

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GC Corporation and GC America, Inc.,

Petitioner

v.

Ardent, Inc.,

Patent Owner

CASE: Unassigned

Patent No. 6,455,451

**DECLARATION OF DR. ARTHUR E. (“BUDDY”) CLARK
IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW**

I, Dr. Arthur E. (“Buddy”) Clark, declare as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I am a Professor in the Division of Prosthodontics at the Department of Restorative Dental Sciences, the College of Dentistry of the University of Florida.

2. I received a Bachelor of Science degree in Metallurgical Engineering in 1969, and a Master of Engineering degree and a Ph.D. degree in Material Science and Engineering in 1974, all from the University of Florida. In 1984, I also received a D.M.D. degree from the College of Dentistry of the University of Florida.

3. Since 1975, I have held various positions at the University of Florida. During the period from 1975 to 1996, I was appointed as an assistant, associate, and full Professor in the Department of Dental Biomaterials and the Department of Prosthodontics, both of the College of Dentistry. Since 1998, I hold affiliate appointments in the Department of Periodontology of the College of Dentistry and the Department of Materials Science and Engineering of the College of Engineering. In 2010, I became a Professor in the Department of Restorative Dental Sciences.

4. During my tenure as a Professor, I have taught undergraduate and graduate courses, conducted researches, and advised undergraduate and graduate

students as well as postdoctoral researchers. Since becoming semi-retired in January 2017, I no longer teaches on a regular basis but remains active in doing research and currently am a co-investigator on a NIH-sponsored grant for developing thin coatings to go onto the surface of currently used all-ceramic bridges.

5. My research interests cover the use and application of novel biotechnology and materials to dental implants and restorations, including the application of all ceramic prostheses. For example, I have investigated Bioglass®, sol-gel technology to manufacture bio-active glasses, and studied, in-vitro and in-vivo, the use of a bio-active powder to treat periodontal bony defects. More recently, my efforts have centered on the in-vitro study of dental glass-ceramics as well as clinical studies of commercial products to document their performance. Specifically, these studies are concerned with the use of ceramic materials as restorative oral prostheses, and a more appropriate in-vitro test to measure the corrosion process as it relates to the oral cavity. I also have examined the clinically observed wear phenomena of all-ceramic materials and am currently a co-investigator on a NIH Research Project Grant Program (R01) grant to develop a coating process that will reduce or eliminate the wear.

6. I am a member of various professional societies, including the International Association for Dental Research, Society for Biomaterials,

International College of Dentists, American Association of Dental Schools, American Dental Association, American Association for Dental Research, American College of Dentists, and the Florida Dental Association.

7. I joined the Editorial Board of the Journal of Oral Implantology in 1988 and served until 1993. Since 1988, and even at the present, I serve as a reviewer for the Journal of Dental Research, the Journal of Biomedical Materials Research, and the Journal of Oral Rehabilitation, as well as for the National Institute of General Medical Services/NIH.

8. I have published more than 70 articles in refereed journals, and over 50 conference abstracts. I have also been named as an inventor on two patents and two patent applications.

9. A more detail description of my background and qualification is provided in my *curriculum vitae*, a copy of which is attached as Exhibit A.

10. In addition to my general knowledge, education, and experience, I considered the materials listed in Exhibit B and identified in the accompanying Petition for *Inter Partes* Review in forming my opinion. For efforts in connection with the preparation of this declaration, I have been compensated at my standard hourly rate of \$400 per hour. My compensation is in no way contingent on the results of this or any other proceedings relating to the above-captioned patent.

II. INFORMATION PROVIDED TO ME

11. In proceedings before the USPTO, I understand that the claims of an unexpired patent are to be given their broadest reasonable interpretation in view of the specification from the perspective of one skilled in the field. I have been informed that the '451 patent has not expired. In comparing the claims of the '451 patent to the known prior art, I have carefully considered the '451 patent and its file history using my experience and knowledge in the relevant field.

12. For purposes of this declaration only, I have assumed a priority date of December 11, 1998 (the earliest possible priority date) in determining whether a reference constitutes prior art.

13. I understand that a claim is unpatentable if its subject matter is anticipated or obvious. I understand that in order to anticipate, a prior art reference “must describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.” I further understand that to establish anticipation, every limitation of a claim must be found either expressly or inherently in a single prior art reference. Therefore, in considering whether a prior art reference anticipates a particular claim, I reviewed the claim on an element by element basis to determine whether every element was disclosed in that prior art reference, either expressly or inherently, in a manner

“sufficient[]to have placed a person of ordinary skill in the field of the invention in possession of it.”

14. I understand that a patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. In considering obviousness, I utilized three inquiries: (1) the scope and content of the prior art; (2) any differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. In particular, I understand that the combination of familiar limitations according to known methods is likely to be obvious when it does no more than yield predictable results.

15. I have been informed that, should “secondary considerations” be considered sufficient, they may result in a claimed invention being considered not obvious. I understand that secondary considerations are objective evidence that (a) the invention achieved unexpected results, (b) the invention satisfied a long-felt need, (c) whether others have tried and failed to make the invention, and (d) whether the invention was commercially successful as a result of the merits of the claimed invention may be considered in determining whether a claimed invention is obvious. I understand that, for secondary considerations to be considered, they must be tied to the claimed invention. Put another way, there needs to be a

“nexus” between the claimed invention and the objective evidence showing “secondary considerations.” I also understand that, in order for evidence of “unexpected results” to be effective to overcome obviousness, the evidence must be commensurate with the scope of the claimed invention. Further, I understand that secondary considerations should be determined on a claim to claim basis, and it would be in error to attempt to reduce claims to a “gist” or “thrust” of the invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

16. I further understand that a claim is obvious if it unites old elements with no change to their respective functions, or alters prior art by mere substitution of one element for another known in the field and that combination yields predictable results. While it may be helpful to identify a reason for this combination, common sense should guide and no rigid requirement of finding a teaching, suggestion or motivation to combine is required. When a product is available, design incentives and other market forces can prompt variations of it, either in the same field or different one. If a person having ordinary skill in the relevant art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person having ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious. I

understand that a claim may be obvious if common sense directs one to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims. I understand that a person of ordinary skill in the art is a person of ordinary creativity, not an automaton.

17. I have been asked to consider U.S. Patent No. 5,219,799 to Beall *et al.* (“Beall”), International application publication No. WO 95/32678 to Petticrew (“Petticrew”) and “New Lithium Disilicate Glass-Ceramics” by Echeverria *et al.* (“Echeverria”; Boletín de la Sociedad Española de Cerámica y Vidrio, 1992, Vol. 5, pp. 183-188). I have also been asked to consider whether the techniques and procedures discussed in each of the aforementioned references, alone or in view of other cited prior art, read on each limitation of independent claims 1, 3, 57 and 61, and dependent claims 2, 4 and 58-60 (collectively “Challenged Claims”) of U.S. Patent No. 6,455,451 (“’451 patent”). My conclusion is that the Challenged Claims of the ’451 patent are unpatentable as rendered obvious over (a) Beall, (b) Echeverria, (c) Petticrew in combination with Beall, and/or (d) Petticrew in combination with Echeverria.

III. THE ’451 PATENT

A. Overview

18. The ’451 patent generally relates to glass-ceramics comprising lithium disilicate and to glass-ceramics for use in the manufacture of dental restorations

and methods of manufacture thereof. Ex. 1002, 1:14-17. According to the '451 patent, the disclosed lithium disilicate based glass-ceramics are “useful in the fabrication of single and multi-unit dental restorations (e.g. anterior bridges).” Ex. 1002, Abstract.

19. The '451 patent acknowledges that the use of lithium disilicate glass-ceramics in dental restorations were known in the prior art. *Id.* at 1:20-21. As an example, the '451 patent acknowledges that U.S. Patent No. 4,189,325 to Barrett *et al.* (“Barrett”) discloses “dental restorations made from castable lithium disilicate glass-ceramics.” Ex. 1002, 1:21-31.

20. The '451 patent notes that many of the lithium disilicate compositions in the prior art require casting the glass into the finally desired shape and thereafter heat treated to crystallize into a lithium disilicate phase. *Id.* at 2:8-12. The '451 patent explains that, because the microstructure was formed by the technician fabricating the dental restoration, the microstructure of the material may be changed to something not preferred or desired by the dental materials manufacturer due to overprocessing by the technician. *Id.* at 2:12-18. The '451 patent states that it is beneficial to provide a lithium disilicate glass-ceramic for use in the fabrication of dental restorations wherein crystallization is carried out by the dental materials manufacturer in the most controlled manner. *Id.* at 2:23-27. The '451 patent describes production of such lithium disilicate glass-ceramic materials in the

shape of pellets and/or blanks which can be then pressed or machined into dental restorations or products. *Id.* at 3:4-9, 17-18.

21. The '451 patent describes the lithium disilicate glass-ceramic compositions in terms of weight percent on the oxide basis in the ranges given in Table 1. *Id.* at 3-6. Notably, all of the glass-ceramic compositions according to the '451 patent comprise silica, lithium oxide, alumina, potassium oxide and phosphorus pentoxide in various amounts. *Id.* at 3:32-35, Table 1. These glass-ceramic compositions may also optionally comprise other oxides, such as B₂O₃, CaO, ZnO, ZrO₂, and CeO₂, among others. *Id.* at Table 1. The '451 patent further illustrates such glass-ceramic compositions by working examples and summarizes those exemplary compositions in Table 2. *Id.* at 8:25-26, Table 2.

B. Overview of Issued Claims

22. As issued, the '451 patent contains 66 claims. Claims 1-16 and 57-65 are product claims related to glass-ceramic compositions and dental restorations. Claims 17-56 and 66 are method claims related to methods of making a lithium disilicate dental restoration or product. The challenged claims in this proceeding are related to certain glass-ceramic compositions and dental restoration product claims, not method claims.

23. The following claims are challenged in this proceeding.

1. A glass-ceramic composition consisting essentially of in weight percent:

about 64 to about 70% SiO_2 ;
about 1.5 to about 6 Al_2O_3 ;
about 10 to about 15% Li_2O ;
about 2.5 to about 5% K_2O ;
about 2 to about 7% P_2O_5
up to about 1.5% F;
up to about 7% BaO;
up to about 1% SrO;
up to about 5% Cs_2O ;
up to about 2.7% B_2O_3 ;
up to about 0.9% CaO;
up to about 3% Na_2O ;
up to about 2% TiO_2 ;
up to about 3% ZrO_2 ;
up to about 1% SnO_2 ;
up to about 1% Sb_2O_3 ;
up to about 3% Y_2O_3 ;
up to about 1% CeO_2 ;
up to about 1% Eu_2O_3 ;
up to about 1% Tb_4O_7 ;
up to about 2% Nb_2O_5 ; and
up to about 2% Ta_2O_5 .

2. The glass-ceramic composition of claim 1 whereby the glass-ceramic is pressable.

3. A glass-ceramic composition consisting essentially of in weight percent:

about 64 to about 70% SiO_2 ;
about 5.2 to about 9 Al_2O_3 ;
about 10 to about 15% Li_2O ;
about 2 to about 7% P_2O_5 ;
up to about 1.5% F;
up to about 7% BaO;
up to about 1% SrO;
up to about 5% Cs_2O ;
up to about 5% K_2O ;
up to about 2.7% B_2O_3 ;
up to about 0.9% CaO;
up to about 3% Na_2O ;

up to about 2% TiO_2 ;
up to about 3% ZrO_2 ;
up to about 1% SnO_2 ;
up to about 1% Sb_2O_3 ;
up to about 3% Y_2O_3 ;
up to about 1% CeO_2 ;
up to about 1% Eu_2O_3 ;
up to about 1% Tb_4O_7 ;
up to about 2% Nb_2O_5 ; and
up to about 2% Ta_2O_5 .

4. The glass-ceramic composition of claim 3 whereby the glass-ceramic is pressable.

57. A dental restoration comprising a glass-ceramic consisting essentially of:

about 62 to about 85% SiO_2 ;
about 1.5 to about 10% Al_2O_3 ;
about 8 to about 19% Li_2O ;
about 2.5 to about 7% K_2O ;
about 0.5 to about 12% P_2O_5 ;
up to about 4.9% B_2O_3 ;
up to about 1.5% F ;
up to about 7% CaO ;
up to about 7% BaO ;
up to about 1% SrO ;
up to about 5% Cs_2O ;
up to about 5% Na_2O ;
up to about 2% TiO_2 ;
up to about 3% ZrO_2 ;
up to about 1% SnO_2 ;
up to about 1% Sb_2O_3 ;
up to about 3% Y_2O_3 ;
up to about 1% CeO_2 ;
up to about 1% Eu_2O_3 ;
up to about 1% Tb_4O_7 ;
up to about 2% Nb_2O_5 ; and
up to about 2% Ta_2O_5 .

58. The dental restoration of claim 57 formed into a component selected from orthodontic appliances, bridges, space maintainers, tooth

replacement appliances, splints, crowns, partial crowns, dentures, posts, teeth, jackets, inlays, onlays, facing, veneers, facets, implants, abutments, cylinders, and connector.

59. A blank for machining the dental restoration of claim 57.

60. A dental restoration comprising the glass-ceramic of claim 1.

61. A dental restoration comprising the glass-ceramic composition comprising:

about 64 to about 70% SiO₂;

about 5.2 to about 9 Al₂O₃;

about 10 to about 15% Li₂O; and

about 2 to about 7% P₂O₅.

C. Prosecution History

24. The patent application resulting in the '451 patent was filed on December 10, 1999, and issued on September 24, 2002. It claimed benefits to three U.S. provisional applications with the earliest priority date of December 11, 1998. *Id.* at cover.

25. The original claims that matured into independent claims 1 and 3 defined the claimed glass-ceramic composition with the transitional phrase “comprising” and did not recite the optional components defined by “up to about.” ('451 patent prosecution history (Ex. 1006) at 28, 32, as-filed claims 43 and 53). Likewise, the original claim that matured into independent claim 57 defined the glass-ceramic comprised in the claimed dental restoration with the transitional phrase “comprising” and did not recite the optional components defined by “up to about.” Ex. 1006 at 21-22, as-filed claims 1 and 4. During prosecution, these

claims were rejected as being anticipated or rendered obvious over prior art disclosing glass-ceramic compositions that either fell within or overlapped with the claimed ranges. *Id.* at 58-61 (January 31, 2001 Office Action at 4-7). In the same Office Action, the original claim that matured into independent claim 61 was identified as being allowable except for certain objectionable informalities. *Id.* at 61 (January 31, 2001 Office Action at 7).

26. In response, the applicants amended the claims that matured into independent claims 1, 3, and 57 to recite the transitional phrase “consisting essentially of” instead of “comprising” and to include certain additional components with optional language “up to about” as appeared in the issued claims. *Id.* at 73-76 (April 23, 2001 Amendment at 5-7). In the remarks, the applicants characterized the claimed glass-ceramic composition as follows:

The claimed invention is now directed to a glass-ceramic composition consisting essentially of SiO₂; Al₂O₃; Li₂O; K₂O; and P₂O as main ingredients in the composition. The following components may also be present; B₂O₃; F; CaO; BaO; SrO; Cs₂O; Na₂O; TiO₂; ZrO₂; SnO₂; Sb₂O₃; Y₂O₃; CeO₂; Eu₂O₃; Tb₄O₇; Nb₂O₅; and Ta₂O₅.

Id. at 80 (April 23, 2001 Amendment at 11).

27. To distinguish the claimed invention from the cited prior art, the applicants further stated:

There is [no] mention of MgO or ZnO in the claimed composition. Goto '522 requires the presence of MgO and ZnO in an amount of at least 0.5%. The claimed invention is not anticipated or rendered obvious over Goto '522. . . .

Schweiger '856 requires the presence of La_2O_3 in an amount of at least 0.1 percent. As set forth in Schweiger '856, La_2O_3 and Al_2O_3 are required in the composition to provide a free-flowing glass ceramic that can be pressed in the plastic state. The claimed invention excludes the presence of La_2O_3 . Moreover, the present invention excludes the presence of MgO and ZnO which may be present in the Schweiger '856 composition. The claims are not anticipated or rendered obvious by the Schweiger '856 reference.

Id. at 80-81 (April 23, 2001 Amendment at 11-12).

28. On May 31, 2001, a Notice of Allowance was issued allowing all of the then-pending claims. *Id.* at 92.

29. On August 16, 2001, the applicants filed a Continued Prosecution Application, or so-called CPA, in order to submit an Information Disclosure Statement for consideration. *Id.* at 101-16.

30. On October 25, 2001, the Examiner issued another non-final Office Action rejecting certain previously allowed claims over a number of references. *Id.* at 117-23 (October 25, 2001 Office Action at 3-4. None of the rejected claims in that Office Action was at issue in this Petition. After some claim amendments, a second Notice of Allowance was issued on March 13, 2002. *Id.* at 143.

IV. THE LEVEL OF ORDINARY SKILL IN THE ART

31. I have been advised that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the invention, the sophistication of the technology, the type of problems encountered in the art, and the prior art solutions to those problems. I have been informed that the level of skill in the art is evidenced by the prior art references. The prior art discussed herein demonstrates that a person of ordinary skill in the art (“POSITA”), at the relevant time (1999 based on the effective filing date of the ’451 patent), would have had knowledge and experience relating to the design, production and use of glass-ceramic compositions for various applications.

32. In my opinion, a person of ordinary skill in the art would have had knowledge and experience relating to the design, production and use of glass ceramic compositions for various applications. Such a person would have been able to design compositions for specific products, taking into account such variables as desired mechanical properties and the application for which the glass ceramic composition is being used. The POSITA would have had a bachelor’s or advanced degree, such as an M.S. or Ph.D. in chemistry, physics, ceramics, materials science and engineering, or chemical engineering, coupled with 2-5 years

of academic or industry experience in the area of glass ceramic research and development or similar work.

33. I am familiar with the perspective of the person having ordinary skill in the art from my university teaching position and my research work. Thus, in reaching my opinions, I have kept in mind that my opinions should reflect not my own perspective as a professor, but rather, my opinion on how a person having ordinary skill in the art at the time the patent application was filed would have understood the patent claims, patent specification, and the prosecution history.

V. CLAIM CONSTRUCTION

A. Consisting Essentially Of

34. The definition given to me was “consisting of SiO_2 , Al_2O_3 , Li_2O , K_2O and P_2O_5 as main ingredients with the following components also permitted— B_2O_3 , F, CaO, BaO, SrO, Cs_2O , Na_2O , TiO_2 , ZrO_2 , SnO_2 , Sb_2O_3 , Y_2O_3 , CeO_2 , Eu_2O_3 , Tb_4O_7 , Nb_2O_5 and Ta_2O_5 .”

35. I understand that the definition comes from several places in the prosecution history that the attorneys provided to me.

B. Dental Restoration

36. In my opinion, the broadest reasonable interpretation for “dental restoration” is “a dental appliance shaped for placement into a patient’s mouth.” This construction is proper in light of the intrinsic record.

37. For example, the Abstract of the '451 patent reads “[t]he glass-ceramics are useful in the fabrication of single and multi-unit dental restorations (e.g. anterior bridges) made by heat pressing into refractory investment molds produced using lost wax techniques.” Ex. 1002, 1. The Abstract also discloses “[t]he resulting glass ceramics are then pulverized into powder and used to form pressable pellets and/or blanks of desired shapes, sizes and structures which are later pressed into dental restorations.” Ex. 1002, 1.

C. Pressable

38. In my opinion, the broadest reasonable interpretation for “pressable” is “able to be formed into dental articles by heat pressing or injection molding using commercially available equipment.” This construction is proper in light of the intrinsic record.

39. The '451 patent defines “pressable” in the specification. “The glass-ceramics have good pressability, i.e., the ability to be formed into dental articles by heat pressing, also known as hot pressing or injection molding, using commercially available equipment.” Ex. 1002, 2:44-48.

D. Blank

40. In my opinion, the broadest reasonable interpretation for “blank” is “a small piece of material in a form (such as a cylinder or rectangular block) suitable for further processing into a dental restoration.” *See* Ex. 1002, 3:4-9, 17-18.

E. About

41. In my opinion, the broadest reasonable interpretation for “about” is “approximately.”

42. I understand that the Patent Owner has taken the position that, in the context of the '894 patent, “about” should be construed to mean “approximately,” and further that “approximately” is understood to have a level of precision of two units in the least significant figure recited. Ex. 1009, 2. In particular, I was present during the opening statements presented to the Chief Administrative Law Judge in Investigation No. 337-TA-1050 in the International Trade Commission. During the opening statement for the Staff, the slide that is submitted as Ex. 1009 in this proceeding was discussed, and Ex. 1009 accurately reflects the position asserted by Patent Owner in 337-TA-1050.

43. According to Patent Owner’s claim construction of ± 2 units in the least significant figure recited, where a claim limitation recites “about 1.5%,” the limitation would encompass 1.3-1.7% because the “5” is the least significant figure recited. Similarly, a recitation of “about 70%” would encompass 68-72% because the “0” is the least significant figure recited.

VI. THE PRIOR ART

A. Petticrew

44. Petticrew was published on December 7, 1995, more than one year before the earliest possible priority date on the face of the '451 patent (December

11, 1998). It is therefore prior art to the '451 patent under 35 U.S.C. § 102(b) (pre-AIA). Similar to the '451 patent, Petticrew is also related to the fabrication of dental restorations from glass-ceramic materials. Ex. 1003 at 1 (Abstract).

45. In fact, Petticrew identifies the same solution realized in the '451 patent for solving the various problems associated with the prior art methods in using glass-ceramic materials for fabricating dental restorations. Like the '451 patent, Petticrew discloses that “it would be desirable to form these restorations directly from a homogeneous molten glass-ceramic material.” *Id.*, 3. To do so, Petticrew discloses that “it may be possible to produce a satisfactory restoration by forcing a molten or plastic glass-ceramic material into a mold having a cavity in the form of the desired dental restoration.” *Id.*

46. Almost the entire Petticrew reference is a discussion of creating dental restorations. The title of the document is “Method for Molding Dental Restorations and Related Apparatus.” *Id.* at 1. The Abstract states, “The present invention is concerned with a process for the formation of dental restorations from glass-ceramic materials and the resulting dental restorations.” *Id.* at 1. In the Summary of the Invention section, Petticrew says “Accordingly, it is an object of the present invention to provide an efficient process whereby dental restorations may be molded from glass-ceramic materials.” *Id.* at 10. In the Description of the Preferred Embodiment, Petticrew says “Figure 1 generally describes the overall

process of the subject invention wherein dental restorations are formed by the molding of a glass-ceramic material.” *Id.* at 14. And there are many other references to dental restorations and forming dental restorations in the Petticrew document.

47. More specifically, Petticrew discloses that a dental restoration may be fabricated by:

- A. placing a glass-ceramic material in a heat-pressure deformable crucible;
- B. heating the crucible and glass-ceramic material to a temperature at which said crucible becomes heat-pressure deformable and the glass-ceramic material is moldable;
- C. bringing the heated crucible into contact with a mold having a preformed cavity therein;
- D. continuing to move the crucible into contact with the mold thereby causing the crucible to deform against the mold, and causing the moldable glass-ceramic material to be injected into said cavity, thereby forming a dental restoration;
- E. cooling the mold and the ceramic dental restoration therein;
- F. removing the formed ceramic restoration from the mold;
- G. heat treating the dental restoration; and
- H. finishing the dental restoration. *Id.* at 11.

48. Petticrew generically discloses glass-ceramic compositions that may be used in the disclosed process for the fabrication of a dental restoration. *See e.g., id.* at 24-25 (Tables I-III). In addition to those glass-ceramic compositions,

Petticrew expressly teaches that lithium disilicate glass-ceramic materials disclosed in Beall can also be used. *Id.* at 23:19-21.

49. Petticrew exemplifies that the dental restorations may be crowns, bridges, inlays, and onlays. *Id.* at 1:7-8.

B. Beall

50. Beall was published on June 15, 1993, more than one year before the earliest possible priority date on the face of the '451 patent (December 11, 1998). It is therefore prior art to the '451 patent under 35 U.S.C. § 102(b) (pre-AIA). Beall is directed to glass-ceramic articles containing lithium disilicate crystals as the predominant crystal phase. Ex. 1004 at Abstract.

51. Beall discloses the preferred embodiments as a group of precursor glass compositions in terms of parts by weight on the oxide basis. *Id.* at 8:55-58. According to Beall, Examples 1-8 provided in Table I (*Id.* at 9-10) reflect operable base compositions. *Id.* at 8:61-62.

52. To prepare the glass-ceramics, Beall discloses:

The batch ingredients were compounded, thoroughly mixed together to assist in securing a homogeneous melt, and charged into platinum crucibles. The crucibles were moved into a furnace operating at about 1450° C. and the batches melted for about 16 hours. The melts were thereafter poured into steel molds to yield glass slabs having dimensions of about 5''×5''×0.5'' (~ 12.7×12.7×1.3 cm), and those

slabs were transferred immediately to an annealer operating at about 450° C. *Id.* at 9:6-14.

After the glass slabs were removed from the annealer, samples for testing purposes were cut from each, e.g., test bars for measuring modulus of rupture, and those test samples plus the remainder of the slabs subjected to the heat treatments reported in Table II, whereby the glasses were crystallized in situ to glass-ceramics. *Id.* at 10:9-14.

53. Table II of Beall discloses two separate heat treatments for each Example, with the first heat treatment in the range of 480°C to 650°C and the second heat treatment in the range of 800°C to 950°C. *Id.* at 10 (Table II). Beall further discloses, in Table II, the annealing point (A.P.) for eight examples. *Id.*

C. Echeverria

54. Echeverria, entitled “New Lithium Disilicate-Glass Ceramics,” was published on 1992, more than one year before the earliest possible priority date on the face of the ’451 patent (December 11, 1998). The reference is an article published by Dr. Lina Echeverria of Corning Inc., who was also a co-inventor on the Beall patent. Dr. Echeverria’s article was published in *Boletin de la Sociedad Española de Cerámica y Vidrio* (i.e., the *Journal of the Spanish Ceramic and Glass Society*). It is prior art to the ’451 patent under 35 U.S.C. § 102(b) (pre-AIA).

55. Echeverria is directed to new lithium disilicate glass-ceramics that exhibit high strength and other properties that make them suitable for a variety of applications. Ex. 1003 at 183. Specifically, Echeverria discloses several lithium disilicate glass-ceramic compositions and their corresponding properties, including microstructure, expansion, density and mechanical properties, including “1) abraded MOR values of 20-35 Ksi, 2) toughness of 2-5 MPa m^{1/2}, 3) good chemical durability, 4) translucency, 5) glossy cerammed surfaces, and 6) low densification upon ceramming.” *Id.* at 184-87. According to Echeverria, such glass-ceramics all share common properties such as excellent strength and toughness, self-glazing and controllable translucency. *Id.* Echeverria further explains that “[s]ome physical properties, such as gloss, translucency, and expansion, are a function of the composition of the accessory glass, whereas mechanical properties, while affected by the composition of the accessory component, are more strongly influenced by the amount of lithium disilicate in the system.” *Id.* Given these statements, a person of ordinary skill in the art of glass-ceramics would certainly appreciate that Echeverria can be used for dental applications.

VII. THE PRIOR ART REFERENCED HEREIN RENDERS OBVIOUS EACH ELEMENT OF EACH CHALLENGED CLAIM OF THE '451 PATENT

A. Ground 1: Claims 1 and 3 Are Unpatentable Over Beall

56. Independent claims 1 and 3 each recite a “glass-ceramic composition consisting essentially of in weight percent” several components in various weight percentages. Ex. 1002, claims 1, 3. It is my opinion that the ranges of components in the disclosed compositions of Beall render obvious the compositions of claims 1 and 3.

1. Claim 1

57. The table provided below shows the components recited in claim 1. As shown, the first five limitations recite components that must be present in amounts within a recited range. Ex. 1002, claim 1. The remaining 17 limitations recite additional components that may optionally be present in the composition “up to about” a certain weight percentage. *Id.*

58. It is my opinion that claim 1 of the '451 patent is obvious in light of the ranges for components and other compositions disclosed in Beall. Ex. 1004, 2:5-9, 10:59-68 (claim 1 of Beall). The ranges permit a wide variety of compositions similar to Example 3 of Beall (which I consider the closest) but having amounts of SiO₂ and Li₂O that are within the numerical range of the components recited in claim 1. A POSITA in the art of glass-ceramics—using only the Beall reference—would be motivated to try different compositions of

glass-ceramics within the ranges identified in the Beall patent claims and as prompted by the different examples shown alongside Example 3. It renders claim 1 obvious because, even though not one specific example falls within the claims, there are other equally valid examples and ranges for SiO₂ and Li₂O components shown in the same patent that are within the numerical range of claim 1. There is also language in the patent itself sufficient to motivate anyone in the field of glass-ceramics to combine these examples and experiment with these ranges to come up with a different formulation or formulations that falls within the numerical range for SiO₂ and Li₂O shown in claim 1.

59. With respect to many of the claimed components in claim 1 that are optional (i.e., those that recite “up to” a certain weight percentage), they are entirely absent from Beall’s disclosed ranges. Ex. 1004, 2:5-9. I have identified those in the table below with “N/A.” For those components that Beall identifies and for which ranges are provided, the disclosed weight percentage ranges in Beall overlap those of claim 1. Ex. 1004, 2:5-9. Thus, as I further discuss below, it is my opinion that the composition of claim 1 would have been obvious in view of Beall.

60. The composition recited in claim 1 of the ’451 patent and the ranges of components disclosed in Beall are included in the table below.

<i>'451 Patent Claim 1</i>	<i>Beall</i>
about 64 to about 70% SiO ₂	65-80%
about 1.5 to about 6 Al ₂ O ₃	0-11%
about 10 to about 15% Li ₂ O	8-19%
about 2.5 to about 5% K ₂ O	0-7%
about 2 to about 7% P ₂ O ₅	1.5-7%
up to about 1.5% F	N/A
up to about 7% BaO	0-6%
up to about 1% SrO	0-6%
up to about 5% Cs ₂ O	N/A
up to about 2.7% B ₂ O ₃	N/A
up to about 0.9% CaO	0-10%
up to about 3% Na ₂ O	0-5%
up to about 2% TiO ₂	N/A
up to about 3% ZrO ₂	0-3%
up to about 1% SnO ₂	N/A
up to about 1% Sb ₂ O ₃	N/A

<i>'451 Patent Claim 1</i>	<i>Beall</i>
up to about 3% Y_2O_3	N/A
up to about 1% CeO_2	N/A
up to about 1% Eu_2O_3	N/A
up to about 1% Tb_4O_7	N/A
up to about 2% Nb_2O_5	N/A
up to about 2% Ta_2O_5	N/A

61. The claimed composition is within each range disclosed in Beall, with the insignificant exception of 64% and 65% SiO_2 . The ranges disclosed in Beall are very close to the recited ranges, and in some cases, are nearly coextensive. And, based on my review of the specification and prosecution history of the '451 patent, there is nothing critical about the recited ranges that would lead to any unexpected result. Rather, the prosecution history suggests that there is nothing remarkable about the recited ranges. Instead of arguing why the specifically claimed ranges would have been critical or would have led to unexpected results, the applicants canceled rejected claims and amended others to recite “consisting essentially of,” arguing that the prior art included other components (MgO , ZnO , and La_2O_3) that would allegedly materially affect the composition. Ex. 1006 at 80-

81. There were no arguments that the recited ranges were somehow critical to the invention or would lead to unexpected results. *Id.* Given that the proportions between Beall and the recited composition are so close, it is my opinion that a POSITA would have expected them to have the same properties.

62. I note that claim 1 recites the transitional phrase “consisting essentially of,” which I understand would require that the disclosure in Beall not include any unlisted components. The only component Beall identifies that is not recited in claim 1 is ZnO in an amount of 0-7%. Ex. 1004, 2:5-9. First, the disclosed range encompasses compositions having no ZnO, at all. If ZnO were so important to the composition, then I would expect its presence to be required in the composition but that is not the case. Ex. 1004, 2:5-9. Further, while the patentee argued “the present invention excludes the presence of MgO and ZnO” to distinguish over Schweiger (Ex. 1006 at 80-81), I note that the ’451 patent actually claims compositions that do include up to about 5% ZnO. Ex. 1002, claims 10, 35.

63. It is my opinion that Beall renders obvious the composition of claim 1.

2. Claim 3

64. Claim 3 recites a “glass-ceramic consisting essentially of in weight percent” several components. I have provided a table below to illustrate the components of claim 3. As shown, four components must be present while the

remaining limitations are optional. Ex. 1002, claim 3. Claim 3 differs with respect to claim 1 in that the amount of Al_2O_3 has been changed to 5.2-9% and K_2O is now recited as an optional component up to about 5%. Ex. 1002, claims 1, 3.

65. It is my opinion that claim 3 of the '451 patent is invalid as obvious in view of Beall, in light of the ranges for components and other compositions disclosed in Beall. Ex. 1004, 2:5-9. Beall discloses lithium disilicate glass-ceramics compositions and their properties and provides multiple examples of compositions. The patent claims a wide range of values for the composition, which provides ample motivation or suggestion to the person of skill in the art to adjust a glass-ceramics composition within the ranges stated in the patent. Many of the claimed optional components in claim 3 are absent from Beall's disclosed ranges, and therefore, have a 0% weight percentage that meets those optional components. Ex. 1004, 2:5-9. For those components that Beall identifies, the disclosed weight percentage ranges overlap those of claim 3. Ex. 1004, 2:5-9.

66. It is a widely known and universally accepted practice in the field of glass-ceramics that compositions and formulations are optimized through trial-and-error experimentation. A POSITA would be expected, even required, to test not only the exact examples disclosed in a reference like Beall but also to combine features from different examples to find even more favorable combinations. Beall states explicitly that different compositions and ranges of compositions are not

only possible but are within the scope of Beall's claimed invention. And so a POSITA would be motivated to try these different combinations suggested in Beall.

67. Thus, it is my opinion that the broad disclosure of Beall would render obvious the composition recited in claim 3.

68. Further, Beall's Example 7 falls either within the numerical range of this composition or is within the numerical range as augmented by "about," based upon Patent Owner's assertion regarding the precision of "about." Ex. 1004, 10:1-8. In this regard, every component disclosed in Beall Example 7 falls within the claimed ranges (± 2 in the least significant figure) in accordance with Patent Owner's interpretation of "about."

<i>'451 Patent Claim 3</i>	<i>Beall Example 7</i>	<i>Beall Ranges</i>
about 64 to about 70% SiO ₂	71.7%	65-80%
about 5.2 to about 9 Al ₂ O ₃	9.49%	0-11%
about 10 to about 15% Li ₂ O	9.47%	8-19%
about 2 to about 7% P ₂ O ₅	5.48%	1.5-7%
up to about 1.5% F	N/A	N/A
up to about 7% BaO	N/A	0-6%
up to about 1% SrO	N/A	0-6%

<i>'451 Patent Claim 3</i>	<i>Beall Example 7</i>	<i>Beall Ranges</i>
up to about 5% Cs ₂ O	N/A	N/A
up to about 5% K ₂ O	N/A	0-7%
up to about 2.7% B ₂ O ₃	N/A	N/A
up to about 0.9% CaO	1.08%	0-10%
up to about 3% Na ₂ O	N/A	0-5%
up to about 2% TiO ₂	N/A	N/A
up to about 3% ZrO ₂	2.49%	0-3%
up to about 1% SnO ₂	N/A	N/A
up to about 1% Sb ₂ O ₃	N/A	N/A
up to about 3% Y ₂ O ₃	N/A	N/A
up to about 1% CeO ₂	N/A	N/A
up to about 1% Eu ₂ O ₃	N/A	N/A
up to about 1% Tb ₄ O ₇	N/A	N/A
up to about 2% Nb ₂ O ₅	N/A	N/A
up to about 2% Ta ₂ O ₅	N/A	N/A

69. As shown in the table above, the claimed composition is within each range disclosed in Beall, with the insignificant exception of 64% (the lower limit in the claim) and 65% (lower limit of Beall) SiO_2 . The ranges disclosed in Beall are very close to the recited ranges, and in some cases, are nearly coextensive. And although no specific example falls precisely within the claimed range is disclosed in Beall, Example 7 is very close. As to Example 7 (and ignoring for now the term “about”) the components outside the specifically recited ranges are SiO_2 (71.7% outside about 64-70%), Al_2O_3 (9.49% outside about 5.2-9%), and CaO (1.08% outside up to about 0.9%). Ex. 1004, 10:1-8.

70. For the same reasons discussed above with respect to claim 1, the ranges disclosed in Beall render obvious the composition recited in claim 3. The applicants have not shown how any of the selected ranges of claim 3, such as “about 64 to about 70% SiO_2 ,” “about 5.2 to about 9 Al_2O_3 ,” “about 10 to about 15% Li_2O ,” and “about 2 to about 7% P_2O_5 ,” lead to anything unexpected compared to the broader ranges disclosed in Beall. Similarly, Beall’s Example 7 has components with weight percentages that are very close to those recited in claim 3. Therefore, in my opinion, a POSITA would have expected Beall’s Example 7 to have the same properties as a glass ceramic composition falling within the claimed ranges in claim 3.

71. Further, when considering the term “about” as applied by Patent Owner, Beall Example 7 discloses every component falling within the recited range. In particular: 71.7% of SiO₂ is about 70% (which corresponds to 68-72%); 9.49% of Al₂O₃ is about 9% (which corresponds to 7-11%); and 1.08% of CaO is about 0.9% (which corresponds to 0.7-1.1%). This is illustrated in the following table.

<i>Claim Limitation</i>	<i>Patent Owner Interpretation</i>	<i>Beall Example 7</i>
about 70% SiO ₂	68-72%	71.7%
about 9 Al ₂ O ₃	7-11%	9.49%
about 0.9% CaO	0.7-1.1%	1.08%

72. As previously discussed, there is no evidence that the applicants in the '451 patent considered any of the recited ranges to be critical to the invention for any of the components. Indeed, the disclosure of the '451 patent suggests that the recited ranges are not critical. For example, the '451 patent discloses, in Table 1, several ranges encompassed by the invention. Ex. 1002, Table 1. Table 1 discloses Ranges 1, 3, and 6 having weight percentage ranges that explicitly encompass Beall Example 7's 71.7% of SiO₂, 9.49% of Al₂O₃, and 1.08% of Li₂O. Ex. 1002, Table 1.

73. As discussed above with respect to claim 1, Beall does not include any additional components that would violate the “consisting essentially of” language of claim 3. In particular, although Beall discloses the potential presence of ZnO in the amount of 0-5%, (Ex. 1004, 2:5-9), (1) the range encompasses 0% ZnO and (2) the range is identical to that recited in claims 10 and 35 of the ’451 patent. Further, with respect to Beall Example 7, every component of the example is recited in claim 3. Ex. 1004, 10:1-8.

74. Accordingly, in my opinion the disclosure of Beall would render obvious the composition recited in claim 3.

B. Ground 3: Claim 3 Is Unpatentable Over Echeverria

75. Claim 3 recites “a glass-ceramic consisting essentially of in weight percent” several components in various percentages. A table setting forth claim 3 is provided below. As shown, four components must be present while the remaining several limitations are optional components. Ex. 1002, claim 3.

76. It is my opinion that claim 3 of the ’451 patent is obvious in light of the compositions disclosed in Echeverria. Echeverria discloses “glass-ceramics” providing specific compositions in Table I including amounts of each constituent in weight percent. Example E reads on each element of claim 3. Ex. 1005, 184. So, Echeverria’s Example E falls either within the numerical range of this

composition or is within the numerical ranges once Patent Owner's construction for the term "about" is applied. Ex. 1005, 184.

77. The composition recited in claim 3 of the '451 patent and Echeverria Example E are included in the table below.

<i>'451 Patent Claim 3</i>	<i>Echeverria Example E</i>
about 64 to about 70% SiO ₂	68.6%
about 5.2 to about 9 Al ₂ O ₃	8.56%
about 10 to about 15% Li ₂ O	11.2%
about 2 to about 7% P ₂ O ₅	4.18%
up to about 1.5% F	N/A
up to about 7% BaO	N/A
up to about 1% SrO	N/A
up to about 5% Cs ₂ O	N/A
up to about 5% K ₂ O	0%
up to about 2.7% B ₂ O ₃	N/A
up to about 0.9% CaO	1.01%
up to about 3% Na ₂ O	N/A
up to about 2% TiO ₂	N/A

<i>'451 Patent Claim 3</i>	<i>Echeverria Example E</i>
up to about 3% ZrO ₂	2.01%
up to about 1% SnO ₂	N/A
up to about 1% Sb ₂ O ₃	N/A
up to about 3% Y ₂ O ₃	N/A
up to about 1% CeO ₂	N/A
up to about 1% Eu ₂ O ₃	N/A
up to about 1% Tb ₄ O ₇	N/A
up to about 2% Nb ₂ O ₅	N/A
up to about 2% Ta ₂ O ₅	N/A

78. In Example E, there is only one component that falls outside of the specifically recited ranges in claim 3, as strictly interpreted: CaO. Ex. 1005, 184. Echeverria Example E discloses CaO in an amount of 1.01%, just outside the “up to about 0.9%” limitation. However, according to Patent Owner’s construction, the 1.01% disclosure of Echeverria Example E is “about 0.9%” as required by claim 3, because “about 0.9%” corresponds to 0.7-1.1%. Ex. 1005, 184. Further, in my opinion, a POSITA would expect Example E to have the same properties as a glass

ceramic composition falling within the claimed ranges given the closeness between Example E and every recited range.

79. Further, the Echeverria reference provides ample motivation or suggestion to the person of skill in the art to adjust a glass-ceramics composition within the ranges stated in the article. Example E from Echeverria already discloses a composition that is within the exact numerical ranges of claim 3, with the only exception being 1.01% CaO. One of ordinary skill in the art could also look to the range for CaO described later in Echeverria (“CaO 0-5 wt%”). Ex. 1005, 187.

80. In my opinion, Echeverria renders obvious claim 3.

C. Ground 2: Claims 2, 4 and 57-61 Are Unpatentable Over Petticrew in View of Beall

81. As discussed above, it is my opinion that Beall renders obvious claims 1 and 3. With regard to claims 2, 4 and 57-61, although Beall may not explicitly disclose some limitations, Petticrew discloses those limitations. And, it would have been obvious to combine Petticrew with Beall.

82. Both Petticrew and Beall were concerned with similar technology. Applicants admitted that “dental restorations made from castable lithium disilicate glass-ceramics” existed in the prior art. Ex. 1002, 1:21-31. Petticrew is one such example, disclosing the use of lithium disilicate glass-ceramics for dental restorations, and even explicitly disclosing using Beall’s compositions as dental

restorations. Ex. 1003, at 23. And, as discussed above, Beall discloses the specific lithium disilicate glass-ceramic compositions and methods for making those glass-ceramics recited in the '451 patent. Ex. 1004, 9:9-10:26.

83. As indicated above, there is explicit motivation provided within Petticrew to combine the disclosure of that reference with the compositions disclosed in Beall. Petticrew specifically refers to the Beall patent, stating “[o]ther lithium disilicate glass-ceramic materials which may be used in this invention are disclosed in U.S. Patent 5,219,799 issued June 15, 1993.” Ex. 1003 at 23. Given Petticrew’s instructions to use the Beall composition as a dental restoration, I believe it would have been at least obvious for a POSITA to try making a dental restoration from the compositions disclosed in Beall according to Petticrew’s procedures. That is what the instructions do, after all, instruct a POSITA to try those compositions in Petticrew’s disclosed process.

84. Further, a POSITA would have had a reasonable expectation of success in forming a dental restoration from any of Beall’s compositions using Petticrew’s process because Petticrew specifically teaches that “[l]ithium disilicate glass-ceramic materials are *particularly suited* for use in the invention” (Ex. 1003, 23 (emphasis added)) and Beall’s compositions are similar to those disclosed in Petticrew, particularly Tables I-III. Moreover, considering that the composition used in Example 15 of Petticrew is far different from those disclosed in Tables I-III

and was shown to be able to form a dental restoration (Ex. 1003, 52-53), a POSITA would have reasonably expected that compositions similar to those disclosed in Tables I-III of Petticrew, such as Beall's compositions, would similarly be able to form dental restorations. In this regard, Petticrew has shown that vastly different compositions could be successfully formed into dental restorations. It therefore stands to reason that a POSITA would have a reasonable expectation of success in using other compositions, and especially when following Petticrew's suggestion to use Beall's composition.

85. The disclosure of Petticrew is directly related to the subject matter of the Challenged Claims. In particular, just as in the Challenged Claims, Petticrew is directed to the use of lithium disilicate glass-ceramics for dental products. *Compare* Ex. 1003 at 11 (“another object of this invention is a process for forming a ceramic dental restoration”) and 23 (“[l]ithium disilicate glass-ceramic materials are particularly suited for use in the invention”) *with* Ex. 1002, 16:16-17 (preamble of claim 1 reciting a “method of making a lithium disilicate dental product”).

86. Moreover, while Petticrew discloses several specific glass-ceramic compositions, Petticrew also indicates that the methods disclosed therein would be suitable for use with lithium disilicate glass-ceramic compositions, including those specifically disclosed in Beall. Ex. 1003 at 23.

87. Accordingly, it is my opinion that a POSITA would have been motivated to use the compositions disclosed in Beall in the methods disclosed in Petticrew to prepare a dental restoration. In addition, given Petticrew's explicit disclosure that the methods disclosed therein would be compatible with Beall's compositions, a POSITA would have had a reasonable expectation of successfully implementing Petticrew's methodology with Beall's compositions. In my opinion, it would have at least been obvious for a POSITA to try making a dental product using Petticrew's methods with Beall's compositions.

88. There are several reasons for why a POSITA would have had a reasonable expectation of success in forming a dental product from the Beall composition using the Petticrew process. First, Petticrew specifically teaches that "[l]ithium disilicate glass-ceramic materials are particularly suited for use in the invention." Ex. 1003 at 23. In other words, if a certain material were "particularly suited" for a particular use, a POSITA would have a reasonable expectation of success in using that material in the suggested way. Second, Beall's compositions are similar to those disclosed in Petticrew. *Compare* Ex. 1003, Table 1 and Ex. 1004, Table 1. Because the compositions are so similar, a POSITA would have no reason to expect difficulties in substituting one composition for another. Third, Petticrew demonstrated that a wide variety of compositions could successfully be used for making a dental product. *See* Ex. 1003 at Table 1 and 52 (Working

Example 15). Because such a wide variety of compositions (for example, having vastly different amounts of SiO₂) could be used to form a dental product in Petticrew, a POSITA would reasonably expect successfully using other compositions in Petticrew's process.

89. I also understand that Patent Owner purchased the Beall patent from Corning and asserted the patent in litigation against Jeneric/Pentron's OPC 3G *pressable glass-ceramic dental restoration material*. Ex. 1007, *Ivoclar N. Am., Inc. v. Jeneric/Pentron Incorporated*, 2000 WL 35516146 (W.D.N.Y.), Complaint ¶¶7, 10-11. If Beall were not related to dental restorations, then why would the Patent Owner assert it against Jeneric/Pentron's dental restoration products?

1. Claims 2 and 4

90. Claim 2 depends from claim 1 and adds "whereby the glass-ceramic is pressable." Ex. 1002, claim 2. Claim 4 depends from claim 3 and similarly adds "whereby the glass-ceramic is pressable." Ex. 1002, claim 4.

91. Beall discloses "[i]t will be recognized that, whereas the above description is drawn to laboratory activity only, the glasses operable in the subject invention can be melted in large commercial melting units and formed into desired shapes via conventional glass melting and forming practice." Ex. 1004, 9:15-20. In other words, the Beall reference itself recognizes that the compositions described in this patent can be melted and formed into desired shapes (such as a

dental restoration) using conventional glass melting and forming practice. A POSITA in the art of glass-ceramics would understand this language to include the forming of dental restorations by conventional pressing technique.

92. Petticrew disclose forming dental restorations through pressing.

Petticrew states

the trade has recognized that in order to produce strong, translucent, metal free dental restorations it would be desirable to form these restorations directly from a homogeneous molten glass-ceramic material. It was realized that it may be possible **to produce a satisfactory restoration by forcing a molten or plastic glass-ceramic material into a mold having a cavity in the form of the desired dental restoration.** The prior art further recognized that the glass- ceramic material could be introduced into the cavity when the glass-ceramic material was in the liquid or in the plastic state.

Ex. 1003, 3 (emphasis added).

93. Petticrew then explains: “the process of the subject invention utilizes a positive mechanically applied force for purposes of injecting the molten dental glass-ceramic material into the preformed mold cavity.” Ex. 1003, 6.

94. Also, dental restorations are discussed throughout Petticrew, including forming “metal free crowns and bridges of outstanding strength and esthetic properties” using the lithium disilicate compositions. Ex. 1003, 22.

95. Thus it is my opinion that a person of ordinary skill in the art would have found it obvious to press the compositions given in Beall into dental restorations, as instructed in Petticrew. In my opinion, a POSITA would understand that Petticrew's glass-ceramic compositions were pressable at least because of its explicit disclosure of forming dental restorations by pressing plastic glass-ceramic material into a mold.

96. Thus, in my opinion, Petticrew discloses the limitations of claims 2 and 4.

2. Claim 57

97. Claim 57 recites "[a] dental restoration comprising a glass-ceramic consisting essentially of" several components set forth in the table below. As shown, the first five limitations recite components that must be present in an amount "about" a recited range. Ex. 1002, claim 57. The remaining several limitations recite additional components that may optionally be present in the composition "up to about" a certain weight percentage. Ex. 1002, claim 57.

98. First, Beall's Example 3 is an exact match for the numerical ranges shown in claim 57. Ex. 1004, 9:59-67. Beall's Example 3 also does not contain any of the additional components recited in claim 57, meeting the "up to about" limitations. Ex. 1004, 9:59-67.

99. Beall discloses broad ranges for the claimed components that overlap the claimed ranges, as set forth in the table below. Ex. 1004, 2:5-9. Thus, Beall discloses compositions with ranges of components that would render obvious the composition recited in claim 57.

100. The composition recited in claim 57 of the '451 patent, Beall Example 3, and the ranges of components disclosed in Beall are included in the table below:

<i>'451 Patent Claim 57</i>	<i>Beall Example 3</i>	<i>Beall Ranges</i>
about 62 to about 85% SiO ₂ ;	74.2%	65-80%
about 1.5 to about 10% Al ₂ O ₃ ;	3.54%	0-11%
about 8 to about 19% Li ₂ O;	15.4%	8-19%
about 2.5 to about 7% K ₂ O;	3.25%	0-7%
about 0.5 to about 12% P ₂ O ₅	3.37%	1.5-7%
up to about 4.9% B ₂ O ₃ ;	N/A	N/A
up to about 1.5% F;	N/A	N/A
up to about 7% CaO;	N/A	0-10%
up to about 7% BaO;	N/A	0-6%
up to about 1% SrO;	N/A	0-6%
up to about 5% Cs ₂ O;	N/A	N/A

<i>'451 Patent Claim 57</i>	<i>Beall Example 3</i>	<i>Beall Ranges</i>
up to about 5% Na ₂ O;	N/A	0-5%
up to about 2% TiO ₂ ;	N/A	N/A
up to about 3% ZrO ₂ ;	N/A	0-3%
up to about 1% SnO ₂ ;	N/A	N/A
up to about 1% Sb ₂ O ₃ ;	N/A	N/A
up to about 3% Y ₂ O ₃ ;	N/A	N/A
up to about 1% CeO ₂ ;	N/A	N/A
up to about 1% Eu ₂ O ₃ ;	N/A	N/A
up to about 1% Tb ₄ O ₇ ;	N/A	N/A
up to about 2% Nb ₂ O ₅ ; and	N/A	N/A
up to about 2% Ta ₂ O ₅ .	N/A	N/A

101. For the same reasons discussed above with respect to claims 1 and 3, claim 57 is also unpatentable as obvious based on the broad disclosure of overlapping ranges in Beall. Once again, the applicants have not shown how any of the ranges, e.g., “about 62 to about 85% SiO₂,” “about 1.5 to about 10 Al₂O₃,” “about 8 to about 19% Li₂O,” “about 2.5 to about 5% K₂O,” and “about 0.5 to

about 12% P₂O₅,” lead to anything unexpected compared to the ranges disclosed in Beall.

102. Regarding the “consisting essentially of” language of the preamble, as I have discussed before with respect to claim 1, the only component Beall identifies that is not recited in claim 57 is ZnO in an amount of 0-7%. Ex. 1004, 2:5-9. This encompasses compositions having no ZnO. Ex. 1004, 2:5-9.

103. Although Beall explicitly discloses the glass-ceramic composition recited in claim 57, Beall does not explicitly state that its compositions are applicable to a “dental restoration” as stated in the preamble of claim 57. This is found explicitly in Petticrew, which discloses that Beall’s compositions are indeed applicable to the field of dental restorations and instructing a POSITA to try Beall’s compositions in Petticrew’s disclosed process. *See* Ex. 1003, 23. Said differently, A POSITA, who is doing nothing more than following the exact written language of Petticrew, would be required to find the compositions of Beall and use them with the invention described in Petticrew.

104. Petticrew, entitled “Method for Molding Dental Restorations and Related Apparatus,” Ex. 1003 at Title, states:

[t]he present invention relates to a process for the molding of metal free dental restorations such as crowns, bridges, inlays, onlays, etc. from glass- ceramic materials. The invention is also concerned with apparatus which permits dental restorations to be easily molded from

glass-ceramic materials and lastly, the invention relates to the resulting dental restorations.

Ex. 1003, 1 (emphasis added). Given Petticrew's explicit instructions to use Beall's compositions as a dental restoration, it would have been at least obvious in my opinion for a POSITA to try making a dental restoration from the Beall compositions according to the Petticrew procedures. Ex. 1003, 23 ("Other lithium disilicate glass-ceramic materials which may be used in this invention are disclosed in [Beall]."). Further, as discussed above, a POSITA would have had a reasonable expectation of success in forming a dental restoration from any of Beall's compositions using Petticrew's process because Petticrew specifically teaches that "[l]ithium disilicate glass-ceramic materials are *particularly suited* for use in the invention (Ex. 1003, 23 (emphasis added)) and Beall's compositions are similar to those disclosed in Petticrew, particularly Tables I-III. Moreover, considering that the composition used in Example 15 of Petticrew is far different from those disclosed in Tables I-III and was shown to be able to form a dental restoration (Ex. 1003, 52-53), a POSITA would have reasonably expected that compositions similar to those disclosed in Tables I-III of Petticrew, such as Beall's compositions, would similarly be able to form dental restorations.

105. It is my opinion that the combination of Petticrew and Beall discloses every limitation recited in claim 57.

3. Claim 58

106. Claim 58 depends from claim 57 and adds the dental restoration “formed into a component selected from orthodontic appliances, bridges, space maintainers, tooth replacement appliances, splints, crowns, partial crowns, dentures, posts, teeth, jackets, inlays, onlays, facing, veneers, facets, implants, abutments, cylinders and connector.” Ex. 1002, claim 58.

107. So at least one of these items is required in the prior art reference. Petticrew discusses dental restorations throughout the entire length of the reference, and specifically that one may use the lithium disilicate compositions to form “metal free crowns and bridges of outstanding strength and esthetic properties.” EX. 1003, 22. Crowns and bridges are both listed in claim 58 of the ’451 patent.

108. Petticrew also discloses:

[t]he present invention relates to a process for the molding of metal free dental restorations such as crowns, bridges, inlays, onlays, etc. from glass- ceramic materials.

Ex. 1003, 1 (emphasis added). Therefore, Petticrew explicitly discloses examples recited in claim 58.

109. Given Petticrew’s explicit instructions to use Beall’s compositions for a dental restoration, it would have been at least obvious to a POSITA try making a dental restoration from the Beall compositions according to the Petticrew

procedures. Ex. 1003, 23. Further, as discussed above, a POSITA would have had a reasonable expectation of success in forming the listed dental restorations from the Beall composition using the Petticrew process.

110. It is my opinion that the combination of Petticrew and Beall discloses every limitation recited in claim 58.

4. Claim 59

111. Claim 59 recites a “blank for machining the dental restoration of claim 57.” Ex. 1002, claim 59.

112. Although neither Petticrew nor Beall contain an explicit description of machining a dental restoration, it would have been obvious to a POSITA to do so.

113. First, it is my opinion that this feature is implicit in Beall’s statement that the glass-ceramics can be “melted in large commercial melting units and formed into desired shapes via conventional glass melting and forming practice.” Ex. 1004, 9:15-20. A POSITA of glass-ceramics, looking at Beall at the time of the filing of the patent application for the ’451 patent, would understand that a “conventional glass melting and forming practice” certainly includes forming a shape by grinding or machining.

114. Second, Petticrew expressly teaches that Beall’s compositions can be used to form dental restorations. Also, in my experience, it was well known in the art at the time that dental restorations could be formed by pressing or machining.

Therefore, it would have been obvious for a POSITA to form Beall's compositions into a shape that is easy for machining.

115. Following are examples of what a POSITA would have known at the time concerning the availability and use of machining for lithium disilicate glass-ceramics. I.L. Denry, "Recent Advances in Ceramics for Dentistry" Crit. Rev. Oral. Biol. Med. 7(21):134-143 (1996) at 138 (Ex. 1008) (disclosing glass-ceramics in forms for CAD-CAM systems); Ex. 1010, 5:24-27 ("[i]t is also possible to process the glass ceramic product in the form of a blank by machining in stage (d2), particularly by CAD/CAM-based milling devices, to obtain a glass ceramic product of the desired geometry"); and J. Robert Kelly, Ceramics in Dentistry: Historical Roots and Current Perspectives, The Journal of Prosthetic Dentistry, vol. 75, no. 1, pp. 18-32 (Jan. 1996) at 23-24 (Ex. 1011) (discussing machining as a "forming method in fabrication of ceramic restorations.").

116. It is my opinion that the combination of Petticrew and Beall discloses every limitation recited in claim 59.

5. Claim 60

117. Claim 60 depends from claim 1 and recites "a dental restoration comprising the glass-ceramic of claim 1." Ex. 1002, claim 60.

118. As discussed above, the composition recited in claim 1 is rendered obvious by the disclosure of Beall. As also discussed above with respect to claim

57, Beall does not explicitly disclose application of its compositions to dental restorations. However, Petticrew explicitly discloses using Beall's compositions to form dental restorations. Ex. 1003, 23.

119. It is my opinion that the combination of Petticrew and Beall discloses every limitation recited in claim 60.

6. Claim 61

120. Claim 61 recites "[a] dental restoration comprising the glass-ceramic composition comprising" several components set forth in the table below. Ex. 1002, claim 61.

121. It is my opinion that claim 61 of the '451 patent is invalid as is obvious in light of Example 4 in combination with Petticrew. The composition of Beall Example 4 matches the numerical ranges of claim 61 exactly. Ex. 1004, 9:59-10:7.

122. Also, the ranges of components disclosed in Beall overlap with the claimed ranges recited in claim 61, rendering the recited ranges obvious. Ex. 1004, 2:5-9. Moreover, claim 61 recites the open-ended transitional term "comprising" rather than "consisting essentially of," which accordingly does not prohibit the presence of additional components beyond those recited in the claim. So it does not matter that there is ZrO₂ or CaO or any other component present in Example 4 of Beall.

123. The composition recited in claim 61 of the '451 patent, Beall Example 4, and the ranges of components disclosed in Beall are included in the table below.

<i>'451 Patent Claim 61</i>	<i>Beall Example 4</i>	<i>Beall Ranges</i>
about 64 to about 70% SiO ₂	68.6%	65-80%
about 5.2 to about 9 Al ₂ O ₃	8.56%	0-11%
about 10 to about 15% Li ₂ O	11.2%	8-19%
about 2 to about 7% P ₂ O ₅	4.18%	1.5-7%

124. As detailed above, Petticrew explicitly instructs a POSITA to use Beall's compositions in the formation of a dental restoration. Ex. 1003, 23. Thus, it would have been at least obvious to a POSITA to try making a dental restoration from the Beall compositions according to the Petticrew procedures. Ex. 1003, 23. Further, as discussed above, a POSITA would have had a reasonable expectation of success in forming the listed dental restorations from any of the Beall compositions using the Petticrew process.

125. It is my opinion that the combination of Petticrew and Beall discloses every limitation recited in claim 61.

D. Ground 4: Claims 4, 57-59 and 61 Are Unpatentable Over Petticrew in View of Echeverria

126. As discussed above, it is my opinion that Echeverria renders obvious claim 3. With regard to claims 4, 57-59 and 61, although Echeverria may not explicitly disclose some limitations, Petticrew discloses those limitations. And, it would have been obvious to combine Petticrew with Echeverria.

127. The disclosure of Petticrew itself suggests that Echeverria's compositions could easily be used in Petticrew's disclosed methods. Petticrew teaches that lithium disilicate glass-ceramic materials are the preferred glass-ceramic materials for use in the disclosed method. See Exhibit 1003, 25 ("As is shown in Table I to IV preferred glass-ceramic materials for use in this invention are lithium disilicate glass- ceramic materials. . . . Lithium disilicate glass-ceramic materials are particularly suited for use in the invention . . . ")(emphasis added). Thus, Petticrew specifically instructs a POSITA that lithium disilicate glass-ceramics, such as those disclosed in Echeverria, are the preferred materials for use in Petticrew's methods.

128. For the same reasons I discussed with respect to Beall, a POSITA would have had a reasonable expectation of success in forming a dental restoration from any of Echeverria's compositions using the Petticrew process because Petticrew specifically teaches that "[l]ithium disilicate glass-ceramic materials are *particularly suited* for use in the invention" (Ex. 1003, 23 (emphasis added)) and Echeverria's compositions are similar to those disclosed in Petticrew, particularly Tables I-III. Moreover, considering that the composition used in Example 15 of Petticrew is far different from those disclosed in Tables I-III and was shown to be able to form a dental restoration (Ex. 1003, 52-53), a POSITA would have reasonably expected that compositions similar to those disclosed in Tables I-III of Petticrew, such as Echeverria's compositions, would similarly be able to form dental restorations. In this regard, Petticrew has shown that vastly different compositions could be successfully formed into dental restorations. It therefore stands to reason that a POSITA would have a reasonable expectation of success in using other compositions, and especially when following Petticrew's suggestion to use Echeverria's composition.

1. Claim 4

129. Claim 4 depends from claim 3 and adds "whereby the glass-ceramic is pressable." Ex. 1002, claim 4.

130. Echeverria discloses “[t]he low viscosity and liquidus simplified delivery and forming of these glasses, and allows diverse forming techniques.” Ex. 1005, 184. Echeverria also discloses that “[t]he precursor glasses have low viscosities, and are amenable to a variety of forming techniques.” Ex. 1005, 187.

131. A POSITA of glass-ceramics at the time of the filing of the application for the ’451 patent would have understood that a composition that is amenable to “diverse forming techniques” and “a variety of forming techniques” would be able to be formed through pressing using commercially available equipment. Ex. 1003 at 184,187. A POSITA would have known that at least from Petticrew.

132. As I discussed above, Petticrew describes in detail the use of lithium disilicate glass-ceramics to form pressable dental restorations, and dental restorations are discussed throughout Petticrew, including forming “metal free crowns and bridges of outstanding strength and esthetic properties” using the lithium disilicate compositions. Ex. 1003, 22.

133. It is my opinion that Petticrew and Echeverria disclose the limitation of claim 4.

2. Claim 57

134. Claim 57 recites “[a] dental restoration comprising a glass-ceramic consisting essentially of” several components set forth in the table below. As

shown, the first five limitations recite components that must be present in an amount “about” a recited range. Ex. 1002, claim 57. The remaining several limitations recite additional components that may optionally be present in the composition “up to about” a certain weight percentage. Ex. 1002, claim 57.

135. It is my opinion that claim 57 of the '451 patent is obvious in light of Example D, in combination with Petticrew. Echeverria's Example D falls exactly within the numerical range of this composition. Ex. 1005, 184. Echeverria's Example D does not contain any of the additional components recited in claim 57.

136. The composition recited in claim 57 of the '451 patent and Echeverria's Example D are included in the table below:

<i>'451 Patent Claim 57</i>	<i>Echeverria Example D</i>
about 62 to about 85% SiO ₂	74.2%
about 1.5 to about 10% Al ₂ O ₃	3.54%
about 8 to about 19% Li ₂ O	15.4%
about 2.5 to about 7% K ₂ O	3.25%
about 0.5 to about 12% P ₂ O ₅	3.37%
up to about 4.9% B ₂ O ₃	N/A
up to about 1.5% F	N/A

<i>'451 Patent Claim 57</i>	<i>Echeverria Example D</i>
up to about 7% CaO	N/A
up to about 7% BaO	N/A
up to about 1% SrO	N/A
up to about 5% Cs ₂ O	N/A
up to about 5% Na ₂ O	N/A
up to about 2% TiO ₂	N/A
up to about 3% ZrO ₂	N/A
up to about 1% SnO ₂	N/A
up to about 1% Sb ₂ O ₃	N/A
up to about 3% Y ₂ O ₃	N/A
up to about 1% CeO ₂	N/A
up to about 1% Eu ₂ O ₃	N/A
up to about 1% Tb ₄ O ₇	N/A
up to about 2% Nb ₂ O ₅	N/A
up to about 2% Ta ₂ O ₅ .	N/A

137. Although Echeverria explicitly discloses the glass-ceramic composition recited in claim 57, Echeverria does not explicitly state that its compositions are applicable to a “dental restoration” as stated in the preamble of claim 57. This is found explicitly in Petticrew, and it would have been obvious to a POSITA to form a dental restoration from Echeverria’s compositions in view of Petticrew for the reason I discussed above. *See* Ex. 1003, 23.

138. It is my opinion that Petticrew and Echeverria disclose the limitations of claim 57.

3. Claim 58

139. Claim 58 depends from claim 57 and adds the dental restoration “formed into a component selected from orthodontic appliances, bridges, space maintainers, tooth replacement appliances, splints, crowns, partial crowns, dentures, posts, teeth, jackets, inlays, onlays, facing, veneers, facets, implants, abutments, cylinders and connector.” Ex. 1002, claim 58.

140. So at least one of these items is required in the prior art reference. Petticrew discusses dental restorations throughout the entire length of the reference, and specifically that one may use the lithium disilicate compositions to form “metal free crowns and bridges of outstanding strength and ethetic properties.” EX. 1003, 22. Crowns and bridges are both listed in claim 58 of the ’451 patent.

141. Petticrew discloses:

[t]he present invention relates to a process for the molding of metal free dental restorations such as crowns, bridges, inlays, onlays, etc. from glass- ceramic materials.

Ex. 1003, 1 (emphasis added). Therefore, Petticrew explicitly discloses examples recited in claim 58.

142. While Petticrew does not specifically instruct to use the compositions of Echeverria, as is the case for Beall, it nevertheless would have been obvious for a POSITA to consider Echeverria's compositions together with the disclosure of Petticrew and at least to try making a dental restoration from the compositions disclosed in Echeverria according to the procedures disclosed in Petticrew. Further, as discussed above, a POSITA would have had a reasonable expectation of success in forming the listed dental restorations from the Echeverria composition using the Petticrew process.

143. It is my opinion that the combination of Petticrew and Echeverria discloses every limitation recited in claim 58.

4. Claim 59

144. Claim 59 recites a "blank for machining the dental restoration of claim 57." Ex. 1002, claim 59.

145. Although neither Petticrew nor Echeverria contain an explicit description of machining a dental restoration, it would have been obvious to a POSITA to do so.

146. First, it is my opinion that this feature is implicit in Echeverria's discussion of how the disclosed compositions are useful in a variety of forming techniques. A person of ordinary skill in the art of glass-ceramics, looking at Echeverria at the time of the filing of the patent application for the '451 patent, would understand that a "variety of forming techniques" certainly includes forming a shape by grinding or machining.

147. Further, as I mentioned, it would have been obvious for a POSITA to consider Echeverria's compositions together with the disclosure of Petticrew. Also, in my experience, it was well known in the art at the time that dental restorations could be formed by pressing or machining. Therefore, it would have been obvious for a POSITA to form Echeverria's compositions into a shape that is easy for machining.

148. Following are examples of what a POSITA would have known at the time concerning the availability and use of machining for lithium disilicate glass-ceramics. I.L. Denry, "Recent Advances in Ceramics for Dentistry" Crit. Rev. Oral. Biol. Med. 7(21):134-143 (1996) at 138 (Ex. 1008) (disclosing glass-ceramics in forms for CAD-CAM systems); Ex. 1010, 5:24-27 ("[i]t is also

possible to process the glass ceramic product in the form of a blank by machining in stage (d2), particularly by CAD/CAM-based milling devices, to obtain a glass ceramic product of the desired geometry”); and J. Robert Kelly, *Ceramics in Dentistry: Historical Roots and Current Perspectives*, *The Journal of Prosthetic Dentistry*, vol. 75, no. 1, pp. 18-32 (Jan. 1996) at 23-24 (Ex. 1011) (discussing machining as a “forming method in fabrication of ceramic restorations.”).

149. It is my opinion that the combination of Petticrew and Echeverria discloses every limitation recited in claim 59.

5. Claim 61

150. Claim 61 recites “[a] dental restoration comprising the glass-ceramic composition comprising” several components set forth in the table below. Ex. 1002, claim 61.

151. It is my opinion that claim 61 of the ’451 patent is obvious in light of Example E, the ranges for components and the compositions disclosed in Echeverria in combination with Petticrew. Echeverria Example E falls exactly within the numerical ranges recited in claim 61. Ex. 1005, 184; Moreover, claim 61 recites the open-ended transitional term “comprising” rather than “consisting essentially of,” which accordingly does not prohibit the presence of additional components beyond those recited in the claim. So it does not matter that there is ZrO₂ or CaO or any other component present in Example E of Echeverria. It is

also my opinion that the ranges of components disclosed in Echeverria overlap with the claimed ranges recited in claim 61, rendering the recited ranges obvious.

Ex. 1005, 187.

152. The composition recited in claim 61 of the '451 patent, Echeverria Example E., and the ranges of components disclosed in Echeverria are included in the table below.

<i>'451 Patent Claim 61</i>	<i>Echeverria Example E</i>	<i>Echeverria Ranges</i>
about 64 to about 70% SiO ₂	68.6% SiO ₂	65-80%
about 5.2 to about 9 Al ₂ O ₃	8.56% Al ₂ O ₃	0-10%
about 10 to about 15% Li ₂ O	11.2% Li ₂ O	8-17%
about 2 to about 7% P ₂ O ₅	4.18% P ₂ O ₅	1-5%

153. Petticrew describes using lithium disilicate glass- ceramic compositions from another patent for the purpose of making dental restorations, a POSITA would appreciate that the lithium disilicate compositions of Echeverria can also be used here. As detailed above, Petticrew explicitly instructs a POSITA to use Beall's compositions in the formation of a dental restoration (Ex. 1003, 23), and given the similarity of Beall and Echeverria, it would have been at least obvious to a POSITA try making a dental restoration from the Echeverria compositions according to the Petticrew procedures. A POSITA would have had a

reasonable expectation of success in forming the listed dental restorations from the Echeverria compositions using the Petticrew process for the reasons I provided above.

154. Thus, it is my opinion that claim 61 would have been obvious over Petticrew in view of Echeverria.

155. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the results of these proceedings.

Date: 4/17/18

Arthur E. Clark

Dr. Arthur E. Clark