplemented with some papers on a technique that Buonocore pioneered, that of sealing the teeth of children to prevent cavities from forming with a bonded material called pit and fissure sealant. I became particularly interested in that material because it was the first time in history that we had a successful, non-invasive technique for the prevention of dental caries in the biting surfaces of back teeth, where fluoride is not so effective. In the early and mid 1970's, therefore, I started research projects relating to the application of sealant for prevention, and also relating to a more conservative method for the treatment of incipient lesions in the teeth of children and young adults, a technique that I eventually named the Preventive Resin Restoration. That technique is now in routine use in clinical dentistry around the globe. My study into the use of pit and fissure sealant was carried out for 15 years and was published in the *Journal of the American Dental Association* in 1991.

From the use of sealants came conservative uses of composite resins that were developed by Dr. Ray Bowen at the (then) National Bureau of Standards. Bowen's work initiated the development of the composite resin systems. Composite resins, as applied to dentistry, are materials formed from two or more constituents that are insoluble to each other. An example of a natural composite would be tooth enamel, formed from a collagen matrix and hydroxyapatite crystals. A dental composite consists of a resin matrix (Bowen developed the BIS-GMA resin molecule) and an inorganic filler (an early example was ground quartz).

The major constituents, therefore, of a resin composite, are the resin matrix and the inorganic filler particles. Other constituents include a coupling agent to enhance the bond between the resin matrix and the filler particles, a chemical for activating polymerization, and other additives, for example, to improve color stability and to prevent premature polymerization. BIS-GMA, being a high molecular weight monomer, and a very thick material, needs the addition of a diluent monomer in order to decrease the viscosity and thereby attain a clinically usable consistency. Inorganic filler particles generally account for between 30 and 70 volume percent to 50 to 85 weight percent of a restorative resin composite. The higher the filler load, the harder it is to work with a composite resin. The viscosity, or thickness, of the composite resin systems, particularly the early systems, was a clinical drawback in terms of handling and placement of the materials. Thus development of the flowable systems, with generally lower filler loads, provided an easier-to-deliver, and an easier-to-handle resin system.

The first composite resins were Addent 12 and Addent 35 from the 3M Company, which were introduced in about 1964. Interestingly, the inorganic filler for these materials was glass beads from 3M's reflective highway signs. These materials were not very successful in terms of clinical performance, and a new material utilizing ground quartz as the filler, called Concise, became the first successful resin composite material for restorative dentistry, along with a similar competitive material, Adaptic from the Johnson & Johnson Company. However, these early materials were not used with the acid etch technique until the late 1960's or early 1970's. The subsequent combination of the acid etch technique with composite resins opened up a new era in restorative dentistry.

The early days of these procedures saw incremental improvements in materials and techniques as dentists gained experience in the use of the composite resin systems. I was active

in the promotion, through lectures and teaching, of these new procedures and techniques from about 1979 on (see Curriculum Vitae for details). In 1989, I accepted an offer from the 3M Company to join the dental industry. During my ten years at 3M, I was able to learn and understand how the dental industry operates, and observe, from the inside, the competitive nature of the business. During my time at 3M, I watched the development of the "flowable composites" with the introduction of a material called Revolution in the fall of 1994.

Flowable composites were introduced to overcome some of the problems often associated with the handling and delivery of the existing composite resins. Flowables made dentistry easier for the dentist and, by extension, better for the patient. Before the advent of flowable composites, the filling materials for prepared cavities were highly viscous and paste-like. Because they were so thick, proper placement required skill and time. Because these pastes did not flow (at least as we think of the term today) it was possible for the dentist to experience difficulty in placing the material, particularly in areas of difficult access. The completed restoration could, therefore, contain porosities, as air could be trapped during the difficult placement. Voids in a restorative material can lead to problems for the restoration (weakness and/or leakage) and the patient (breakdown of the filling or sensitivity).

In contrast, flowable composites were introduced in syringe applicators, with tips that allowed the dentist to quickly and accurately deliver the filling material to prepared cavities. Because these materials were flowable, the likelihood of forming a void or porosity in the filling decreased as compared to the composite resins on the market. Flowable composites were particularly useful in areas of difficult access. Flowable composites have secured a place in modern restorative dentistry.

After the introduction of Revolution, the market potential of this category became evident to many manufacturers. Since 1994, most dental materials manufacturers have introduced their own flowable composites. Many dentists adopted flowables after they recognized the benefits of the ease of use, the easy delivery of restorative material through use of a syringe and a single-use tip, and the use of the tip in shaping and forming the restoration. It is, I believe, important to note that the term *flowable*, as used today to describe a specific category of materials with certain specific physical properties, was not part of the dental vernacular until after the introduction of Revolution in the fall of 1994.

C. Analysis of Issues Relevant to the Infringement of the Hasel Patents-in-Suit

I received a package of Pulpdent's Flows-Rite flowable composite. I opened the package in order to become familiar with the handling characteristics of the flowable composite and its instructions for use. I extruded material from the supplied syringe for the product. I observed that the material readily flowed out of the syringe through one of the supplied needle tips when only mild pressure was applied to the syringe plunger. I further observed that a bead of material less than 5 mm in diameter or less than 2 mm in thickness did not spread perceptibly in the time between finishing placement of the material and initiating the curing process.

In applying Flows-Rite in dabs less than about 5 mm diameter or layers less than 2 mm in thickness to the surface of teeth through a 20-gauge needle, I observed that Flows-Rite does not run off the surface in a clinically significant time. From that I deduce the following: (1) Flows-Rite can be applied to the hollow of a tooth through an 20-gauge needle attached to the syringe in which Flows-Rite is sold; (2) a dab less than about 5 mm diameter or a layer less than 2 mm in thickness would not run out of the tooth; (3) a desired shape on the tooth can be achieved by alternately layering the material and then curing; (4) Flows-Rite can be manipulated with the

supplied needle-tip into a desired shape; (5) Flows-Rite can be dispensed as a bead less than about 2 mm thick; (6) Flows-Rite can be applied in a layer less than 2 mm in thickness; (7) Flows-Rite can be layered to achieve a desired shape; and (8) Flows-Rite would not run out of the hollow during the procedure.

It is my opinion that the Pulpdent Flows-Rite flowable composite is substantially the same as the flowable composites described in the Hasel patents-in-suit in terms of how it is used, its handling characteristics, its intended method of use, and its intended purpose and function.

It is my understanding from a review of Pulpdent's documents and excerpts from the 30(b)(6) deposition of Kenneth Berk that the meaning of the following claim terms appear to be in dispute: "thixotropic," "running," "will not run," and "to not run."

The specifications of the '527 and '567 patents define "thixotropic" as a property of a material related to viscosity. When a thixotropic material is subjected to stress, the viscosity of the material is less than when it is not subjected to stress. '527 patent, col. 7, ll. 2-19; '567 patent, col. 7, ll. 9-26. The file histories for the patents-in-suit are consistent with the definition in the specifications. '379 file history at AD 100074; '527 file history at AD 100332 and AD 100336. Judge Kyle in the Kerr litigation construed the term "thixotropic" in a manner consistent with the manner in which the term is defined in the patents. I have reviewed his opinion.

The '527 and '567 patents define "running," "will not run," and "to not run" as follows: A restorative composition does not run if it does not flow or drip out of the tooth under gravity. '527 patent, col. 3, ll. 35-36; '567 patent, col. 7, ll. 25-26.

Based on my familiarity with the handling characteristics of this product, it is my opinion that: (1) Flows-Rite appears to behave as a thixotropic substance (it is readily extruded from a

syringe with a small needle-tip, yet after it has been extruded, it becomes more firm); and, (2) if used as directed, it will not run out of the tooth during any clinically significant period of time, i.e., prior to light curing.

It is my opinion that Flows-Rite and its method of use meet all of the limitations of claims 1–8, 10-20, 22 and 27-38 of the '527 patent, and of claims 1-21 of the '567 patent. It is my opinion that with respect to Flows-Rite, Pulpdent has induced dentists to practice the methods and use the materials in claims 1–8, 10-20, 22 and 27-38 of the '527 patent and claims 1-21 of the '567 patent. The bases for my opinions are set forth, in part, in the claims charts attached as Exhibits C-1 and C-2. My opinions are also based on excerpts from the 30(b)(6) deposition of Kenneth Berk attached hereto as Exhibit D.

I have reviewed the expert report of Dr. Edward Combe. I rely on his analysis of whether Flows-Rite technically is thixotropic, whether it contains a thixotropic agent, and whether its inorganic filler portion contains certain glass fillers.

VII. Exhibits to be used as Support for or in Summary of My Opinions

I currently expect to use one or more of the following exhibits to support my testimony at trial of this matter: (1) any documents listed in any exhibits attached to my report; (2) any deposition exhibits relating to deposition testimony referred to during the course of my testimony at trial; (3) Pulpdent's Flows-Rite flowable composite; (4) pastes and sealants; (5) the photographic exhibit attached as Exhibit E; and (6) any trial exhibits used by other witnesses to describe infringement or noninfringement arguments, the subject matter of Hasel's patents-in-suit, or the method of use or composition of Pulpdent's Flows-Rite flowable composite.

Date: November _____, 2002

_____
Richard J. Simonsen, D.D.S., M.S.