

Declaration of Alan Jeffrey Giacomini in Support of
Petition for *Inter Partes* Review of
U.S. Patent No. 10,870,263

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY,
Petitioner

v.

BAY MATERIALS, LLC,
Patent Owner

Case No. IPR2023-00243

U.S. Patent No. 10,870,263

Filing Date: December 18, 2019

Issue Date: December 22, 2020

Title: Dual Shell Dental Appliance and Material Constructions

DECLARATION OF ALAN JEFFREY GIACOMINI, PH.D.

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I, Alan Jeffrey Giacomini, Ph.D. declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

A. Qualifications and Experience

1. I received a Bachelor of Science with honours in Chemical Engineering from Queen's University in 1981, a Master of Science in Chemical Engineering from Queen's University in 1983 and a Doctor of Philosophy in Chemical Engineering from McGill University in 1987. I am a licensed Professional Engineer in Wisconsin (#31292-6) and Ontario (#100200622).

2. I am currently a Professor of Chemical Engineering, of Mechanical and Materials Engineering and of Physics, Engineering Physics and Astronomy at Queen's University at Kingston in Canada where I hold the title of Tier 1 Canada Research Chair in Physics of Fluids. I have also been serving as an Adjunct Professor at the University of Nevada in Reno, Nevada since 2020. I teach three courses at Queen's University involving polymer manufacturing and rheology. Rheology is the study of flow and deformation.

3. Before joining the faculty at Queen's University, I served as the chair of the Rheology Research Center at the University of Wisconsin for nearly twenty years. I have also held visiting professorships at McGill University, the University of Sherbrooke, the Swiss Federal Institute of Technology, the Paris School of Mines, the National University of Singapore, Chung Yuan University near Taipei, Yunlin

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University, in southern Taiwan, Shandong University in mainland China, and the University of Nevada, Reno.

4. I am currently the immediate Past-President of the Canadian Society of Rheology and sole Editor-in-Chief of *Physics of Fluids*. I am also the former President of The Society of Rheology and former Associate Editor for Business of the *Journal of Rheology*. In addition to these roles, I am also a member of more than a dozen other professional organizations where I have held elected and appointed leadership positions.

5. My research focuses on the role played by rheology in polymer processing or in plastics manufacturing. In particular, my research has focused on experimental and theoretical investigations in plastics thermoforming and extrusion, as well as the mechanical properties, including the relation between polymer hardness and elastic modulus.

6. Over the course of my career, I have published more than 175 refereed journal publications, many of which related to polymer rheology. I have published on ASTM standards, and specifically on the hardness standard, ASTM D2240, in the *Journal of Testing and Evaluation*, the archival peer-reviewed journal of the American Society for Testing and Materials, and also in *Polymer-Plastics Technology and Engineering*. The *Journal of Testing and Evaluation* publications

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are incorporated by reference in the patents at issue in this case. On thermoforming, I have published in *Polymer Engineering and Science*, *Journal of Plastic Film and Sheeting*, *Journal of Polymer Engineering*, *Journal of Advanced Engineering*, *AIChE Journal*, and *Zeitschrift Kunststofftechnik (Journal of Plastics Technology)*.

7. I have served as a peer reviewer for many refereed journals including *International Polymer Processing*, *Journal of Rheology*, *Physics of Fluids*, *Polymer Engineering and Science*, and *Polymer-Plastics Technology and Engineering* among others.

8. I have presented my research at conferences and universities across the world. I have been extended the invitation to be the keynote speaker and speak at national and international conferences including the keynote for the 62nd Canadian Chemical Engineering Conference, the keynote for the Annual Meeting of the Canadian Society of Rheology, and most recently a plenary lecture for The 30th International Symposium on Transport Phenomena in Vietnam.

9. I am a named inventor of U.S. Patent No. 5,637,268 titled “Method of Extruding Plastics,” which is related to a process for minimizing flow instability of molten plastics caused by slippage of the melt at the die wall during extrusion.

10. I have attached a more detailed list of my qualifications as Ex.1139.

11. I am being compensated for my time working on this matter at my

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standard hourly rate plus expenses. I do not have any personal or financial stake or interest in the outcome of the present proceeding, and the compensation is not dependent on the outcome of this IPR and in no way affects the substance of my statements in this Declaration.

B. Materials Considered

12. The analysis that I provide in this Declaration is based on my education, research, and experience, as well as the documents I have considered. In forming my opinions, I have read and considered U.S. Patent No. 10,870,263 B2 (“263” or “263 patent”) (Ex.1101) and its prosecution history. I have cited to the following documents in my analysis below:

Ex. No.	Description of Document
1101	U.S. Patent No. 10,870,263 B2 to Ray F. Stewart, et al. (filed December 18, 2019, issued December 22, 2020) (“263” or “263 patent”)
1102	Declaration of Alan Jeffrey Giacomini (“Giacomini”)
1103	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Complaint (D.I. 1)
1104	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Summons (D.I. 24)
1105	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Order Staying Case (D.I.)
1106	Service rejection letter to Bay Materials (November 16, 2021)

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Ex. No.	Description of Document
1107	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Plaintiff's Identification of Asserted Claims
1108	File Wrapper of U.S. Patent No. 10,870,263
1109	Claim Listing of Challenged Claims
1110	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), 3M's Answering Brief in Opposition to Plaintiff's Motion for Preliminary Injunction (D.I. 87)
1111	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Reply Brief in Support of Plaintiff's Motion for Preliminary Injunction (D.I. 101)
1112	U.S. Patent No. 10,946,630 ("630 patent")
1113	U.S. Provisional Pat. Appl. No. 62/512,786 ("786 provisional")
1114	U.S. Provisional Pat. Appl. No. 62/590,627 ("627 provisional")
1115	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Opening Brief in Support of Plaintiff's Motion for Preliminary Injunction (D.I. 14)
1116	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Declaration of Dr. Tim A. Osswald in Support of Plaintiff's Motion for Preliminary Injunction (D.I. 17)
1117	WO 2010/043419 A1 to Rolf Hinz (filed Oct. 19, 2009, published Apr. 22, 2010) and English translation thereof ("Hinz")
1118	Affidavit of Nathaniel E Frank-White (Internet Archives)
1119	Produktdatenblatt DURASOFT® with English Translation ("Durasoft (TPU/PC) Data Sheet") available at https://web.archive.org/web/20160808102931/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-

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Ex. No.	Description of Document
	DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-DURASOFT_bis-LOT-1614A.pdf
1120	Screenshot of archived Durasoft (TPU/PC) Data Sheet web page at: https://web.archive.org/web/20160808102931/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-DURASOFT_bis-LOT-1614A.pdf
1121	Produktdatenblatt DURASOFT® with English Translation (“Durasoft (TPU/PETG) Data Sheet”) available at: https://web.archive.org/web/20160808110356/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_ab-LOT-1714A.pdf
1122	Screenshot of archived DURASOFT (TPU/PETG) Data Sheet web page at: https://web.archive.org/web/20160808110356/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenblätter/Produktdatenblatt-DURASOFT_ab-LOT-1714A.pdf
1123	Produktdatenblatt IMPRELON® S pd with English Translation (“Imprelon S (Copolyester) Data Sheet”) available at: https://web.archive.org/web/20160809214649/https://www.scheu-dental.com/fileadmin/medienablage/SCHEU-DENTAL/Downloads/Produktdatenbl%C3%A4tter/Produktdatenblatt-IMPRELON-S_ab-LOT-3615A.pdf
1124	U.S. Pub. No. 2004/0224283 A1 to Benjamin J. Sun, et al. (filed: Nov. 26, 2003, published November 11, 2004) (“Sun”)
1125	Handbook of Thermoplastics, Second Edition, Chapter 9: Thermoplastic Polyesters (“Kannan”)

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Ex. No.	Description of Document
1126	Declaration of Sylvia Hall-Ellis
1127	U.S. Patent No. 9,655,691 (“Li”)
1128	Int’l Pat. Publ. No. WO2017/007962 (“Boronkay”)
1129	U.S. Patent No. 8,758,009 (“Chen”)
1130	Int’l Pat. Publ. No. WO2013/130552 (“Stewart”)
1131	Dr. Henry C.A. Lim, Ch. 20, Thermoplastic Polyesters (2017)
1132	Wiley Encyclopedia of Packaging Technology (2009) - Sheet, PETG
1133	Drobny, <i>Handbook of Thermoplastic Elastomers</i> (2014)
1134	WO 2013/172812 A1 Craig Pehlert, et al. (filed May 14, 2012, published Nov. 21, 2013) (“Pehlert”)
1135	<i>Bay Materials, LLC v. 3M Company</i> , No. 21-1610-RGA (D. Del.), Deposition of Dr. Tim A. Osswald (D.I. 88-1)
1136	Mix, A. W., & Giacomini, A. J. (2011). Standardized polymer durometry. <i>Journal of Testing and evaluation</i> , 39(4), 696-705
1137	Qi, H. J., Joyce, K., & Boyce, M. C. (2003). Durometer hardness and the stress-strain behavior of elastomeric materials. <i>Rubber chemistry and technology</i> , 76(2), 419-435
1138	Beer, <i>Mechanics of Materials</i> (2001)
1139	Dr. Giacomini’s CV

II. PERSON OF ORDINARY SKILL IN THE ART (“POSA”)

13. I understand that, under the patent laws in effect after the America Invents Act (“AIA”) of 2011, an assessment of claims of a patent filed after the AIA

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took effect should be undertaken from the perspective of a person of ordinary skill in the art (POSA) as of the “effective filing date” of the patent’s claimed inventions. I understand that because the ’263 patent (and each application to which it claims priority) was filed after the AIA came into effect, the ’263 patent is evaluated from a skilled artisan’s perspective as of the patent’s effective filing date. I understand that the ’263 patent was filed on December 18, 2019. (*See* Ex.1101 (’263 patent), cover page.)

14. I understand that the ’263 patent, as stated on its face is a “continuation-in-part application of U.S. application Ser. No. 16/211,176 (the “’176 application” (Ex.1028)), filed Dec. 5, 2018, which is a continuation-in-part application of International Application Serial No. PCT/US2018/035384 (ultimately published as WO 2018/222,864 (“Stewart ’864”)) which has International filing date May 31, 2018, and further claims the benefit of U.S. Provisional Application No. 62/512,786 filed May 31, 2017 and U.S. Provisional Application No. 62/590,627, filed Nov. 26, 2017.” (Ex.1101 (’263 patent), 1:7-15.) It is my opinion that the challenged claims of the ’263 patent are not entitled to an effective date earlier than the ’263 patent’s actual filing date of December 18, 2019, however, as I explain in Section VI below, for the purposes of this declaration I have assumed an effective filing date of the parent application filed on May 31, 2018. However, my opinions would not change

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even if the effective filing date were considered to be May 31, 2017 (i.e., the earliest filed provisional application) since all references in the Grounds set for the below were available to the public and skilled artisans before May 31, 2017.

15. I have been advised that to determine the appropriate level of a person having ordinary skill in the art, the following factors may be considered: (1) the types of problems encountered by those working in the field and prior art solutions thereto; (2) the sophistication of the technology in question, and the rapidity with which innovations occur in the field; (3) the educational level of active workers in the field; and (4) the educational level of the inventor.

16. As indicated in the “Technical Field” section of the ’263 patent, the ’263 patent generally describes “[c]ompositions in the form of polymeric sheets.” (Ex.1101 (’263 patent), 1:20.) The ’263 patent explains that “[t]he polymeric sheets are useful, *for example*, in a dental appliance, and are constructed of layers that impart flexibility and strength and stain resistance to devices made from the sheets.” (Ex.1101 (’263 patent), 1:21-24 (emphasis added).)

17. In my opinion, a person of ordinary skill in the art as of the effective filing date of the ’263 patent assumed for the purposes of this declaration¹ would

¹ As noted in section VI below, for the purposes of this declaration I have assumed that the Challenged Claims of the ’263 patent have an effective filing date of May 31, 2018 although I do not believe that the claims are entitled to an effective filing

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have possessed at least a bachelor's degree in mechanical, biomedical, or chemical engineering, or chemistry, materials science, or an equivalent science or engineering field and two years of experience in designing, manufacturing, and processing polymeric sheets, such as thermoforming, for use in various applications.²

date earlier than the December 18, 2019 filing date of the '263 patent. However, in my opinion, the level of skill of a person of ordinary skill in the art did not change between the years of 2017-2019.

² The '263 patent describes use with dental appliances as one *exemplary* application of the allegedly inventive polymeric sheets disclosed, but neither the specification nor the claims limit use of the disclosed polymeric sheets to dental appliances. (See, e.g., Ex.1101 ('263 patent), 1:21-22 ("The polymeric sheets are useful, *for example*, in a dental appliance....") (emphasis added); claim 1 ("A polymeric sheet composition, comprising..."). Accordingly, the '263 patent is not strictly limited to the use of the claimed polymeric sheet compositions in the form of a dental appliance. In my opinion, this conclusion is further supported by the fact that all Challenged Claims except 1 (claim 18) are directed to "polymeric sheet compositions" without any recitation of a "dental appliance." Accordingly, in my opinion, though dental appliances are one potential application of the polymeric sheet compositions of the '263 patent, a POSA would not necessarily require specialized experience with "dental appliances" *per se* to be able to apply the express teachings of the prior art to the claims since the prior art herein expressly disclosed thermoforming of polymeric sheets into a dental appliance/tray, (e.g., Ex.1127 (Li), Figs. 3-4, 3:39-47 ("fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model"), 6:60-64 ("For example, methods for making the appliances can include thermoforming a multilayer sheet into an aligner by heating the sheet and then molding the sheet to a particular configuration"); Ex.1130 (Stewart), 19:16-20 ("thermoforming the sheet around a physical model of the teeth"); Ex.1117 (Hinz), 6:177-178 ("Figure 1 schematically shows a method for producing a multilayer dental splint in a deep-drawing device ")) , which a POSA would readily understand how to perform to create a thermoformed dental appliance from a multilayer polymeric sheet. (See Ex.1101 ('263 patent), 15:23-29 ("thermoforming may be performed using a roll fed thermoformer, a vacuum former or other *known thermoforming techniques*")

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Additional education could compensate for less practical experience. Conversely, additional practical experience could compensate for less education. That is, a person could also have qualified as a person of ordinary skill in the art with some combination of (1) more formal education (such as a Master of Science degree) and less technical experience, or (2) less formal education and more technical or professional experience in the technical disciplines identified above. As part of the person's education or work experience, the person would have gained a familiarity with polymeric materials and the construction of such materials. (*See* Ex.1101 ('263 patent), 4:34-36.) As part of the person's education or work experience, the person would also have gained a familiarity with processing techniques associated with polymeric materials, including extrusion, coextrusion, calendaring, laminating, adhesive bonding, 3D printing, dip coating, thermoforming, molding, and other similar standard polymer processing techniques known in the art. (*See* Ex.1101 ('263 patent), 4:27-36.)

18. My opinions regarding the level of ordinary skill in the art are based on, among other things, my over 40 years of experience in the field of polymer and materials science, my understanding of the basic qualifications that would be

(emphasis added).)

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relevant to an engineer or scientist tasked with investigating methods and systems in the relevant area, and my familiarity with the backgrounds of colleagues, co-workers, and employees, both past and present.

19. Although my qualifications and experience exceed those of the hypothetical person having ordinary skill in the art defined above, my analysis and opinions regarding the '263 patent have been based on the perspective of a person of ordinary skill in the art as of December 2019 for the purposes of this declaration.

20. I understand that in the underlying district court litigation, one of the Patent Owner's expert witnesses has articulated a slightly different formulation for the person of ordinary skill in the art, as follows:

[S]omeone with at least a bachelor's degree in mechanical engineering, biomedical engineering, chemical engineering, materials science, or other similar type of engineering degree, and who would have taken courses in polymer processing or polymer materials science, combined with at least two years of experience in the field of design, manufacture, and processing of thermoformable polymer sheets for use in various applications, such as in orthodontic and dental appliances. More relevant experience could compensate for less education, and more relevant education could likewise compensate for less experience. This level of education and background provides the necessary training and understanding combined with at least two years of experience in the field of design and manufacturing of polymer orthodontic and dental appliances.

(Ex.1116 (Osswald Decl.), ¶18.)

21. To the extent the Patent Owner's formulation would exclude persons

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having a scientific degree that is not an *engineering* degree (such as chemistry), such a requirement would not be appropriate. For example, I have been informed that one of the co-inventors of the '263 patent, John Lahlouh, does not have an engineering degree. Furthermore, to the extent the Patent Owner's formulation would limit the relevant education or experience of the ordinarily skilled artisan to only that associated with *thermoformable* polymeric sheets for use in dental appliances, such a requirement also would not be appropriate. The '263 patent expressly contemplates polymeric sheets, structures, and devices "made by 3D printing" or "dip coating" among other techniques and dental appliances are simply one exemplary application. (Ex. Ex.1101 ('263 patent), 4:30-34, 15:32-35 ("Multilayer appliances may be fabricated through one or more 3D printing processes or by sequential dip coating, spray coating, powder coating or similar processes known for producing films, sheets and 3D structures"), 1:21-22 ("The polymeric sheets are useful, *for example*, in a dental appliance....") (emphasis added).)

22. In my opinion, under my description of a person of ordinary skill in the art, the person of ordinary skill in the art would at least have been familiar with how to create multilayer polymeric films (or sheets) using standard techniques within the art and would understand how to process those sheets into shaped objects also using

standard techniques within the art, such as by thermoforming. (*See, e.g.*, Ex.1133 (Drobny), 33-167.) In this regard, “[t]hermoforming is a process for converting thermoplastics into shell forms, using sheet material as a preform.” (*Id.*, 133-138.) The process of thermoforming is performed by clamping a heated thermoplastic sheet (such that it is pliable) over a mold cavity and drawing a vacuum or applying pressure in the cavity to press the sheet into the mold cavity, where it is cooled to retain the formed shape. (*Id.*)

23. The thermoforming of a multilayer polymeric sheet into a dental appliance simply involves the thermoforming of a film or sheet against a model mold of a patient’s teeth or jaw. A person of ordinary skill in the art would have readily understood this process as one application of thermoforming around a mold intending to create a shaped product that conforms to the teeth. A POSA would have understood that thermoforming a multilayer polymeric sheet to create a dental appliance would follow, for example, the following teachings of the prior art:

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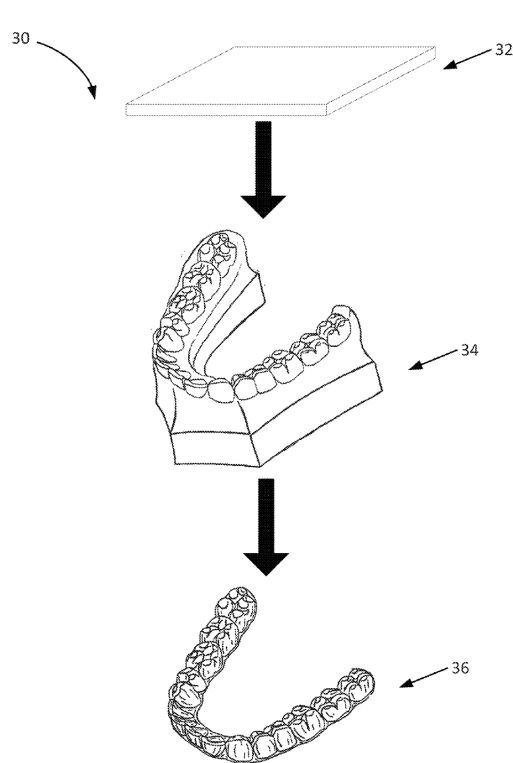


FIG. 3

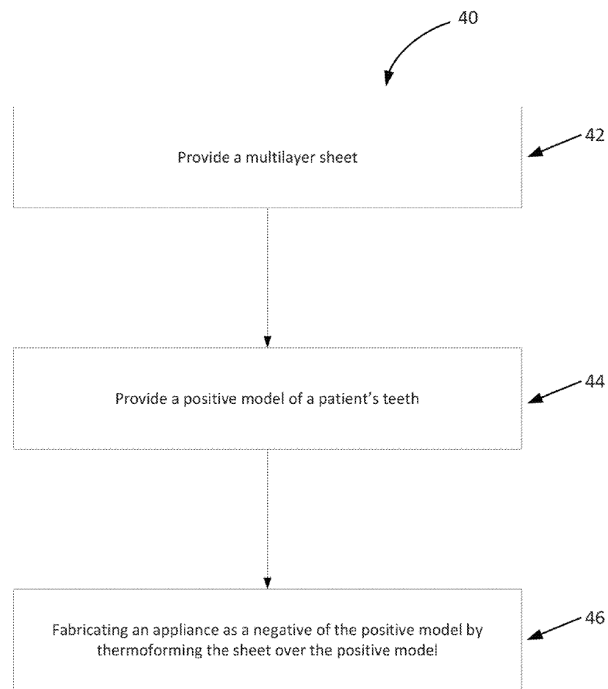


FIG. 4

(Ex.1127 (Li), Figs. 3-4, 2:30-35, 7:4-53 (“The tooth positioning appliance 36 can be produced by heating the thermoformable multilayer sheet 32 and then vacuum or pressure forming the sheet over the teeth in the physical tooth model 34. The tooth positioning appliance 36 is a direct representation of the physical tooth model.”).)

24. The '263 patent is consistent with this knowledge of a person of ordinary skill in the art as it discloses that a person of ordinary skill in the art would be familiar with the “known methods” for forming multilayer sheets and “known thermoforming techniques” and “similar processes known for producing films, sheets and 3D structures”:

Construction Methods

Multilayer sheets may be prepared by several means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or other known methods. Sheets may be fully prepared before forming into an orthodontic appliance, or an appliance may be produced using a sequence of individual thermoforming steps to create multiple layers.

Thermoforming of sheets to produce test samples or dental appliances may be performed using a “Biostar” pressure former available from Great Lakes Orthodontics using procedures commonly used in the industry. Alternatively, ***thermoforming may be performed using a roll fed thermoformer, a vacuum former or other known thermoforming techniques.*** Thermoforming may be conducted using different conditions, forms or models to vary draw ratio and part thickness. Multilayer appliances may be fabricated through one or more 3D printing processes or by sequential dip coating, spray coating, powder coating or ***similar processes known*** for producing films, sheets and 3D structures.

(Ex.1101 (’263 patent), 15:15-35 (emphasis added).)

25. A person of ordinary skill in the art would have been familiar with various machines and methods that would have enabled the thermoforming of multilayer dental sheets into shapes that conform with the teeth (i.e., creating a dental appliance). For instance, the Hinz prior art reference expressly discloses the use of the same “Biostar” thermoforming instrument as disclosed in the ’263 patent, and a person of ordinary skill in the art would have understood that such an instrument could be used to make thermoformed dental appliances from multilayer polymer films or sheets: “The deep-drawing [thermoforming] device can be, for example, a

universal compression molding device for all applications of dental deep-drawing technology and orthodontics, as is sold under the tradename BIOSTAR® by Scheu-Dental GmbH.” (Ex.1117 (Hinz), 6:179-181.)

26. In any event, my qualifications and experience exceed those of the hypothetical person having ordinary skill in the art defined according to either my formulation or the Patent Owner’s formulation. Further, my opinions expressed in this Declaration would remain the same even if I were to apply the Patent Owner’s definition.

III. STATEMENT OF LEGAL PRINCIPLES

A. Claim Construction

27. I understand that a purpose of claim construction is to determine what a person of ordinary skill in the art would have understood the claim terms to mean. I understand that under the legal principles, claim terms are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the art in question as of the critical date—here, the effective filing date of the patent application.

28. I understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. I

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understand that the patent specification, under the legal principles, has been described as the single best guide to the meaning of a claim term, and is thus highly relevant to the interpretation of claim terms. And I understand for terms that do not have a customary meaning within the art, the specification usually supplies the best context to understand the meaning of those terms.

29. I further understand that other claims of the patent in question, both asserted and unasserted, can be valuable sources of information as to the meaning of a claim term. Because the claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.

30. I understand that the prosecution history can further inform the meaning of the claim language by demonstrating how the inventors understood the invention and whether the inventors limited the invention during prosecution, making the claim scope narrower than it otherwise would be. Extrinsic evidence, such as dictionaries, may also be consulted in construing the claim terms.

31. I understand that, in *Inter Partes* Review (IPR) proceedings, a claim of a patent shall be construed using the same claim construction standard that would be used to construe the claim in a civil action filed in a U.S. district court (which I

understand is called the “*Phillips*” claim construction standard), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.

32. I have been instructed by counsel to apply the “*Phillips*” claim construction standard for purposes of interpreting the claims in this proceeding, to the extent they require an explicit construction. The description of the legal principles set forth above thus provides my understanding of the “*Phillips*” standard as provided to me by counsel.

B. Obviousness

33. I understand that a patent claim is obvious if, as of the critical date (i.e., the effective filing date (under AIA)), it would have been obvious to a person having ordinary skill in the field of the technology (the “art”) to which the claimed subject matter belongs.

34. I understand that the following factors should be considered in analyzing obviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; and (3) the level of ordinary skill in the pertinent art. I also understand that, when present, evidence of “secondary considerations” of non-obviousness are to be considered. Such secondary considerations can include:

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copying, industry praise, commercial success, long-felt need, failure of others, skepticism, as well as other types of considerations. I am further informed that to support a finding of non-obviousness, the inventor must generally show a “nexus” between the secondary considerations and the features of the invention as claimed. For example, a secondary consideration such as commercial success is not relevant to non-obviousness unless the evidence shows that the commercial success was attributable to features of the claimed invention as opposed to attributable to features that already existed in the prior art.

35. I understand that a reference qualifies as prior art for obviousness purposes when it is analogous to the claimed invention. The test for determining what art is analogous is: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

36. I understand that a person of ordinary skill in the art is assumed to have knowledge of all prior art. I understand that one skilled in the art can combine various prior art references based on the teachings of those prior art references, the general knowledge present in the art, or common sense. I understand that a motivation to combine references may be implicit in the prior art, and there is no

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requirement that there be an actual or explicit teaching to combine two references. Thus, one may take into account the inferences and creative steps that a person of ordinary skill in the art would employ to combine the known elements in the prior art in the manner claimed by the patent at issue. I understand that one should avoid “hindsight bias” and ex post reasoning in performing an obviousness analysis. However, this does not mean that a person of ordinary skill in the art for purposes of the obviousness inquiry does not have recourse to common sense.

37. I understand that when determining whether a patent claim is obvious in light of the prior art, neither the particular motivation for the patent nor the stated purpose of the patentee is controlling. The primary inquiry has to do with the objective reach of the claims, and that if those claims extend to something that is obvious, then the entire patent claim is invalid. By objective reach, I mean some portion of the claim clearly covers any subject matter that would be obvious from the prior art, even if the claims include other subject matter.

38. I understand one way that a patent can be found obvious is if there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent’s claims. I understand that a motivation to combine various prior art references to solve a particular problem may come from a variety of sources, including market demand or scientific literature. I understand

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that a need or problem known in the field at the time of the invention can also provide a reason to combine prior art references and render a patent claim invalid for obviousness. I understand that familiar items may have obvious uses beyond their primary purpose, and that a person of ordinary skill in the art will be able to fit the teachings of multiple prior art references together like the pieces of a puzzle. I understand that a person of ordinary skill is also a person of at least ordinary creativity. I understand when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this finite number of predictable solutions leads to the anticipated success, I understand that the invention is likely the product of ordinary skill and common sense, and not of any sort of innovation. I understand that the fact that a combination was obvious to try might also show that it was obvious, and hence invalid, under the patent laws. I understand that if a patent claims a combination of familiar elements according to known methods, the combination is likely to be obvious when it does no more than yield predictable results. Thus, if a person of ordinary skill in the art can implement a predictable variation, an invention is likely obvious. I understand that combining embodiments disclosed near each other in a prior art reference would not ordinarily require a leap of inventiveness.

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39. I understand that obviousness may be shown by demonstrating that it would have been obvious to modify what is taught in a single piece of prior art to create the patented invention. Obviousness may also be shown by demonstrating that it would have been obvious to combine the teachings of more than one item of prior art. I understand that a claimed invention may be obvious if some teaching, suggestion, or motivation exists that would have led a person of ordinary skill in the art to combine the invalidating references. I also understand that this suggestion or motivation may come from the knowledge of a person having ordinary skill in the art, or from sources such as explicit statements in the prior art. I understand that when there is a design need or market pressure, and there are a finite number of predictable solutions, a person of ordinary skill may be motivated to apply common sense and his skill to combine the known options to solve the problem.

40. I understand the following are examples of approaches and rationales that may be considered in determining whether a piece of prior art could have been combined with other prior art or with other information within the knowledge of a person having ordinary skill in the art:

- (1) Some teaching, motivation, or suggestion in the prior art that would have led a person of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention;

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- (2) Known work in one field of endeavor may prompt variations of it for use in the same field or a different field based on design incentives or other market forces if the variations would have been predictable to a person of ordinary skill in the art;
- (3) Combining prior art elements according to known methods to yield predictable results;
- (4) Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- (5) Applying a technique or approach that would have been “obvious to try” (choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success);
- (6) Simple substitution of one known element for another to obtain predictable results; or
- (7) Use of a known technique to improve similar products, devices, or methods in the same way.

41. I understand that, when determining whether a claimed combination is obvious, the correct analysis is not whether one of ordinary skill in the art, writing on a blank slate, would have chosen the particular combination of elements described in the claim. Instead, I understand the correct analysis considers whether

one of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to selecting the combination claimed.

42. I understand that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. By *bodily incorporated*, I mean that the express combination of the disclosures of the prior art have already been combined in the manner that renders the claim invalid for obviousness. Rather, in other words, the test for obviousness is not whether the references could be physically combined without any modification from the disclosures therein, but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.

43. I understand that a statement in the challenged patent that something is in the prior art is binding on the patentee for determinations of obviousness.

44. I have been informed that when a range disclosed in the prior art overlaps with a range in a patent claim that the overlap creates a presumption of obviousness. I have been informed that a patent owner can rebut the presumption of obviousness based on claiming an overlapping range with the prior art, such as where: (1) the claimed range differs from the prior art range in a manner that produces a new and unexpected result for the claimed invention which differs in kind and not merely in degree from that of the prior art; (2) the prior art taught away from

the claimed range despite the overlap with the prior art; and (3) if the claimed parameter was not recognized as a result-effective parameter (but a recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective); and (4) the prior art range is extremely broad such that it does not permit routine optimization.

IV. THE '263 PATENT

A. Overview of the '263 Patent and Specification

45. The '263 patent, entitled “Dual shell dental appliance and material constructions,” issued from U.S. App. No. 16/719,256, filed on December 18, 2019, as a continuation-in-part of the '176 application, filed December 5, 2018, which was a continuation-in-part of application No. PCT/US2018/035384 (“PCT '384 application”), filed on May 31, 2018. (Ex.1101, 1:7-15.) The '263 patent further claims the benefit of U.S. Provisional Application No. 62/512,786 (“'786 provisional”), filed May 31, 2017 and of U.S. Provisional Application No. 62/590,627 (“'627 provisional”), filed Nov. 26, 2017 (collectively, “the provisional applications”). (*Id.*)

46. The '263 patent is directed to multilayer, polymeric sheet compositions. (Ex.1101 ('263 patent), Abstract). “The polymeric sheets are useful, for example, in a dental appliance, and are constructed of layers that impart flexibility and strength

and stain resistance to devices made from the sheets.” (*Id.*, 1:21-24.) The polymeric sheet compositions “useful for making dental appliances having outer layers comprised of a material having a modulus of from about 1,000 MPa to 2,500 MPa (‘hard’) and an inner core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa (‘soft’)[.]” (Ex.1101, Abstract).

47. In addition to referring to the “modulus” of the layers, the ’263 patent also refers to them by “hardness.” (*E.g.*, Ex.1101, 6:60-67.) The term “hardness” refers to a “Shore hardness scale,” such as Shore A or Shore D, which is measured using a durometer. (*Id.*) “Materials with higher durometer values will be harder compared to materials with a lower durometer value.” (*Id.*) The ’263 patent further explains: “Shore hardness and modulus are generally correlated and can be converted by approximation if only one value is known by methods described in the art.” (*Id.*, 6:67-7:2; *see also id.*, 17:45 (Table 2) (modulus can be “estimated based on Shore hardness”).)

48. The disclosed multilayer polymeric sheet compositions are “comprised of at least two outer layers A and C and a middle layer B....” (Ex.1101, 1:51-52.) “Each layer A, B and C, may be a [*sic*] comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.”

49. Figure 1A depicts “a cross sectional view of a three-layer sheet with a

simple ABC construction” where each of layers A, B, and C are single layers:

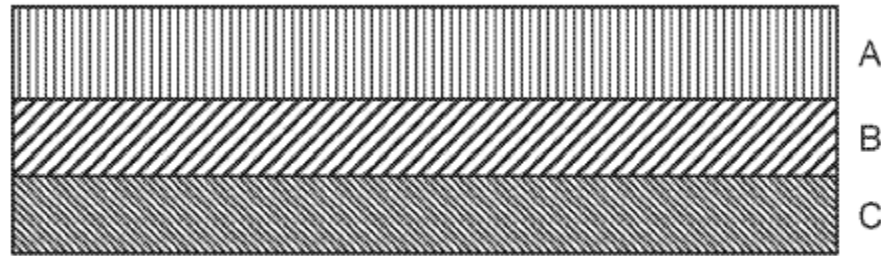


FIG. 1A

(Ex.1101 ('263 patent), 3:41-42, Fig. 1A.)

50. Figure 1B of the old disclosure depicts a cross-sectional view of a six-layer sheet, though again critically with an ABC construction, where each of layers A, B, and C include multiple constituent layers, i.e., “[l]ayer A may be comprised of more than one layer, for example, layer a and a', layer B may be comprised of more than one layer, for example, layer b and b', and layer C may be comprised of more than one layer, for example, layer c and c'”:

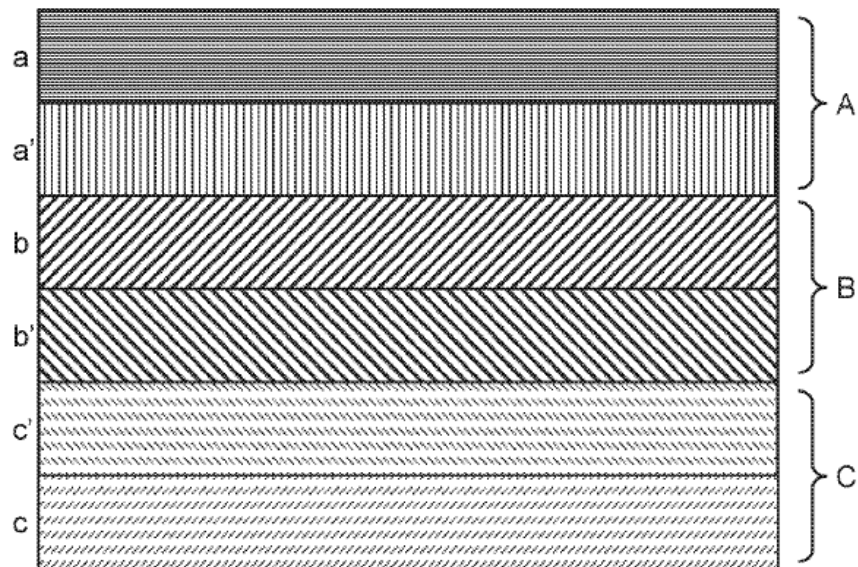


FIG. 1B

(Ex.1101('263 patent), Fig. 1B, 3:47-55 (layer A corresponds to layers a and a', layer B corresponds to layers b and b', and layer C corresponds to layers c and c').)

51. In addition to a multilayer sheet with a layer A-layer B-layer C configuration, the '263 patent discloses the following:

In one embodiment, a polymeric sheet composition comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B' and at least a rigid or hard inner layer, D are provided. The A, C and D layers may be the same or different. The B and B' layers may be the same or different.

(*Id.*, 12:25-30.)

52. “Multilayer sheets may be prepared by a number of means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or *other known methods*.” (Ex.1101, 15:17-20

(emphasis added).) The specification further explains that “[d]ental appliances may be constructed by thermoforming” the “dual shell” multilayer sheets over a model of one or more teeth. (*Id.*, 5:62-6:2.)

B. The Challenged Claims

53. This Declaration addresses claims 1-4, 7, 11-14, 16, 18 and 31. (*See* Ex.1023 (Listing of Challenged Claims).) Claims 1, 11, and 31 are independent claims. Claims 2-4 and 7 are dependent claims that depend from claim 1. Claims 12-14, 16, and 18 are dependent claims that depend from claim 11.

54. Independent claim 1 recites:

1. A polymeric sheet composition, comprising:
 - [a] at least two outer layers A and C and an elastomeric inner layer B,
 - [b] wherein one or both of the outer layers A and C individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 Mpa, and
 - [c] the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85.

(’263, cl. 1.)

55. Independent claim 11 recites:

11. A polymeric sheet composition comprised of:
 - [a] at least two rigid or hard outer layers A and C,

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- [b] at least two soft inner layers B and B', and
- [c] at least a rigid or hard inner layer, D,
- [d] wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and
- [e] the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.

('263, cl. 11 (bracketed notation (e.g., [a]) added).)

56. Claim 31, which has the same limitations as claim 1 and adds subject matter from dependent claims 2 and 7, recites:

31. A polymeric sheet composition, comprising:

- [a] at least two outer layers A and C and an elastomeric inner layer B,
- [b] wherein (i) one or both of the outer layers A and C individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa,
- [c] (ii) the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85,
- [d] (iii) the A, B and C layers of the polymeric sheet composition have a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa, and
- [e] (iv) one or more of the A and C layers comprises a co-polyester having a:

(c) a dicarboxylic acid component and

(d) a diol component, wherein the-copolyester exhibits a glass transition temperature (T_g) from 80° C. to 150° C.

57. Independent claim 11 recites a polymeric sheet composition with “outer layers A and C,” “inner layers B and B’,” and “inner layer D.” (Ex.1101 (’263 patent), cl. 11.) Independent claims 1 and 31 recite polymeric sheet compositions that have “outer layers A and C” and “inner layer B.” (Ex.1101 (’263 patent), cls. 1, 31.).)

58. I address the claims further in my detailed analysis below.

V. CLAIM CONSTRUCTION

59. All Challenged Claims of the ’263 patent recite “layers A and C” and “layer B.” There is no plain and ordinary meaning for the recited “layer A,” “layer B,” or “layer C” to a POSA in the art. I understand, however, that the Petitioner has proposed (and I agree) that the claim terms “layer A,” “layer B,” and “layer C” be construed from the express definition provided in the specification as follows: “Each layer A, B and C, may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials.” (*See* Ex.1008 (3M Answering PI Brief), p.13.) In my opinion, this is the proper construction because it expressly supported by the definition from the specification for these terms that have no ordinary meaning. (*See, e.g.*, Ex.1101 (’263 patent),

3:48:51, Fig. 1B.)

60. In response to Petitioner’s construction of the claim terms “layer A,” “layer B,” and “layer C” from the express definition in the specification, I understand that the Patent Owner did not appear to oppose the Petitioner’s construction. Rather, by citing to the same portion of the ’263 patent specification, Patent owner explained that “the layers ‘may be comprised of more than one layer.’” (Ex.1111 (Patent Owner’s PI Reply Br.), p.3.) Thus, the Patent Owner does not appear to dispute the Petitioner’s construction for “layer A,” “layer B,” and “layer C,” as those terms are variously recited in the Challenged Claims. “may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials,” as expressly set forth in the specification.

61. However, I understand that in IPR2022-01215, Patent Owner has asserted that the naked term “layer,” by itself, should be construed according to the specification’s express definition of “[e]ach layer A, B and C.” (IPR2022-01215, Paper 6, 19-20.) In my opinion, this is incorrect. While the patent provides an express definition for each of “layer A, B and C,” as recited in the Challenged Claims, the term “layer” *per se* has its plain and ordinary meaning—i.e., “layer” refers to a single layer and layers refers multiple layers. (See Ex.1101, 3:48:51 (“a *single layer* or *multiple layers*”).) There is no express redefinition of “layer” away

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from that plain and ordinary meaning within the specification to support Patent Owner's attempt to construe "layer" the same as "layer A," "layer B," and "layer C." Thus, in my opinion, Petitioner's interpretation of "layer" *per se* is incorrect.

62. Furthermore, every recitation of layer is only in the context of layer A, layer B, layer C, etc., which are the terms used in the Challenged Claims. This is in contrast to other patents related to the '263 patent, where the patent claims do recite inventions with "layer" or "layers" *per se* and do not recite "layers A and C" or "layer B." For instance, U.S. Patent No. 10,946,630, which issued from a parent application to the '263 patent, includes claims that recite *both* "layers A and C" and "layer B" as well as claims that recite "layer" *per se*. (*Compare* Ex.1112 ('630 patent) claim 1 "layers A and C" and "layer B") with claim 15("layers").) In claim 15 of the '630 patent, the term "layer(s)" has its plain and ordinary meaning within the art—i.e., "layer" is singular (i.e., one layer) and "layers" is plural (i.e., multiple layers)—whereas claim 1 recites "layers A and C" and "layer B" according to the shared express definition for each of layers A, B, C in both the '630 patent and '263 patent. (*See* Ex.1101, 3:48:51; Ex.1112, 3:48-51.) In my opinion, these different claims in the '630 patent, reciting inventions with different claim scope according to the specification's definition for "layer A, B, and C" or simply the plain meaning of "layer" or "layers" *per se*, further demonstrates that the inventions reciting "layer

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A,” “layer B,” and “layer C” are intentionally meant to be distinct and different from inventions disclosed only in the context of “layer” or “layers.”

63. Although the Patent Owner has not put forth an explicit definition for layers A, B, and C in the district court litigation, the Patent Owner has implicitly interpreted the claims against the Petitioner’s five-layer accused product; thus asserting layers A, B, B’, C, and D are satisfied by *single* layers. (Ex.1116 (Osswald PI Decl.), ¶126.) I understand that the Patent Owner’s claim construction positions taken during the preliminary injunction proceeding may be considered in an IPR. Accordingly, for the purposes of my declaration, I have applied the Patent Owner’s interpretation of the scope of the claims in the instances where the Patent Owner has adopted an interpretation.³

³ I further understand that in response to the Patent Owner’s motion for a preliminary injunction in the district court, the Petitioner additionally alleged that the definition of layers A, B, and C within the specification of the ’263 patent as being comprised of a single or multiple layers with one or more materials, when applied to polymeric sheets wherein layers A, B, or C are *multiple* layers, renders the full scope of the claims indefinite and I agree with that conclusion. (See Ex.1110 (3M Answering Brief), 13.) However, under the Patent Owner’s interpretation of the claims against the accused five-layer material, Patent Owner contends that each of layers A, B, B’, C, and D are satisfied by *single* layers. (See Ex.1116 (Osswald Decl.), ¶126.) Accordingly, in my opinion, the Board can determine whether the prior art Grounds asserted herein satisfy the Challenged Claims under the Patent Owner’s *single* layer infringement theories for layers A, B, B’, C, and D despite the indefiniteness that arises when layers A, B, B’, C, and D are comprised of *multiple* layers.

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64. This pending claim construction dispute between the parties in the preliminary injunction proceedings poses no obstacle to my mapping of the prior art to the claim language for purposes of demonstrating anticipation. To the extent the district court or the Board were to determine that the Petitioner’s proposed construction for “layer A,” “layer B,” and “layer C” is the correct one, the prior art would still meet such a construction because for each of “layer A,” “layer B,” and “layer C,” as detailed in Section VII.B-C below, where I describe how the prior art teaches a corresponding *single layer comprised of one (and only one) type of material*, which is expressly permitted under the Petitioner’s construction. My conclusions of anticipation, therefore, would not change regardless of whether the Petitioner’s construction is adopted by the district court or the Board.

65. Independent claim 11 recites a polymeric sheet composition that further includes a “layer D” and a “layer B’,” in addition to layers A, B, and C. (Ex.1101 (’263 patent), claim 11.) The new matter within the ’263 patent explains that “[t]he A, C and D layers may be the same or different” and “[t]he B and B’ layers may be the same or different.” (*Id.*, 12:28-30.) In my opinion, “layer D” and “layer B” should be construed as having the same general interpretation as layers A, B, and C—i.e., each of “layer D” and “layer B” individually “may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials

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or a blend of materials.”

66. I understand that in the preliminary injunction proceeding, the Patent Owner asserted claims 1, 2, and 9 from the related '630 patent that is a direct continuation from the '176 application. (Ex.1115, 8.) Those claims recite ABC polymeric sheet compositions with “outer layers A and C” and “inner layer B[.]” (Ex.1112 ('630 patent), claim 1.) Based on the disclosures within the '630 patent, which does not include the new matter added to the '263 patent, I understand the Petitioner proposed (and I supported) a construction of the term “inner layer B” within claim 1 of the '630 patent (and as would be supported by the '176 application) meaning “the middle core layer B” of a multilayer polymeric sheet. (See Ex.1110, 16.) Because the '263 patent maintains all of the same disclosure from the '176 application found in the '630 patent, the Petitioner noted that “[i]t is presumed that the same claim term in the same patent or related patents—like “inner layer B” here—carries the same construed meaning” and, in my opinion, should therefore also apply to the same language in the '263 patent. (See *id.*, 17.)

67. I understand that the Patent Owner opposed the Petitioner's construction of “inner layer B” as recited in the '630 patent by relying on the new matter contained in the '263 patent. (Ex.1111, 2.) I understand that the Patent Owner took the position that “claim 11 of the '263 patent recites at least three inner

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layers, showing that ‘inner layer’ does not refer only to a core, middle, or innermost layer.” (*Id.*) The language of claim 11 of the ’263 patent, on which the Patent Owner relied to support its interpretation of an “inner layer,” is essentially verbatim with the new matter added to the ’263 patent’s specification:

’263 patent claim 11	New Matter in the ’263 Patent⁴
11. A polymeric sheet composition comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D,	a polymeric sheet composition comprised of at least two rigid or hard outer layers A and C, at least two soft inner layers B and B' and at least a rigid or hard inner layer, D
wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and	the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa
the soft inner layers B and B' individually comprise an elastomeric material having a hardness from about A 60 to D 85.	the inner layers B and B' comprise a polymeric material with a hardness of from about A 60 to D 85

68. For the sole purpose of the opinions I set forth in this present Declaration, I have adopted the Patent Owner’s position from the district court that an “inner layer,” recited in conjunction with inner layer B, inner layer B', and inner layer D, such that it “does not refer only to a core, middle, or innermost layer,”

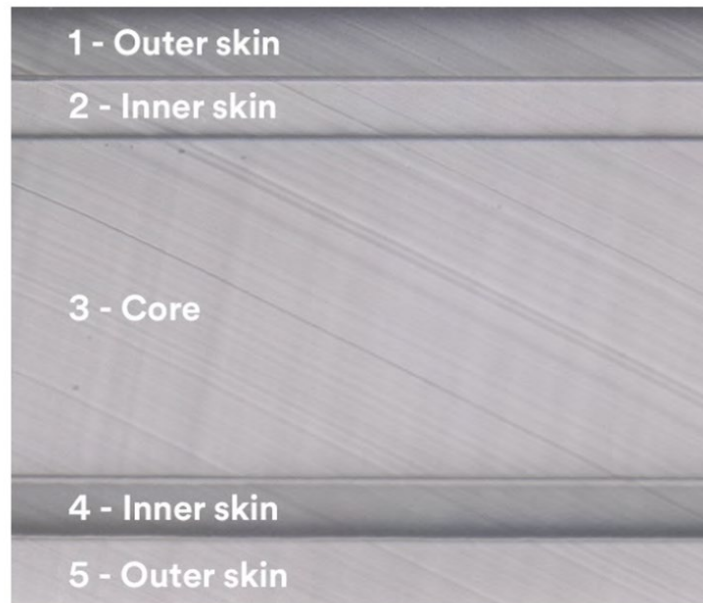
⁴ Ex.1101 (’263 patent), 12:25-28, 12:31-33, 12:64-66.

(Ex.1111, 2), to demonstrate how, under the Patent Owner's interpretation of the claims, the Challenged Claims are invalid.

69. I also understand that under the legal principles, courts need only construe terms that are in controversy, and only to the extent necessary to resolve the controversy. I have not included express claim construction analysis that is unnecessary to my mapping of the prior art to the claim language for purposes of demonstrating anticipation and obviousness. In the event the Patent Owner later attempts to distinguish the prior art from the claim language by advocating for explicit or implicit claim constructions, I reserve the right to respond to any such proposed constructions.

2. The Parties' Infringement Dispute

70. The five-layer material of the Petitioner's accused product is constructed of two inner and outer "skin" layers around a "core," as shown below:



(See, e.g., Ex.1116 (Osswald PI Decl.), ¶60.)

71. In the underlying district court litigation, the Patent Owner has argued that the five layers of the Petitioner’s accused product align with the claimed layers (A, B, B', C, and D of claim 11) as follows:

“Outer skin” layers 1 and 5 correspond to the hard or rigid outer layers A and C, “Core” layer 3 corresponds to hard or rigid inner layer D and is shown as being the same material as layers “1” and “5”, and “Inner skin” layers 2 and 4 correspond to inner layers B and B'.”

(Ex.1116 (Osswald Decl.), ¶126.) In the below chart, I have mapped the correspondence of the accused product’s layers to the claimed layers in accordance with the Patent Owner’s infringement position:

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Layer #	Accused Product	Claimed layer
1	Outer skin	A
2	Inner skin	B
3	Core	D
4	Inner skin	B'
5	Outer skin	C

72. Solely for purposes of Grounds 4-5 in Sections VII.E and VII.F, I have applied the Patent Owner's application of layers A, B, B', C, and D against the obvious hard-soft-hard-soft-hard five-layer polymeric sheet from the combination of Li and Boronkay in the same manner that the Patent Owner is applying it against the accused 5-layer polymeric sheet, though I disagree with that interpretation.

B. The Parties' Indefiniteness Disputes

73. I understand that as part of the preliminary injunction proceedings, the Petitioner has asserted indefiniteness based on the "layer A," "layer B," and "layer C" claim terms, as well as the claimed "flexural modulus" ranges. I have been informed by counsel that the Board may not cancel claims for indefiniteness in IPR, and I have not included indefiniteness analyses that are unnecessary to my mapping of the prior art to the claim language for purposes of demonstrating anticipation and obviousness.

74. However, I have reviewed the Petitioner's brief from the preliminary injunction proceedings and submitted a supporting declaration that sets forth my

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support of the Petitioner's asserted bases for indefiniteness. I have also been informed by counsel that under governing law, the indefiniteness of a claim does not necessarily imply inability to conduct a prior-art analysis needed for IPR. Rather, as I have been informed, indefiniteness of a claim limitation precludes a prior-art based patentability (or unpatentability) determination only when the indefiniteness renders the claim limitation logically impossible for the Board to reach such a decision.

75. In my opinion, the bases for indefiniteness previously asserted by the Petitioner (as part of the preliminary injunction proceedings) do not render the claim language logically impossible for a POSA to evaluate and ultimately reach a conclusion as to whether the challenged claims are anticipated based on the specific references that I have cited herein and under the Patent Owner's application of the claims for purposes of infringement.

76. With respect to the "layer A," "layer B," and "layer C" claim terms, the Petitioner's contention of indefiniteness is premised on an "express definition" of those terms, i.e., "each layer A, B and C, may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials," that encompasses at least two alternative options, i.e., each of "layer A," "layer B," and "layer C" may (1) be a single layer comprised of one (and only

one) type of material *or* (2) be itself comprised of multiple layers as well as different types of materials. (Ex.1110, p.13 (citing '263, 3:47-55).) Here, as detailed in Sections VII.B-D, my opinions of invalidity under the identified Grounds rely on the prior art's teaching of a corresponding *single layer comprised of one (and only one) type of material* (option 1) for each of "layer A," "layer B," and "layer C" as applied by the Patent Owner in alleging infringement. Because I am able to determine that the prior art covers at least option 1 when applying the Patent Owner's interpretation of the claims, I am able to conclude that the prior art satisfies "layer A," "layer B," and "layer C" without having to undertake a comparison of the prior art with option 2 (which, in my opinion, causes the indefiniteness of the claims).

77. With respect to the claimed "flexural modulus" ranges, indefiniteness is premised on there being "[d]ifferent accepted standards [that] exist for determining 'flexural modulus,' [and] those different standards yield[ing] different values." (Ex.1110, p.14.) However, as clearly indicated by the section header in the Petitioner's brief ("flexural modulus' *cut-off values* are indefinite"), whether a given material falls within the claimed flexural modulus cut-off values based on different accepted standards yielding different values is only ambiguous when the different standards yield different values for the same material that lie above and below the cut-off value. Here, while the indefiniteness may affect the full scope of

the claims, all of the identified flexural modulus values from the materials of the prior art fall squarely within the claimed flexural modulus ranges. In this regard, a POSA would know that a “chord” flexural modulus standard (such as ISO 178) would yield a value *smaller* than a standard that uses a “tangent” flexural modulus (such as ASTM D790). Yet, in no case for any of the values of flexural modulus that I rely upon in the analysis in Section VII below would a POSA expect the different values for different standards to bridge the claimed flexural modulus cut-off values—i.e., under any method the flexural modulus values would satisfy the claimed range.

VI. THE CHALLENGED CLAIMS OF THE ’263 PATENT DO NOT HAVE AN EFFECTIVE FILING DATE FROM EITHER PROVISIONAL APPLICATION

78. I understand that the ’263 patent issued from U.S. App. No. 16/719,256, filed on December 18, 2019, as a continuation-in-part of the ’176 application, filed December 5, 2018, which was a continuation-in-part of application No. PCT/US2018/035384 (“PCT ’384 application”), filed on May 31, 2018. (*Id.*, 1:7-15.) The ’263 patent further claims the benefit of U.S. Provisional Application No. 62/512,786 (“’786 provisional” (Ex.1113), filed May 31, 2017 and of U.S. Provisional Application No. 62/590,627 (“’627 provisional” (Ex.1114)), filed Nov. 26, 2017 (collectively, “the provisional applications”). (*Id.*)

79. I have been informed by counsel that the presumptive effective filing

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date of a continuation-in-part patent application, like the '263 patent here, is the date on which the continuation-in-part application was filed. Thus, the presumptive effective filing date of the challenged claims of the '263 patent is December 18, 2019. Nevertheless, for the sole purposes of the present Declaration, I have assumed (without conceding) that the Challenged Claims have an effective filing date as of the May 31, 2018 filing date of the PCT '384 application. However, in my opinion, Patent Owner cannot demonstrate entitlement to an earlier effective filing date to the provisional applications.

80. I have also been informed by counsel that the Patent Owner bears the burden of demonstrating that a Challenged Claim is entitled to an effective filing date of a provisional application. I have been informed that for the claimed inventions recited in Challenged Claims of the '263 patent to be entitled to the benefit of the earlier provisional applications, the Patent Owner has the burden of demonstrating that the provisional applications provide enablement and written description for the full scope of the claimed inventions.

81. I further understand that the test for adequate written description in an earlier application is whether the disclosure of the earlier application (here, the provisional applications) conveys with reasonable clarity to those skilled in the art that the inventor had possession of the claimed subject matter based on the

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disclosures within the earlier application. Here, I understand this adequacy requires the specification of the earlier provisional applications to convey with reasonable clarity that the inventors had possession of what the challenged claims 1-4, 7, 11-14, 16, 18 and 31 of the '263 patent recite. By recite, I mean the full scope of the subject matter of the claimed inventions. I further understand that written description for entitlement to a filing date does not extend to subject matter which is not disclosed in the provisional applications, even if such subject matter would be obvious from the actual subject matter that is expressly disclosed. Further, I understand that in the case of a claimed range, a skilled artisan must be able to reasonably discern a disclosure of the claimed range.

82. I have been asked by counsel to assess whether, in my opinion, the disclosure of the provisional applications could reasonably convey to those skilled in the art that the inventors had possession of the subject matter of challenged claims 1-4, 7, 11-14, 16, 18 and 31 of the '263 patent, so as to entitle these claims to the benefit of an earlier provisional application filing date. In my opinion, the challenged claims 1-4, 7, 11-14, 16, 18 and 31 of the '263 patent cannot claim an effective filing date to the earlier dates of either provisional application.

83. While I understand the presumption is that the claims are not automatically entitled to an earlier effective filing date of a provisional application

and that it is the Patent Owner's burden to demonstrate entitlement to such an earlier filing date by demonstrating written description and enablement for the claimed inventions, I can identify multiple reasons that a POSA would not recognize that the patentee had possession of the claimed inventions of the Challenged Claims in the provisional applications.

84. First, claim 1 recites "inner layer B" and claim 11 recites "inner layers B and B'" as "having a hardness from about A60 to D85." The maximum hardness disclosed for any embodiments or teachings for a soft or elastic "inner layer" within the '786 provisional or '627 provisional applications is D75. Since the provisional applications fail to demonstrate the inventors were in possession of the full scope of claimed hardness, including specifically up to D75-D85, the Challenged Claims do not have an earlier effective filing date based on either of the provisional applications at least for this reason. Second, the provisional applications have no disclosure of any multilayer sheets possessing "at least two rigid or hard outer layers A and C, at least two soft inner layers B and B', and at least a rigid or hard inner layer, D" as recited in independent claim 11. Specifically, there is no mention of a "layer D" anywhere within the provisional applications and a POSA would therefore not find that the inventors were in possession of claim 11 and the other claims dependent therefrom based on the disclosures within the provisional applications at least also

for this reason.

85. I reserve my right to respond to any arguments or assertions put forth by or on behalf of the Patent Owner to respond if it attempts to demonstrate entitlement of an effective filing date for the challenged claims to the provisional applications.

VII. APPLICATION OF THE PRIOR ART TO CHALLENGED CLAIMS

86. I have reviewed and analyzed the prior art references and materials listed in Section I.B, above. In my opinion, the claims I have been asked to analyze in the '263 patent are invalid for obviousness based on the following grounds.

Ground	Prior Art References	Claim(s)
1	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet	1
2	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet and Sun	2-4
3	Hinz in view of Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet, Sun, and Handbook of Thermoplastics	7, 31
4	Li, Boronkay and Chen	11
5	Li, Boronkay, and Chen in view of Stewart	12-14, 16, 18

87. I understand that each of the references cited in the grounds identified

above qualifies as prior art to the challenged claims because each reference was effectively filed or published before the '263 patent's earliest possible effective filing date of May 30, 2017. I next provide a brief summary of these references before applying them to the claims.

A. Brief Summary of the Prior Art

1. Hinz [Ex.1117]

88. Hinz is an international patent application entitled "Method for Producing a Multilayer Dental Splint in a Deep-Drawing Device and Dental Splint," published on April 22, 2010. (Ex.1117.) Hinz qualifies as prior art under § 102(a).

89. Hinz discloses "a method for producing a multilayer dental splint." (Hinz, 1:3-4.) Hinz discloses an embodiment for making a multilayer dental appliance with two hard outer layers and a soft inner layer (i.e., a multilayer polymeric dental appliance with a hard-soft-hard configuration) from a pre-thermoformed hard-soft-hard multi-layered film:

Figure 3 shows that a three-layer dental splint according to the invention can also be obtained in a single step deep-drawing process by deep drawing *a deep-drawing film 11 which has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard*

layers 12, 13 . . .

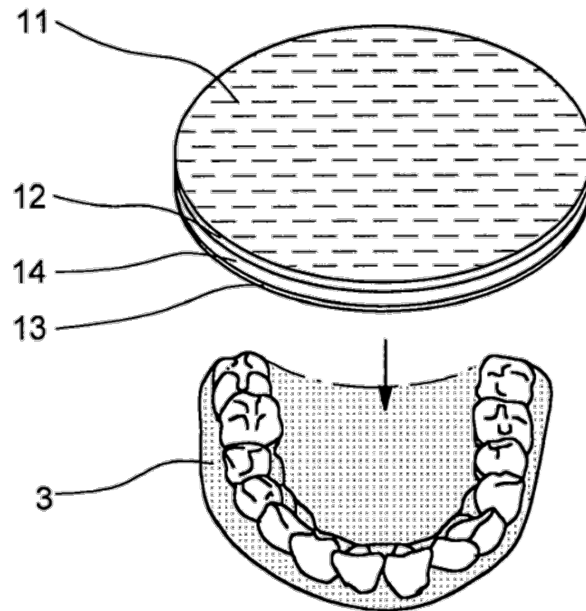


Fig. 3

(Hinz, Fig. 3, 8:240-244 (emphasis added).)

90. Hinz discloses exemplary materials for the hard and soft layers of the disclosed hard-soft-hard multilayer dental splints. (*E.g.*, Hinz, 3:80-93; *see also* 8:240-244.) Hinz discloses “a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET)” and “a soft layer made of a thermoplastic polyurethane (TPU).” (*Id.*, 3:80-90.) Hinz further discloses that “[t]he dental splint according to the invention preferably has hard layers made of the same plastic material.” (*Id.*, 3:86-87.)

91. Hinz also expressly discloses the exemplary use of the polymeric

materials in “DURASOFT®” and “Imprelon ‘S’” from Scheu-Dental GmbH to create the disclosed hard-soft-hard multilayer dental splints. (*See* Hinz, 6:185-189, 7:206-207; *see also id.*, 6:177-7:217.) Hinz explains that Durasoft is “a two-layer structure having a hard layer 5 made of polycarbonate and a soft layer 6 made of a thermoplastic polyurethane” in the form of “a composite plate having a hard layer and a soft layer” and that Imprelon S, another alternative hard material, is a polycarbonate. (*Id.*, 7:205-207, 6:185-189.)

2. Durasoft (TPU/PC) Data Sheet [Ex.1119]

92. Durasoft (TPU/PC) Data Sheet is a publication entitled “Produktdatenblatt DURASOFT®,”⁵ which I understand was publicly available at least as of August 8, 2016. (Ex.1119.) The Durasoft (TPU/PC) Data Sheet indicates that it is “valid through LOT1614A,” meaning it was valid for “DURASOFT®” lots produced through the 16th week of 2014. (*Id.*)

93. Durasoft (TPU/PC) consists of two layers: a hard layer of polycarbonate (“PC”) and a soft layer of thermoplastic polyurethane (“TPU”). It is expressly promoted for the “[m]anufacture of thermoformed dental splints.” (*Id.*)

⁵ Translated versions of the German-language datasheets are included with the exhibits containing the German-language datasheets.

The hard polycarbonate (“PC-Durasoft”⁶) layer has an elastic modulus of 2,400 MPa, a Shore D hardness of D88, and Rockwell hardness of R110. (*Id.*) The soft thermoplastic polyurethane (“TPU-Durasoft”⁷) has a CAS Registry Number 75701-44-9, an elastic modulus of 172 MPa, a Shore A hardness of A88, and a Shore D hardness of D33. (*Id.*)

3. Durasoft (TPU/PETG) Data Sheet [Ex.1121]

94. Durasoft (TPU/PETG) Data Sheet is a publication entitled “Produktdatenblatt DURASOFT®,” which I understand was publicly available at least as of August 8, 2016. (Ex.1121.) The Durasoft (TPU/PETG) Data Sheet indicates that it is “valid from LOT1714A,” meaning it was valid for “DURASOFT®” lots produced after the 17th week of 2014. (*Id.*)

95. Durasoft (TPU/PETG) Data Sheet discloses that Durasoft (TPU/PETG) consists of two layers: a hard layer of polyethyleneterephthalate-glycol copolyester

⁶ References hereinafter to “PC-Durasoft” refers to the properties of the polycarbonate (PC) material disclosed in Durasoft (TPU/PC) Data Sheet.

⁷ References hereinafter to “TPU-Durasoft” refers to the properties of the thermoplastic polyurethane (TPU) material disclosed in Durasoft (TPU/PC) Data Sheet.

(PETG) and a soft layer of thermoplastic polyurethane (TPU), and that Durasoft (TPU/PETG) is used in the “[m]anufacture of thermoformed dental splints.” (*Id.*) The hard polyethyleneterephthalate-glycol copolyester (“PETG-Durasoft”⁸) layer has an elastic modulus of 2,200 MPa, a Shore D hardness of D78, and Rockwell hardness of R115. (*Id.*) The soft thermoplastic polyurethane (TPU-Durasoft) is identified as having CAS Registry Number 75701-44-9, a Shore A hardness of A86, and a Shore D hardness of D35. (*Id.*)

96. Although the Durasoft (TPU/PETG) Data Sheet does not disclose an elastic modulus value for the thermoplastic polyurethane (TPU) material, it has the same CAS registration number, and nearly identical hardness values for both Shore A (A86 v. A88) and Shore D (D35 v. D33) as the TPU material in Durasoft (TPU/PC) Data Sheet. Accordingly, a POSA would have recognized that the TPU material disclosed in Durasoft (TPU/PETG) Data Sheet is essentially the same TPU material, with essentially the same elastic modulus, as the TPU in the Durasoft (TPU/PC) Data Sheet. (*Id.*) Therefore, I am applying the elastic modulus of 172

⁸ References hereinafter to “PETG-Durasoft” refers to the properties of the polyethyleneterephthalate-glycol copolyester (PETG) material disclosed in Durasoft (TPU/PETG) Data Sheet.

MPa for TPU-Durasoft as set forth in the Durasoft (TPU/PC) Data Sheet for Grounds 1-3 herein.

4. Imprelon-S (Copolyester) Data Sheet [Ex.1123]

97. Imprelon-S (Copolyester) Data Sheet is a publication entitled “Produktdatenblatt IMPRELON[®] S pd,” which I understand was publicly available at least as of August 9, 2016, as established by the Internet Archives. (Ex.1123.) The Imprelon-S (Copolyester) Data Sheet indicates that it is “valid from LOT3615A,” meaning it was valid for “IMPRELON[®] S” lots produced after the 36th week of 2015. (*Id.*)

98. Imprelon-S (Copolyester) Data Sheet provides technical information regarding a copolyester material supplied by Scheu Dental. (*Id.*) Imprelon-S (Copolyester) Data Sheet discloses that the material is used in the “[m]anufacture of thermoformed dental splints.” (*Id.*) The copolyester material (“Copolyester-Imprelon”⁹) layer has an elastic modulus of 1,624 MPa, a Shore D hardness of D78, Rockwell hardness of R115, and the CAS Registry Number 261716-94-3. (*Id.*)

⁹ References hereinafter to “Copolyester-Imprelon” refers to the properties of the copolyester material disclosed in Imprelon-S (Copolyester) Data Sheet.

5. Sun [Ex.1124]

99. Sun is a patent application entitled “Method of Forming a Dental Product,” published on November 11, 2004. Sun discloses a “method of making dental night guards and splints” from sheets, including those with “flexible and rigid layers,” as well as their preferred flexural modulus to ensure they are readily removable without discomfort. (*E.g.*, Ex.1124, [0002]-[0004], [0011]-[0012], [0029]-[0040].)

6. Kannan [Ex.1125]

100. Kannan is a chapter entitled “Thermoplastic Polyesters” in the Handbook of Thermoplastics. (Ex.1125.)

7. Li [Ex.1127]

101. Li is U.S. Patent No. 9,655,691, entitled “Multilayer Dental Appliances and Related Methods and Systems,” filed on May 14, 2012 and issued May 23, 2017. (Ex.1127.)

102. Li discloses that “[i]n general, the structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances”—i.e., aligners. (Li, 1:54-55.) In the preferred embodiment, the appliance “includes a hard polymer layer having a hard polymer layer elastic modulus disposed between a first soft polymer layer having a first soft polymer layer elastic modulus and a second soft polymer layer having a second soft polymer layer elastic modulus.” (Li,

Abstract.) More specifically, “[i]n one embodiment, the multilayer appliances can include a hard polymer layer of one type of material (e.g., a co-polyester), and two soft polymer layers of other types of material that can be the same or different (e.g., two soft polymer layers of thermoplastic polyurethane elastomer).” (Li, 6:29-34)

103. Figure 2 of Li “shows a multilayer structure according to the present invention. As shown, a multilayer sheet **20** can include a three layer structure: a hard polymer layer **24** and two soft polymer layers **22, 26**” (i.e., a soft-hard-soft layering configuration):

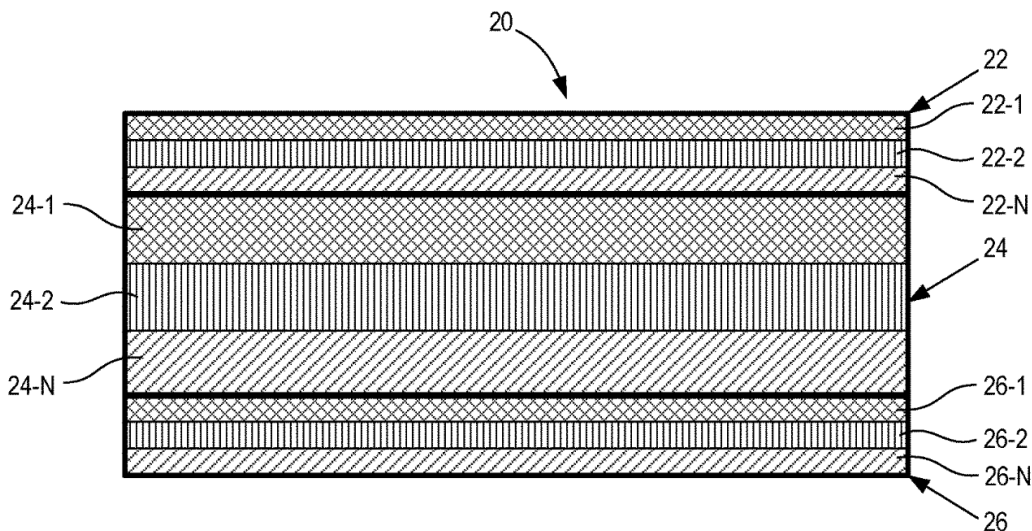


FIG. 2

(Li, 5:12-15, Fig. 2.) Li further explains that “the hard layer can be composed of multiple hard layers, e.g., two or three hard polymer layers **24-1, 24-2, 24-N** co-extruded to form one hard layer” and “the soft polymer layers **22, 26** can include a layer of several polymer layers **22-1, 22-2, 22-N** and **26-1, 26-2, 26-N**, respectively,

laminated together.” (Li, 5:46-49; 6:47-52.)

104. Figures 3 and 4 of Li depict a method of thermoforming a dental appliance from the disclosed multilayer sheets:

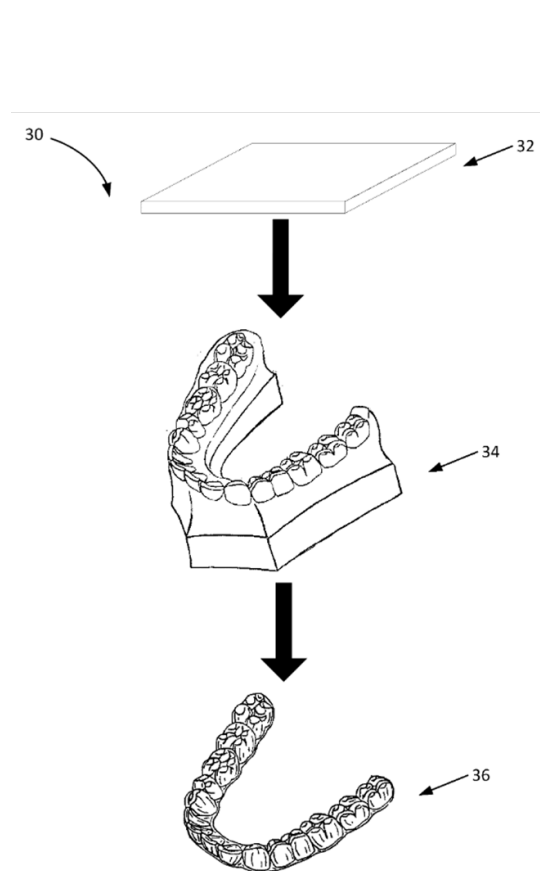


FIG. 3

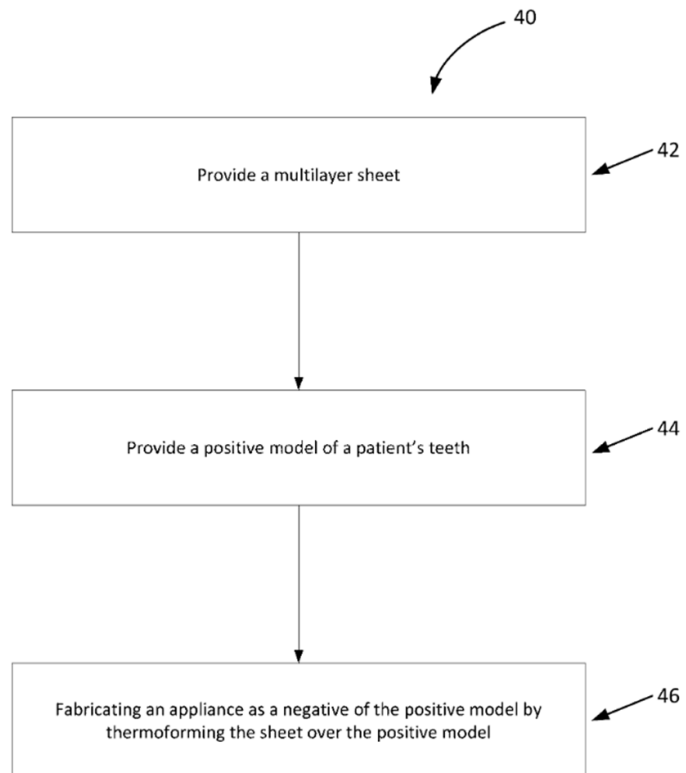


FIG. 4

(Li, 7:4-20, 7:36-50, Figs. 3-4.)

105. Li discloses all aspects of the construction of the multilayer sheets for forming a dental appliance, including: (1) suitable polymeric materials and physical properties for the hard layer(s) (Li, 5:34-67); (2) suitable polymeric materials and physical properties for the soft layers (Li, 6:1-26); and (3) the thickness of the hard

and soft layers, as well as the overall sheet thickness (Li, 5:18-31).

8. Boronkay [Ex.1128]

106. Boronkay is an international patent application (WO2017007962) entitled “Fabrication of Attachment Templates and Multi-Material Aligners.” Boronkay published on January 12, 2017. (Ex.1128.)

107. Boronkay discloses “[s]ystems, methods, and devices for producing orthodontic appliances”—i.e., aligners. (Boronkay, Abstract.) Figure 1A “illustrates an exemplary tooth positioning appliance or aligner 100”:

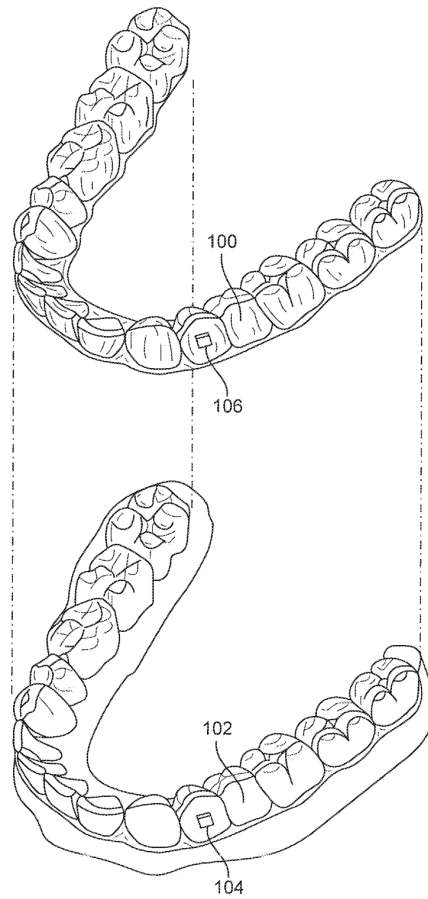


FIG. 1A

(Boronkay, [0088].)

108. Boronkay discloses multilayer aligners with hard and soft layers, including specifically an embodiment with a soft-hard-soft configuration: “FIG. 3C illustrates an appliance portion 320, having a compliant tooth facing or inner structure 324 (depicted herein as a layer) and a compliant outer structure 326 while

having a stiff middle layer 322, also called a shell”:¹⁰

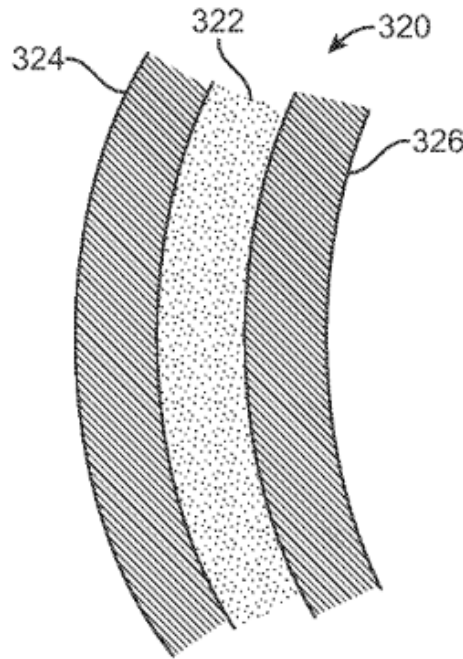


FIG. 3C

(Boronkay, [00108], Fig. 3C; *see also* [0095] (“‘Compliant’ or ‘relatively compliant’ may be used herein to denote an appliance portion having a stiffness less than a stiffness of another appliance portion”); [00108] (“the orthodontic appliance can be considered a multilayered appliance”).)

¹⁰ Boronkay refers to “inner” in reference to the layer of the dental aligner that is “tooth facing” and “outer” in reference to the opposing outside layer of the dental aligner (i.e., the outside layer facing the patient’s mouth tissues). Also, Boronkay uses “middle” layer as referring to the layer between the “inner” and “outer” layers.

109. Boronkay further discloses that “[t]he orthodontic appliances provided herein can include other components in addition to a stiff outer shell and compliant inner structure,” such as “one or more additional layers coupled to the inner surface of the outer shell and/or inner structure, and these layers can perform various different functions.” (Boronkay, [00144]-[00145].) For instance, “a compliant, inner structure can be provided with a protective layer” and that such a “protective layer can be formed as a. material layer or as a coating deposited on the compliant inner structure.” (Boronkay, [00134].) This “innermost layer can be stiffer and/or harder than the inner structure, e.g., to protect the inner structure from abrasion, wear, staining, biological interactions, and the like.” (Boronkay, [00145].) Boronkay similarly discloses a stiff or hard protective “outermost layer” that also serves “to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like.” (Boronkay, [00144].)

110. Boronkay discloses that the hard protective “innermost” and “outermost” layers “can have a hardness greater than or equal to about 70 Shore D or about 90 Shore D.” (Boronkay, [00144], [00145].) Boronkay further teaches that the additional protective innermost and outermost layers should be thinner than the other layers of the appliance—i.e., the “outer shell and/or inner structure”—in order

to reduce the contributions of the innermost and outermost layers “to the overall properties of the appliance.” (*Id.*)

111. Boronkay further discloses that its aligners “can be produced using indirect fabrication techniques, such as by thermoforming” over a mold. ([00146].)

9. Chen [Ex.1129]

112. Chen is a U.S. patent 8,758,009, entitled “Restorative Dental Appliances,” and published on June 24, 2014. (Ex.1129.)

113. Chen discloses polymeric “aligner-type dental appliances for realigning teeth” that “may include a single or a plurality of polymeric material layers.” (Chen, 1:10-11, 3:45-46; *see also* 5:14-35.) The “dental appliance 100” comprising a polymeric concave trough 102 is illustrated in Figure 1:

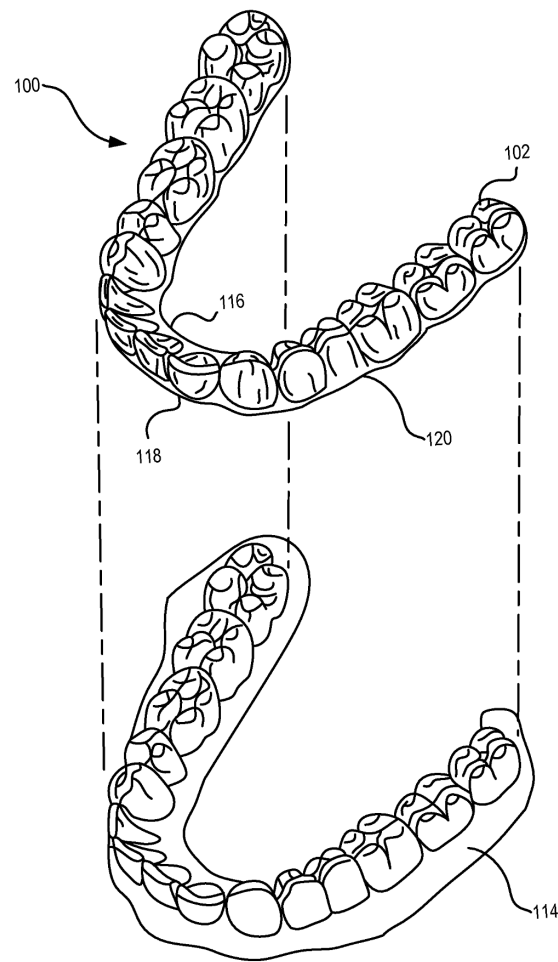


FIG. 1

(Chen, 2:33-41, Fig. 1.)

114. Chen teaches that “[c]ertain areas of the appliance will confer orthodontic forces onto the teeth” and, accordingly, that “[t]he concave trough **102** is made of a material that has a predetermined modulus.” (Chen, 2:50-53, 3:22-23.) “The modulus can be predetermined to match the compliance required to reposition the teeth,” and this is “preferably” a modulus range between “about 0.8 GPa to 1.5 GPa.” (Chen, 3:28-33.)

115. Chen further explains that “[t]he dental appliance **100**, in some embodiments, has a polymeric material layer fabricated into at least two segments, one segment harder than the other segment.” (Chen, 4:31-33.) Chen discloses that the layering geometry for the hard and soft segments may comprise a plurality of layers, including two outer layers 134 and four or three inner layers 132:

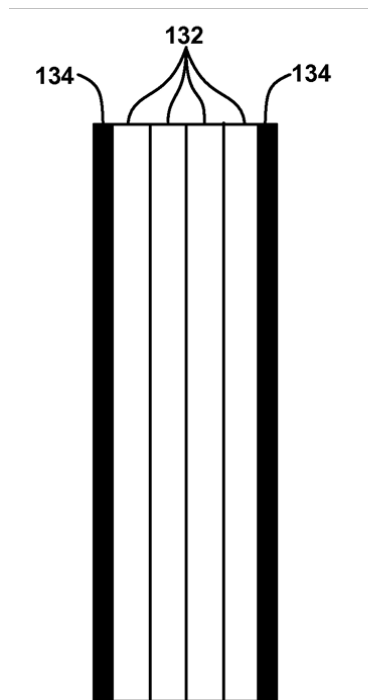


FIG. 4A

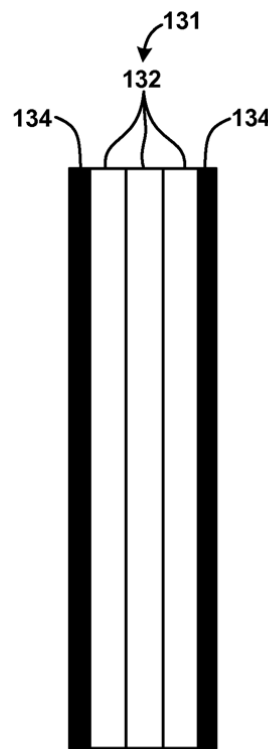


FIG. 4B

(Chen, 5:15-25, Figs. 4A, 4B.) Chen further explains that “the layers may be formed in various orientations and configurations to suit the modulus an application requirements” and that “the layers may be formed by any process, such as thermoforming or similar process, such as co-extrusion, lamination, or any other process where layers are formed.” (Chen, 5:25-35.)

10. Stewart [Ex.1130]

116. Stewart is an international patent application (WO2013/130552) entitled “Dental Products and Procedures.” (Ex.1130.)

117. Stewart ’552 discloses appliances in the form of polymeric “shells” made by thermoforming polymeric sheets that can “hav[e] two or more layers of different polymeric compositions.” (Stewart, 2:10-12, 3:15-18, 12:26-30, 13:19-20, 15:9-12, 19:17-20.) Stewart teaches that “[i]n orthodontic procedures, the objective is to change the relative positions of two or more teeth” and for an “orthodontic appliance, it is desirable to use a polymeric sheet which, before being thermoformed, is 0.5 to 0.8 mm thick and for the polymeric composition to have a flexural modulus between 1000 and 3000 MPa.” (Stewart, 1:12-13, 20:21-24.)

B. Ground 1: Obviousness of Claim 1 Based on Hinz in view of Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet

1. Motivation to Combine and Reasonable Expectation of Success

118. Hinz, Durasoft (TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S (Copolyester) Data Sheet are each explicitly for the same specific application: construction of thermoformed dental splints. (*See* Hinz, 1:3-4; Ex.1119; Ex.1121; Ex.1123.) A POSA would have been motivated to construct pre-thermoformed multilayer hard-soft-hard films of Hinz using the polymeric materials disclosed in the Durasoft (TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and/or Imprelon S Data Sheet for thermoforming into Hinz’s hard-soft-hard dental splints, based at least on the express disclosures within the references themselves. Specifically, a POSA would have been motivated to use TPU-Durasoft as the soft inner layer and two hard outer layers of either PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon in pre-thermoformed hard-soft-hard films and use those films to create Hinz’s hard-soft-hard dental splints.

119. Hinz explicitly discloses the creation of dental splints with a three-layer hard-soft-hard structure—e.g., “two hard outer layers and having a soft inner layer embedded between the hard layers,” (*e.g.*, Hinz, 3:68-70.) A POSA would have been motivated to select the polymers and associated material properties of the hard

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and soft polymeric materials of DURASOFT® and the hard IMPRELON® S polymer within Hinz’s hard-soft-hard dental splints at least because Hinz expressly teaches their specific use within his splints. (*Id.*, 7:206-207 (“a hard layer and a soft layer having the trade name DURASOFT® from Scheu-Dental GmbH.”), 6:185-187 (“IMPRELON® ‘S’ from Scheu-Dental GmbH can be used”).) As a consistent and reciprocal motivation, each of the material data sheets for these materials—Durasoft(TPU/PC) Data Sheet, Durasoft(TPU/PETG) Data Sheet, and Imprelon S (Copolyester) Data Sheet—each expressly disclose the use of the materials for the “[m]anufacture of thermoformed dental splints,” which is precisely what is taught by Hinz. (Ex.1119 (“Use of the substance/composition: Manufacture of thermoformed dental splints”); Ex.1121 (same); Ex1123 (same).)

120. Furthermore, a POSA would have recognized that the polymers within the materials from Scheu-Dental used in the manufacture of thermoformed dental splints are the same explicitly preferred polymers for the hard and soft layers taught by Hinz, providing further motivation for using these same polymeric materials to construct Hinz’s hard-soft-hard dental splints. (Hinz, 3:80-82 (“a deep-drawing film having a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET), is selected to produce the dental splint”), 3:89-90 (“a deep-drawing film having a soft layer made of a thermoplastic

polyurethane (TPU) . . . is selected”); Ex.1119 (TPU, polycarbonate); Ex.1121 (TPU, PETG); Ex.1123 (Copolyester).) In this regard, Hinz expressly discloses a preferred embodiment of the hard-soft-hard composite splint having a “soft inner layer” made from thermoplastic polyurethane (TPU), as well as the benefits obtained from selecting this soft material:

In a further preferred embodiment, a deep-drawing film having a soft layer made of a thermoplastic polyurethane (TPU) or ethylene vinyl acetate (EVA) is selected. The above-mentioned plastic materials result in a sufficiently high elasticity of the dental splint according to the invention, so that breakage of the dental splint during insertion and removal and while it is worn does not have to be a concern.

(Hinz, 3:89-93.) Accordingly, a POSA would have recognized and been motivated to use the TPU-Durasoft polymer disclosed in Durasoft (TPU/PC) Data Sheet and Durasoft(TPU/PETG) Data Sheet as a suitable material for the soft inner TPU layer of Hinz’s hard-soft-hard dental splints.¹¹

¹¹ At least by as early as 2016, a POSA would have understood that Scheu Dental had introduced a new version of Durasoft, which substituted a PETG polymer for the hard layer in lieu of the PC polymer in the earlier version of Durasoft. (*Id.*, ¶127;

121. Hinz further teaches that the “hard outer layers” can be made of “a polyester plastic, preferably a polycarbonate (PC) or a polyethylene terephthalate (PET),” and that these hard outer layers provide beneficial properties to the hard-soft-hard splint:

In one preferred embodiment of the invention, a deep-drawing film having a hard layer made of a polyester plastic, preferably made of polycarbonate (PC) or polyethylene terephthalate (PET), is selected to produce the dental splint. The external hard layers made of the polyester plastic in the layered composite are stable against discoloration and enable a crystal-clear appearance of the dental splint according to the invention. In addition, the hard layer is sufficiently break-resistant . . .

(Hinz, 3:80-86.)

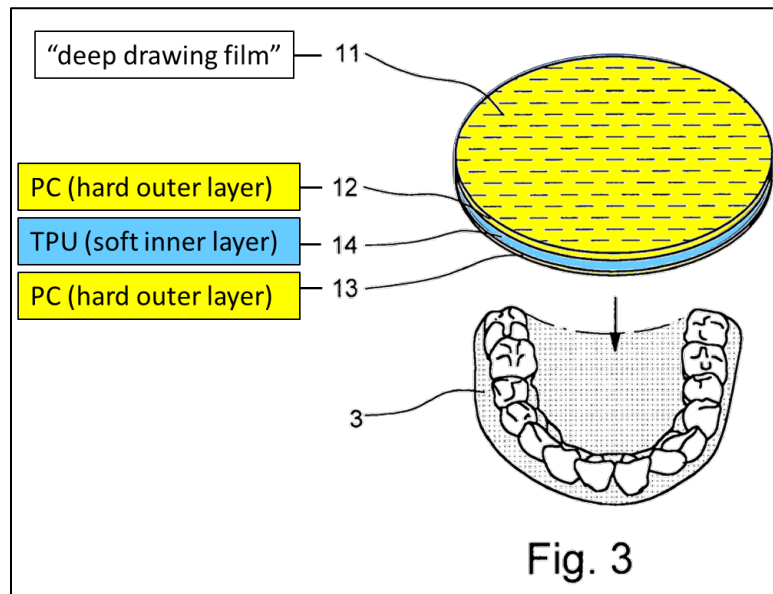
122. Hinz also expressly discloses that “[t]he dental splint according to the invention preferably has hard layers made of the same plastic material.” (*Id.*, 3:86-

Ex.1014.) A POSA would also have recognized that the TPU in Durasoft (TPU/PETG) Data Sheet was essentially (if not) the same as the TPU in Durasoft (TPU/PC) Data Sheet, since it is identified as having the same CAS Registry Number and similar hardness values. (*Id.*)

87.) Accordingly, a POSA would have recognized and been motivated to use either the PC-Durasoft polymer (a “polycarbonate (PC)”) disclosed in Durasoft (TPU/PC) Data Sheet, the PETG-Durasoft polymer (a “polyethylene terephthalate (PET)”) disclosed in Durasoft(TPU/PETG) Data Sheet, or the Copolyester-Imprelon polymer (a “polyester plastic”) disclosed in Imprelon S (Copolyester) Data Sheet as the two hard outer layers of Hinz’s hard-soft-hard dental splints.

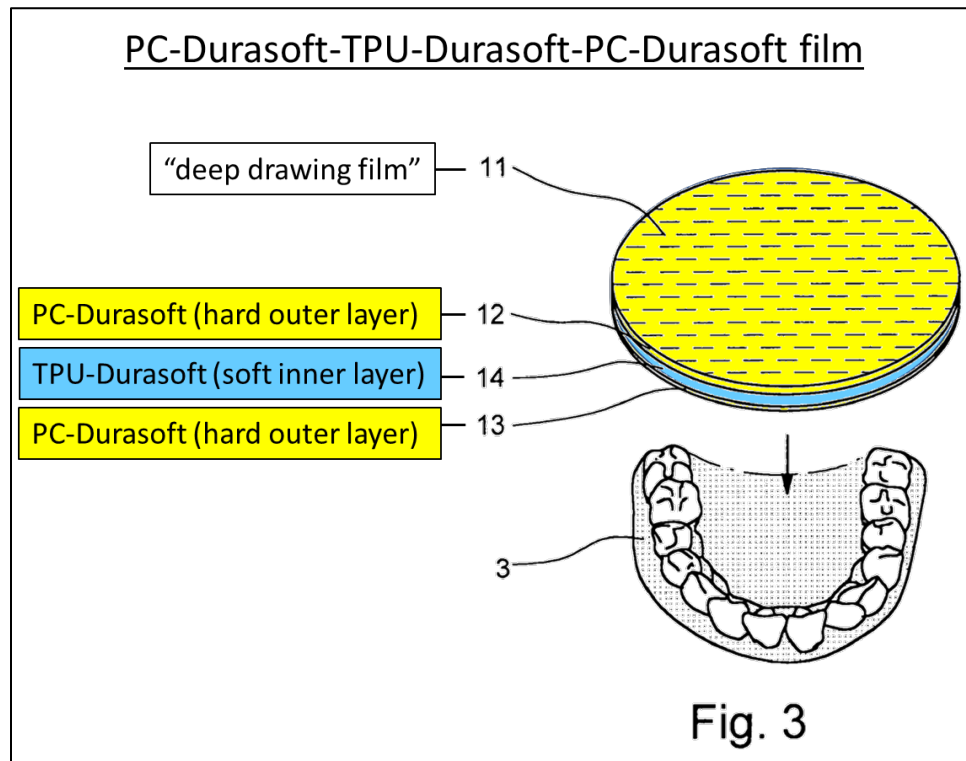
123. Hinz expressly discloses an embodiment for making a hard-soft-hard dental splint using a pre-thermoformed multilayer hard-soft-hard film in Figure 3. (Hinz, 6:173-175, 7:240- Fig. 3.) In the expressly disclosed embodiment, Hinz teaches the use hard PC and soft TPU polymers in a three-layer pre-thermoformed PC-TPU-PC (hard-soft-hard) film for creating a thermoformed three-layer hard-soft-hard dental splint:

Figure 3 shows that a three-layer dental splint according to the invention can also be obtained in a single step deep-drawing process by deep drawing a deep-drawing film 11 which *has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13.*



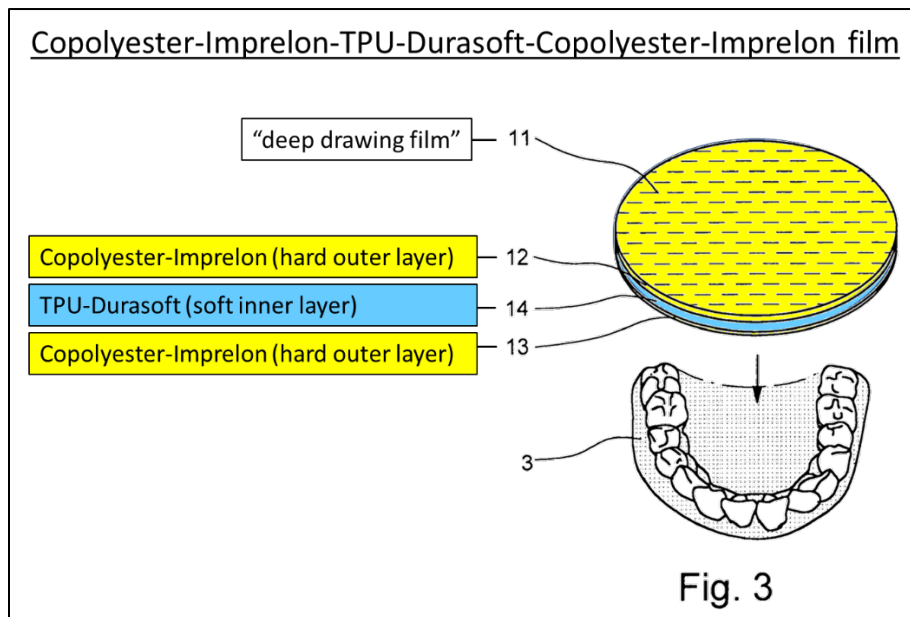
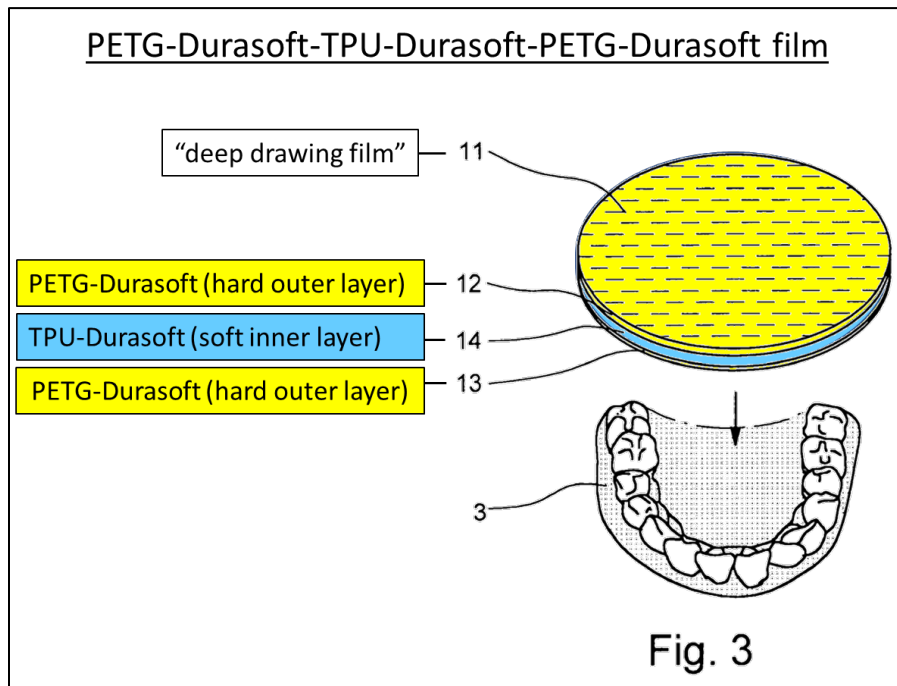
(Hinz, 8:240-244 (emphasis added), Fig. 3 (annotated), 8:240-244.)

124. A POSA would have immediately recognized the suitability of the hard PC-Durasoft and soft TPU-Durasoft polymeric materials for the hard-soft-hard pre-thermoformed film of Hinz's Figure 3 embodiment because the embodiment expressly teaches a pre-thermoformed hard PC polymer for the outer layers and a soft TPU polymer for the inner layer. Thus, a POSA would have found it obvious to construct the following PC-Durasoft-TPU-Durasoft-PC-Durasoft film under this Ground:



125. A POSA would also have understood that Hinz’s hard-soft-hard dental splints could also be created according to the embodiment of Hinz Figure 3 using PETG-Durasoft or Copolyester-Imprelon polymers as the hard layers of the pre-thermoformed film because these are expressly disclosed by Hinz as alternative preferred polymers for the hard outer layers. (*E.g.*, Hinz, 3:80-81 (“having a hard layer made of a *polyester* plastic, preferably made of . . . *polyethylene terephthalate (PET)*”) (emphasis added).) Thus, a POSA would also have found it obvious under this Ground to construct pre-thermoformed hard-soft-hard PETG-Durasoft-TPU-Durasoft-PETG-Durasoft and/or Copolyester-Imprelon-TPU-Durasoft-

Copolyester-Imprelon films, as follows:



126. A POSA would have found it routine and thus would have reasonably expected to be able to successfully construct pre-thermoformed three-layer hard-

soft-hard films with TPU-Durasoft as the soft inner layer and two hard outer layers of either PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon. First, Hinz expressly discloses the embodiment of a pre-thermoformed film with “a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13” associated with Figure 3. (Hinz, 8:240-244.) Hinz also discloses the use of TPU, polyester, PC, and PET polymers as preferred embodiments “of the invention,” and a POSA would have reasonably expected to be able to successfully utilize these explicitly disclosed preferred polymers within the embodiment of Figure 3 to construct Hinz’s hard-soft-hard dental splints. (See Hinz, 3:80-93.)

127. Second, TPU, PC, PETG, and Copolyester were common, regularly used thermoplastic polymers for the formation of thermoformed multilayer dental appliances. (E.g., Li, 5:34-46 (multilayer dental appliances with hard layer of polyester, co-polyester, PC, and PET and soft layer of a polyurethane elastomer), 6:27-34).) Indeed, the Background section of the ’263 patent admits that the prior art disclosed dental appliances made from “[e]xisting materials and products [] constructed from single layer materials, bi-layer materials, or tri-layer materials[.]” (Ex.1101, 1:31-33.) A POSA would have found the selection from existing polymeric materials for dental applications, such as those advertised by Scheu-

Dental, to involve no inventive effort. Rather, a POSA would have found the identification and selection of polymeric materials to be a routine step in the construction of a multilayer sheet, including specifically in the context of a sheet that would be used to construct a dental appliance.

128. Third, the fact that Durasoft was already available as a two-layer “composite plate” of hard PC-Durasoft or PETG-Durasoft and soft TPU-Durasoft would have led a POSA to reasonably expect that the same hard PC-Durasoft and PETG materials could be readily formed onto both sides of the TPU-Durasoft to make a pre-thermoformed three-layer hard-soft-hard film. (*See* Hinz, 7:206-207 (“The deep-drawing film 2 is a composite plate having a hard layer and a soft layer having the tradename DURASOFT® from Scheu-Dental GmbH.”).) The prior art also disclosed multilayer plastic films with layers of copolyester bonded with TPU, further demonstrating a POSA’s reasonable expectation in successfully making a pre-thermoformed Copolyester-Imprelon-TPU-Durasoft-Copolyester Imprelon film.

129. Fourth, Hinz also discloses that the films making up the multilayer dental splint “are bonded to one another by deep-drawing” and that they are “are bonded to one another in such a way that a layered composite having a hard outer layer on each of the two outer sides of the dental splint and having a soft inner layer

embedded between the hard layers is obtained.” (Hinz, 2:61-3:73 (emphasis added).) A POSA would have therefore understood that pre-thermoformed multilayer hard-soft-hard films with the TPU, PC, PETG, and copolyester materials of this Ground could be made by any number of different known methods utilizing the application of heat and/or pressure processing, for example, co-extrusion or lamination processes. The ’263 patent admits these are methods known to a POSA for making multilayer polymeric sheets: “Multilayer sheets may be prepared by a number of means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or other known methods.” (Ex.1101, 15:17-20 (emphasis added).)

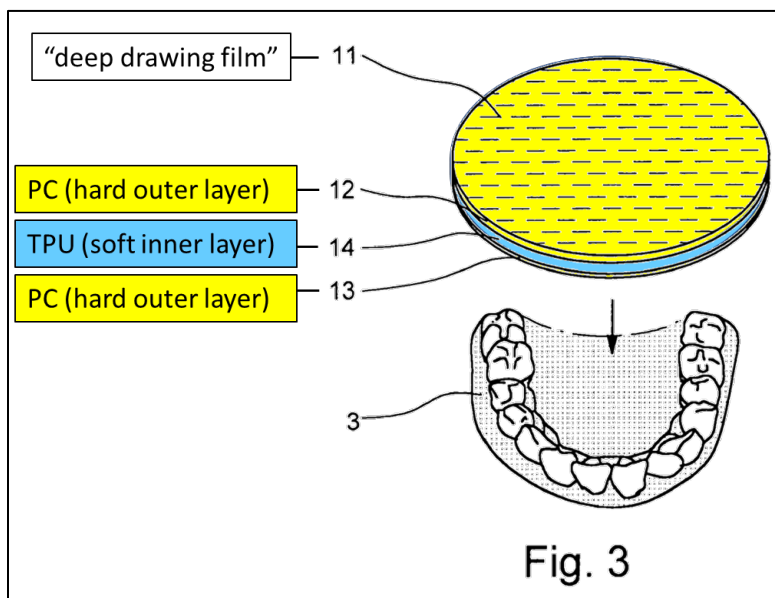
130. A POSA would therefore have readily understood that TPU, PC, PETG, and Copolyester could be obtained or synthesized with the same properties as TPU-Durasoft, PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon set forth in the data sheets and then used to construct the pre-thermoformed hard-soft-hard films taught by Hinz. Accordingly, a POSA would have had a reasonable expectation of success in utilizing TPU-Durasoft, PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon disclosed in the Scheu Dental datasheets to create the pre-thermoformed hard-soft-hard multilayer films taught by Hinz, and this obvious hard-soft-hard film satisfies all elements of claim 1.

2. Independent Claim 1

131. Claim 1 is obvious over Hinz in view of Durasoft (TPU/PC) Data Sheet, Durasoft (TPU/PETG) Data Sheet, and/or Imprelon (Copolyester) Data Sheet since these materials can be used to construct Hinz's soft layers from TPU and Hinz's hard layers of either PC, PETG, or Copolyester.

a. Claim 1[pre]: “[a] polymeric sheet composition, comprising:”

132. To the extent the preamble is limiting, it is disclosed by Hinz. Hinz discloses “a deep-drawing film 11 which has a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13” in Figure 3:



(Hinz, Fig. 3 (annotated), 8:240-244.) A POSA would have recognized that Hinz also, alternatively, discloses that the hard outer layers can be made of polyester or

PET, and that these polymers can also be used to create the pre-thermoformed film of Hinz's Figure 3 embodiment.

133. Accordingly, Ground 1 satisfies 1[pre].

b. Claim 1[a]: “at least two outer layers A and C and an elastomeric inner layer B”

134. Claim element 1[a] is disclosed and rendered obvious by Hinz's hard-soft-hard pre-thermoformed film, and in combination with hard outer layers of either PC-Durasoft, PETG-Durasoft, or Copolyester-Imprelon and a soft inner layer of TPU-Durasoft. Hinz Figure 3 depicts a film with “a three-layer structure having two outer hard layers 12, 13 made of polycarbonate and a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:240-243.) Hinz's “two outer hard layers 12, 13 made of polycarbonate,” including specifically the obvious combination of Hinz using hard outer layers made of PC-Durasoft and, alternatively, PETG-Durasoft, or Copolyester-Imprelon, are “at least two outer layers A and C.”

135. Hinz also discloses “an elastomeric inner layer B” in the form of “a soft layer 14 made of polyurethane embedded between hard layers 12, 13.” (Hinz, 8:242-243.) Hinz describes this “internal soft layer” as providing a dental splint with “increased elasticity” caused by “the internal soft layer having higher elasticity.” (Id., 3:73-76.) Hinz also refers to the polyurethane used for the “soft layer” as a

“thermoplastic polyurethane (TPU),” and explains that use of this material “result[s] in a sufficiently high elasticity of the dental splint according to the invention....” (Id., 3:89-91; see also 9:278, 10:323.) A POSA would also have reasonably understood and found it obvious that Hinz’s “soft layer 14 made of polyurethane” is referring to a soft, elastomeric polyurethane and therefore satisfies “an elastomeric inner layer B.” (Ex.1101, 5:20-21 (“[h]ighly elastic polymers such as thermoplastic polyurethane elastomers (TPU)”).)

136. A POSA also would have understood that TPU-Durasoft disclosed in Durasoft (TPU/PC) Data Sheet and was a polyurethane elastomer. TPU-Durasoft has an elastic modulus of 172 MPa and a Shore hardness of A88 and D33. (Ex.1119.) The ’263 patent explains that “the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa” and “the elastomeric middle layer comprises a polyurethane having a hardness from about A 80 to D 75[.]” (Ex.1101, 1:56-58, 3:11-13.) Fig. 3A of the ’263 patent further discloses “a middle B layer with different hardness TPU elastomers” with shore hardness values from 75A to 65D. (Id., 4:1-7, Fig. 3A.) TPU-Durasoft falls within these elastic modulus and Shore hardness ranges. A POSA would understand that the obvious use of TPU-Durasoft as the inner layer in the three-layer embodiment of Hinz is an “elastomeric inner layer B.”

137. Accordingly, Ground 1 satisfies 1[a].

- c. **(c) Claim 1[b]: “wherein one or both of the outer layers A and C individually comprise a thermoplastic polymer having a flexural modulus of from about 1,000 MPa to 2,500 MPa”**

138. Hinz, in combination with each of the hard polymeric materials in the datasheets of this ground disclose 1[b]. A POSA would have known that PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon are thermoplastic polymers, at least because the datasheets indicate the materials are thermoformable.

139. The '263 patent discloses that “[f]or isotropic materials such as A, B and C, flexural modulus and modulus (which may also be referred to as elastic modulus) are substantially the same and one or the other may be measured dependent upon the circumstances.” (Ex.1101, 7:8-12.) PC-Durasoft, PETG-Durasoft, and Copolyester-Imprelon have a listed elastic modulus values of 2,400 MPa, 2,200 MPa, and 1,624 MPa, respectively, each of falls within the claimed range of “about 1,000 MPa to 2,500 MPa” and, as isotropic materials, would have substantially the same flexural modulus. (*See* Ex.1119; Ex.1121; Ex.1123.)

140. Accordingly, Ground 1 satisfies 1[b].

- d. **Claim 1[c]: “and the inner layer B is comprised of an elastomeric material having a hardness from about A 60 to D 85”**

141. Hinz in combination with TPU-Durasoft satisfies 1[c]. As discussed

above with respect to claim element 1[a], a POSA would understand that Hinz's preferred "soft inner layer embedded between the hard layers" is made of polyurethane and would understand the obvious use of TPU-Durasoft as the material for the "soft inner layer" is an "elastomeric inner layer B." TPU-Durasoft is identified as having a hardness of A88 and D33, which falls within the range of "a hardness from about A80 to D75." (Ex.1119.)

142. Accordingly, Ground 1 satisfies 1[c] and renders claim 1 obvious.

C. Ground 2: Obviousness of Claims 2-4 Based on Ground 1 and Sun

143. Ground 2 relies on the same obvious hard-soft-hard films as rendering claim 1 obvious under Ground 1, but further includes the express teachings regarding the beneficial and expressly disclosed flexural modulus values for a dental splint according to Sun for the challenged claims that depend on claim 1.

1. Motivation to Combine and Reasonable Expectation of Success

144. Sun discloses an "invention" that "relates to method of making dental night guards and splints." (Sun, [0002], [0003] ("night guards, splints, retainers . . . orthodontic appliances").) Thus, like Hinz and the datasheets of Ground 1, Sun is also directed to the field of dental splints. In my opinion, a POSA would therefore have been motivated to look to the interrelated teachings of Hinz and Sun to understand the desirable mechanical properties for a dental splint, and would apply

those interrelated teachings in the context of the obvious multilayer hard-soft-hard dental splints of Hinz constructed with the polymeric materials of the Scheu Dental data sheets of Ground 1.

145. In this regard, Sun explains that “[t]he flexibility and softness of these dental night guards and dental splints enables them to be readily removable from a patient’s mouth without discomfort to the patient.” (Sun, [0004].) Sun further discloses preferred ranges for the flexural modulus of the dental splints. As preferred maximum flexural modulus, Sun discloses that the “[f]lexible dental polymeric material useful in accordance with the invention has a flexural modulus in order of increasing preference of less than 350,000; 300,000; 250,000; 200,000; 170,000 psi . . . at 23° C” and (Sun, [0012].) When converted to MPa, Sun’s preferred maximum equates to “a flexural modulus in order of increasing preference of less than [2,413], [2,068], [1,723], [1,378] and [1,172 MPa].” As preferred minimum flexural modulus, Sun discloses “a flexural modulus in order of increasing preference of at least 10,000; 20,000; or 50,000 psi,” which correlates to “a flexural modulus in order of increasing preference of at least [69]; [138]; or [345 MPa].” (Sun, [0013].)

146. A POSA would have been motivated to combine Sun with the teachings of Hinz (per Ground 1), as both are directed to the interrelated construction of dental

splints with “improved mechanical properties” that “may be inserted into and removed from patients easily.” (Hinz, 2:54-59; Sun, [0004].) Although Sun teaches a different polymeric composition for forming a dental splint than the multilayer hard-soft-hard splints of Hinz, the final appliances remain the same—a dental splint. A POSA would therefore look to the specific teachings of the flexural modulus of the dental splints of Sun as guidance for achieving (at least) the mechanical properties of a dental splint that have “better insertion and removal behavior due to increased elasticity” with the dental splints taught by Hinz. (Sun, [0012]-[0013]; Hinz, 3:74-76.) Thus, a POSA would have been motivated to follow Sun’s teaching regarding the flexural modulus values desired for a flexible and easily inserted and removed dental splint constructed according to the teachings of Hinz. (*Id.*)

147. A POSA would have reasonably anticipated success in forming the films and dental splints taught by Hinz to achieve the desired flexural modulus values of Sun by selecting from the specific polymeric materials and multilayer configurations expressly taught by Hinz in view of the Scheu Dental polymeric materials. As noted in Ground 1 above, Hinz expressly discloses and suggests the use of obvious hard polymer outer layers (PETG-Durasoft or Copolyester-Imprelon) and a soft elastomeric TPU-Durasoft from Scheu Dental, and Hinz further discloses preferred thicknesses for the layers within the hard-soft-hard films and dental splints.

As set forth in Ground 1, a POSA would readily understand how to follow the teachings of Hinz to make multilayer hard-soft-hard films and dental splints with the TPU-Durasoft, PETG-Durasoft, and Copolyester-Imprelon polymers, and would have reasonably expected success in achieving the preferred flexural modulus values taught by Sun.

2. Dependent Claim 2

148. Claim 2 recites “[t]he polymeric sheet composition of claim 1, wherein the A, B and C layers of the polymeric sheet composition have a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa.” Claim 1 is obvious under Ground 1. The combination of Ground 1 with Sun discloses and renders obvious claim 2 under this Ground .

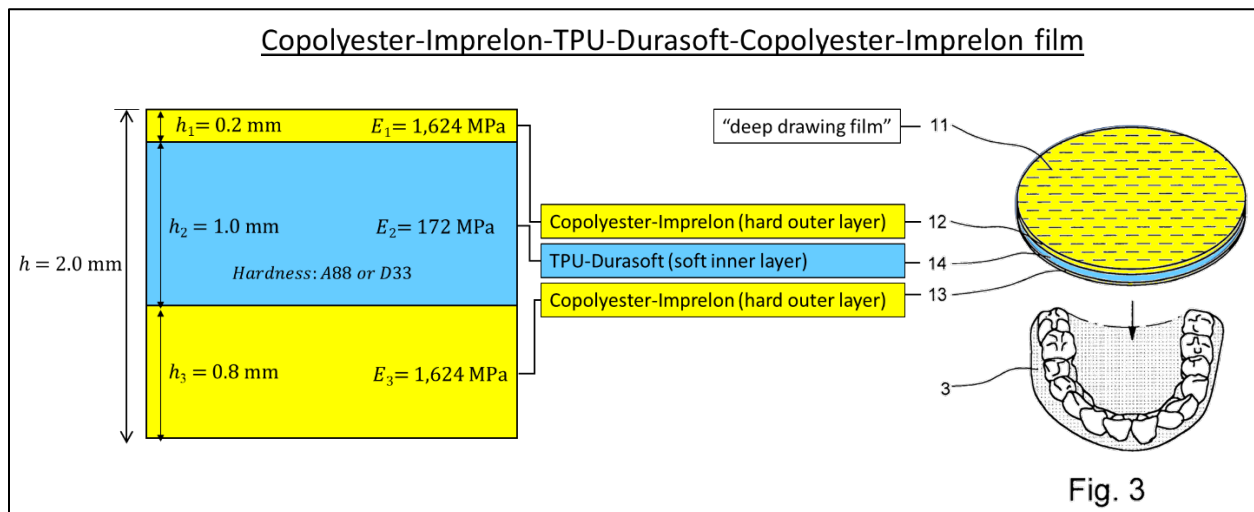
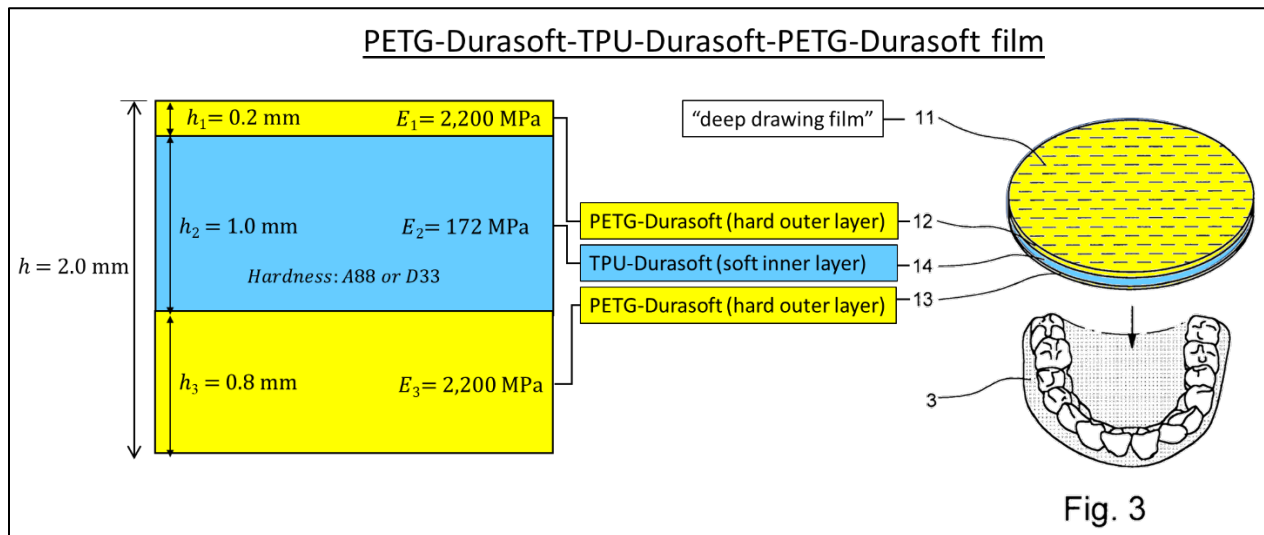
149. Sun discloses a most-preferred minimum flexural modulus for a dental splint of 345 MPa. (See Sun, [0013] (“a flexural modulus in order of increasing preference of at least [69]; [138]; or [345 MPa]”).) Sun also discloses a most-preferred maximum flexural modulus for a dental splint of 1,172 MPa, a second-most-preferred maximum flexural modulus for a dental splint of 1,378 MPa, and a third-most-preferred flexural modulus for a dental splint of 1,723 MPa. (Sun, [0013] (“a flexural modulus in order of increasing preference of less than [2,413], [2,068], [1,723], [1,378] and [1,172 MPa]”).) Thus, Sun explicitly discloses a most-preferred

flexural modulus range of 345-1,172 MPa, a second-most-preferred flexural modulus range of 345-1,378 MPa, and a third-most flexural modulus range of 345-1,723 MPa. These preferred flexural modulus ranges expressly disclosed by Sun have substantial commensurate overlap and therefore, in my opinion, satisfy and render obvious the “flexural modulus of from 500 MPa to 1,500 MPa” limitation of claim 2.

150. Hinz discloses a three-layer hard-soft-hard dental splint wherein the thickness of one outer hard layer is “in particular of less than 0.2 mm,” the soft layer has a thickness of “in particular of less than 1.0 mm[,]” and the other hard outer later has a thickness of “in particular of less than 0.8 mm.” (Hinz, 10:317-11:333 (claims 11-14).) Claims 11-14 of Hinz disclose this embodiment of a dental splint with a “three-layer structure” having two outer hard layers “made of a polyester plastic, preferably made of . . . polyethylene terephthalate (PET)” and an inner soft layer “made of a thermoplastic polyurethane (TPU),” which, in conjunction with Hinz’s express teachings under Ground 1, would have directed a POSA to the selection of either the PETG-Durasoft or Copolyester-Imprelon for the two hard outer layers and TPU-Durasoft as the inner soft layer. (*Id.*) Hinz also discloses that “it is obvious that the layer thickness of the [pre-thermoformed] deep-drawing film is reduced upon deep drawing [thermoforming]” and that “[t]he layer thicknesses provided

according to the invention of the deep-drawing [pre-thermoformed] films used ensure very good mechanical properties of the dental splint according to the invention.” (Hinz, 4:116-119.)

151. Accordingly, a POSA would recognize that Hinz expressly discloses and teaches, at least Hinz’s claims 11-14,” the formation of a hard-soft-hard dental splint from a pre-thermoformed film that includes an outer hard layer with a thickness of 0.2 mm, an inner soft layer with thickness of 1.0 mm, and an outer hard layer with a thickness of 0.8 mm, such that upon thermoforming the thickness of the layers would be “less than 0.2 mm,” “less than 1.0 mm,” and “less than 0.8 mm,” respectively. This obvious construction of a pre-thermoformed hard-soft-hard film according to Hinz, utilizing the expressly suggested PETG-Durasoft or Copolyester-Impreton hard polymer layers and TPU-Durasoft soft inner layers for making a thermoformed dental splint, are depicted as follows:



(Annotated to include the thickness (h_i), elastic modulus (E_i) and/or hardness (A88 or D33) of the individual layers.)

152. The combined thickness for the hard-soft-hard “A, B and C layers” of the foregoing Hinz embodiments is 2.0 mm (0.2/1.0/0.8), satisfying the claimed combined thickness of “from 250 microns to 2,000 microns” limitation of claim 2. The calculated flexural modulus of the pre-thermoformed hard(PETG-Durasoft)-soft(TPU-Durasoft)-hard(PETG-Durasoft) polymeric sheet composition is 1,439

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MPa,¹² which is falls within the third-most-preferred flexural modulus range of Sun. The calculated flexural modulus of the pre-thermoformed hard(Copolyester-Imprelon)-soft(TPU-Durasoft)-hard(Copolyester-Imprelon) polymeric sheet composition is 1,088 MPa, which is falls within the most-preferred flexural modulus range of Sun and, accordingly, a POSA would have recognized that this would be a highly preferred hard-soft-hard film that satisfies and renders obvious claim 2.

Flexural Modulus (Ef) calculation for PETG-Durasoft(0.2 mm)-TPU-Durasoft(1.0 mm)-PETG-Durasoft (0.8 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	2200	1.9	1	0.38	0.2	1.156492	0.26749494	0.008
TPU-Durasoft	2	1	172	1.3	0.078182	0.101636364	0.078182	0.556492	0.024211643	0.0781818
PETG-Durasoft	3	0.8	2200	0.4	1	0.32	0.8	0.343508	0.094397971	0.512
sum (i=1,2,3)		2.0				0.801636364	1.078182		0.386104553	0.5981818

Y-bar= 0.743508

Ef= 1439

Flexural Modulus (Ef) calculation for Copolyester-Imprelon(0.2 mm)-TPU-Durasoft(1.0 mm)-Copolyester-Imprelon (0.8 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	1624	1.9	1	0.38	0.2	1.142539	0.261079062	0.008
TPU-Durasoft	2	1	172	1.3	0.105911	0.137684729	0.105911	0.542539	0.031174845	0.1059113
PETG-Durasoft	3	0.8	1624	0.4	1	0.32	0.8	0.357461	0.102222707	0.512
sum (i=1,2,3)		2.0				0.837684729	1.105911		0.394476615	0.6259113

Y-bar= 0.757461

Ef= 1088

(See Attachment A.)

153. Hinz also discloses and suggests preferred multilayer hard-soft-hard films wherein the hard layers “have a layer thickness . . . in particular of 0.2 to 0.5

¹² The flexural modulus calculation herein utilizes the same elastic beam theory calculation relied on by Patent Owner in the district court litigation to allege infringement. *See* Section IX, below.

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mm” and “[t]he soft layer can have a layer thickness . . . in particular of 1.0 to 1.3 mm.” (Hinz, 4:112-114 *see also* Hinz, 9:285-10:294 (claims 5 and 6).) Hinz further explicitly discloses that “[i]t is obvious that all intermediate values of the above-mentioned intervals are disclosed, even if this is not described in detail.” (*Id.*, 4:114-117.) Thus, Hinz further teaches that the layer thickness for the hard-soft-hard films can be from 0.2 and 0.5 mm for the hard layers and 1.0 to 1.3 mm for the soft inner layer, which results in films with overall combined thickness of 1.4 to 2.3 mm. The combined thickness of the layers taught by Hinz for a hard-soft-hard film overlap and, in my opinion, therefore satisfy and render obvious the “combined thickness of from 250 microns to 2,000 microns” limitation of claim 2, in addition to the above described embodiment of Hinz.

154. A POSA seeking to achieve the desirable and preferred flexural modulus values disclosed by Sun would have known that individual layer thickness and elastic modulus are the result-effective variables for the overall flexural modulus of a multilayer film. Accordingly, a POSA would have known that optimizing the overall flexural modulus of Hinz’s hard-soft hard films to achieve, for example, Sun’s most-preferred flexural modulus range of 345-1,172 MPa or second-most-preferred flexural modulus range of 345-1,378 MPa, could be achieved by modifying the layer thickness within Hinz’s disclosed thickness ranges and/or

selecting polymeric materials with different elastic modulus values. Accordingly, a person following Hinz's suggestion to utilize the Scheu-Dental materials (with their specific elastic modulus values) of Ground 1 would have known that the flexural modulus of the resulting hard-soft-hard films made from them could be optimized towards Sun's preferred flexural modulus values by modifying layer thickness.

155. Furthermore, since a POSA would have recognized that the elastic modulus value of 2,200 MPa for PETG-Durasoft and 1,624 MPa for Copolyester-Imprelon are higher than the more preferred ranges for flexural modulus taught by Sun (e.g., 345-1,172 MPa (most-preferred) or 345-1,378 MPa (second-most-preferred)), a POSA would have recognized that relatively thinner layers of these hard materials and a relatively thicker layer of the soft inner layer would result in hard-soft-hard films with flexural modulus values leading to Sun's preferred disclosed values. That is, a POSA following Hinz's teaching that the hard layers "have a layer thickness . . . in particular of 0.2 to 0.5 mm" and "[t]he soft layer can have a layer thickness . . . in particular of 1.0 to 1.3 mm," would have recognized that selecting hard layers with 0.2 mm thickness and a soft layer of 1.3 mm thickness best optimizes the overall flexural modulus of the hard-soft-hard film according to the teachings of Sun. Indeed, these layer thicknesses result in films with combined layer thickness of 1.7 mm and overall flexural modulus values of 1,293 MPa and

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1,088 MPa when using hard layers of PETG-Durasoft or Copolyester-Imprelon, respectively, and fall within the most-preferred and second-most-preferred values for flexural modulus taught by Sun. These obvious hard-soft-hard films also satisfy and render obvious the limitations of dependent claim 2. Of course, these are just two mere examples of how one of skill in the art would have been motivated to follow the teachings of Hinz for making hard-soft-hard dental splints, utilizing the materials from Scheu-Dental for making dental splints, to achieve Sun's preferred flexural modulus in a manner that satisfies and renders obvious claim 2 of the '263 patent.

Flexural Modulus (Ef) calculation for PETG-Durasoft(0.2 mm)-TPU-Durasoft(1.3 mm)-PETG-Durasoft (0.2 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i)	y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	2200	1.6	1	0.32	0.2	0.75	0.1125	0.008	
TPU-Durasoft	2	1.3	172	0.85	0.078182	0.086390909	0.101636	1.11E-16	1.25276E-33	0.1717655	
PETG-Durasoft	3	0.2	2200	0.1	1	0.02	0.2	0.75	0.1125	0.008	
sum (i=1,2,3)		1.7				0.426390909	0.501636		0.225	0.1877655	

Y-bar= 0.85

Ef= 1293

Flexural Modulus (Ef) calculation for Copolyester-Imprelon(0.2 mm)-TPU-Durasoft(1.3 mm)-Copolyester-Imprelon(0.2 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i)	y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	1624	1.6	1	0.32	0.2	0.75	0.1125	0.008	
TPU-Durasoft	2	1.3	172	0.85	0.105911	0.11703202	0.137685	1.11E-16	1.6971E-33	0.2326872	
PETG-Durasoft	3	0.2	1624	0.1	1	0.02	0.2	0.75	0.1125	0.008	
sum (i=1,2,3)		1.7				0.45703202	0.537685		0.225	0.2486872	

Y-bar= 0.85

Ef= 975

(See Attachment A.)

156. Accordingly, claim 2 is obvious under Ground 2.

3. Dependent Claim 3

157. Claim 3 recites: "The polymeric sheet composition of claim 2, wherein the outer layers A and C comprise one or more of a polyester, a co-polyester"

Hinz discloses “a hard layer made of a polyester plastic, preferably made of . . . polyethylene terephthalate (PET).” (Hinz, 3:80-93.) As set forth above regarding claim 2 and in claim element 1[a] of Ground 1, the claimed “outer layers A and C” of Ground 2 are either PETG-Durasoft or Copolyester-Imprelon. PETG-Durasoft is identified as “polyethylene terephthalate glycol copolyester” and Copolyester-Imprelon is a copolyester, both which satisfy claim 3. (Ex.1121; Ex.1123.)

4. Dependent Claim 4

158. Claim 4 recites: “The polymeric sheet composition of claim 2, wherein the inner layer B comprises one or more of a polyurethane elastomer” Hinz teaches “a soft layer made of a thermoplastic polyurethane (TPU)[,]” (Hinz, 3:89-90), and TPU-Durasoft, as described above in claim element 1[a] of Ground 1 and claim 2 of this Ground, is a thermoplastic polyurethane that a POSA would have recognize it as being a “polyurethane elastomer.”

D. Ground 3: Obviousness of Claims 7 and 31 Based on Ground 2 further in view of Handbook of Thermoplastics

159. Ground 3 relies on Ground 2 further in view of Kannan.

1. Dependent Claim 7

160. Claim 7 recites: “[t]he polymeric sheet composition of claim 2, wherein one or more of the A and C layers comprises a co-polyester having: (a) a dicarboxylic acid component and (b) a diol component, wherein the co-polyester exhibits a glass

transition temperature (T_g) from 80° C to 150° C.”

161. The PETG-Durasoft outer layers A and C under Ground 2 are a “polyethylene terephthalate glycol copolyester.” (Ex.1121.) A POSA would have known that this PETG copolyester, as described in Kannan, is synthesized from monomers of terephthalic acid (TPA), which is a dicarboxylic acid component, and the diols cyclohexanedimethanol (CHDM) and ethylene glycol (EG). (Kannan, 333; *see also* Ex.1131, 538 (Table 20.1), 527.) A POSA would have known from the express disclosure of Kannan that PETG has a glass transition temperature of 81° C. (Kannan, 334 (Table 9.7); Ex.1132 (Wiley Encyclopedia – Sheet, PETG), 1096.) Thus, the obvious use of hard outer layers made of PETG-Durasoft within the hard-soft-hard films taught by Hinz satisfies and renders obvious claim 7.

2. Claim 31

162. Independent claim 31 is substantively identical to the combined limitations of challenged claim 7, which is dependent on claims 2 and 1. Accordingly, for the same reasons discussed for claims 1, 2, and 7 above, Ground 3 also renders claim 31 obvious.

E. Ground 4: Obviousness of Claim 11 Based on Li, Boronkay, and Chen

163. The combination of Li, Boronkay, and Chen discloses, teaches, suggests, and renders obvious at least a five-layer polymeric sheet with a hard-soft-

hard-soft-hard layering configuration that satisfies all elements of claim 11.

1. Motivation to Combine

164. Li, Boronkay, and Chen are in the same field—multilayered polymeric dental aligners. (*See, e.g.*, Li, 1:6-8; Boronkay, [0064], [00107], [00119]; Chen, 3:45-52, 5:15-35.) They are each assigned to the same entity—Align Technologies—and each expressly refers to and/or incorporates by reference Align’s technological developments relating to dental aligners. (*See e.g.*, Li, 1:18-28, 4:8-15; Boronkay, [0088]; Chen. 2:60-3:3.) Li, Boronkay, and Chen also include overlapping co-inventors (Yan Chen (Li, Boronkay and Chen) and Chunhua Li (Li and Chen)). (*Id.*) They each disclose the use of the combination of hard polymer layers and soft polymer layers within multilayer aligners. (*E.g.*, Li 5:12-6:59, Boronkay [0098]-[0099], [00108], [00176]-[00177], Chen, 4:31-42, 5:51-53) Considering this substantial overlap, in my opinion, a POSA would have understood that Li, Boronkay, and Chen disclose interrelated teachings related to the creation of dental aligners that reasonably would have been combined in predictable ways as of at least the earliest possible effective filing date of the ’263 patent.

165. A POSA would have understood that Li, Boronkay, and Chen disclosed and suggested various improvements for a multilayer polymeric dental aligner. For instance, Chen discloses a dental aligner that may include a plurality of polymeric

layers with layers consisting of similar and/or different materials. (Chen, 3:45-49, 5:63-64 (“The cross section view of the dental appliance **148** shows several layers, such as inner layers **150** and outer layer **152**.”), 6:1-2 (“In various embodiments, a plurality of inner layers **150** is sandwiched between the outer layer **152**.”).) Chen further discloses multilayer aligners with soft and hard layering geometries that include two outer layers and a variable number of inner layers, and explains that “[t]he layers may be formed in various orientations and configurations to suit the modulus and application requirements.” (Chen, 5:29, 31; *see also* Chen, 5:15-35, 5:51-53 (“In various embodiments, the softer segment may consist of one or more layers and the harder segment may consist of one or more layers.”), 6:2-4 (“The inner and outer layers may have variable thickness and variable glass transition temperatures depending on the modulus requirements.”); 6:13-16 (“The layer or layers with the lower glass transition temperature may be the softer segment, as discussed herein. The layer or layers with the higher glass transition temperature may be the harder segment, as discussed herein.”).) Chen further teaches that the dental aligner “is made of a material that has a predetermined modulus” and that “[t]he modulus can be predetermined to match the compliance required to reposition the teeth.” (Chen, 3:2-31.) Chen specifically teaches that a dental aligner “may have a modulus in the range of between 0.1 GPa to 4.0 GPa, usually 0.5 GPa to 3 GPa,

and preferably about 0.8 GPa to 1.5 GPa.” (Chen, 3:31-33.) Accordingly, Chen expressly discloses that a multilayer dental aligner constructed from hard and soft polymer layers should have a preferred predetermined modulus of 800 MPa to 1,500 MPa.

166. Li discloses a multilayer sheet with a hard-soft-hard configuration that can be used in making improved multilayer dental aligners:

The multilayer sheet can include three layers in which a hard polymer layer is disposed between two soft polymer layers. The multilayer sheets used in the present invention can be used in making dental aligners having improved durability for use, e.g., to the elastic properties of the multilayer sheet when formed into an aligner.

(Li, 5:1-11; *see also* Li, 3:5-19 (“As provided by the present invention, the aligners that include multilayer sheets can, for example, provide increased durability so that they can better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment. In addition, the aligners have improved elastic properties that allow for less degradation in the shape of the teeth receiving cavities during a stage of treatment. For example, during a multistage orthodontic treatment, the force exerted by an aligner to perform defined tooth movement can degrade and may cause the treatment to include more aligners to

reach a final ideal arrangement and/or result in a mid-course correction that could be prevented by using aligners with improved physical properties, such as those provided herein”).) Li further explains additional benefits of the soft-hard-soft layering configuration, noting that “[t]he multilayer dental appliances of the present invention, among many aspects, provide, for example, improved material performance, stress relaxation properties and longer working range.” (Li, 1:62-65.) “In addition, the mechanical properties of the materials and appliances described herein can improve orthodontic treatments by, for example, reducing the need for midcourse corrections during treatment and the number of aligners used for a given treatment.” (Li, 1:65-2:3.) A POSA would therefore have been motivated to utilize Li’s disclosed soft-hard-soft multilayer sheet to achieve dental aligners with these expressly disclosed benefits. (Li, 5:1-3 (“In general, structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances.”).)

167. Li’s Figure 2 shows the beneficial hard-soft-hard multilayer sheet “according to the present invention,” wherein the multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 (yellow, below) disposed between two soft polymer layers 22, 26 (blue, below):

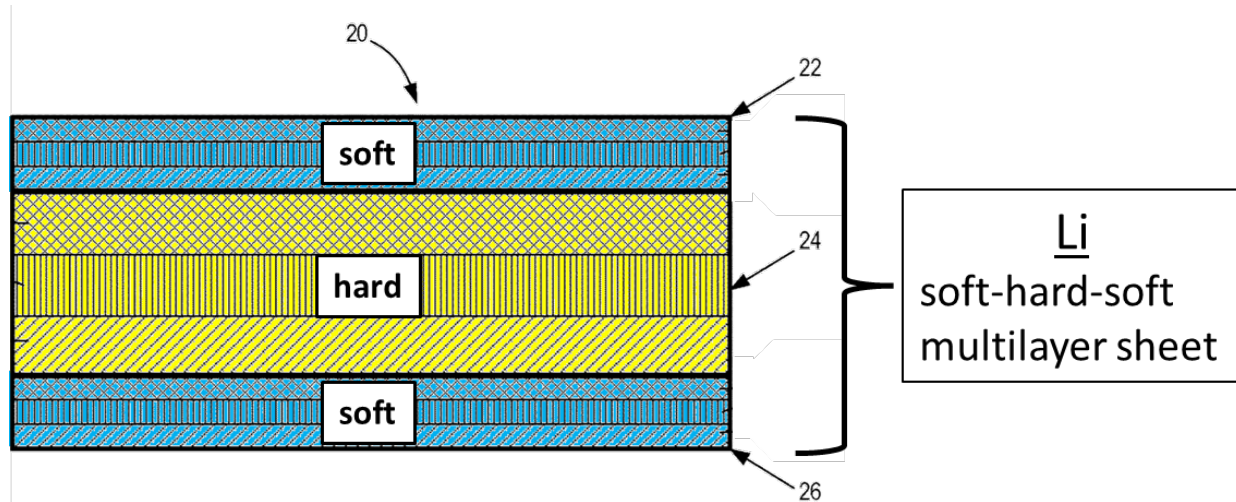


FIG. 2

(Li, 5:12-17, Fig 2 (annotated).)

168. Li further discloses “a method of making a dental appliance for positioning a patient's teeth”—i.e., an “aligner”—that includes “providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer, providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model,” (Li, 3:39-47), which is illustrated in Figures 3 and 4:

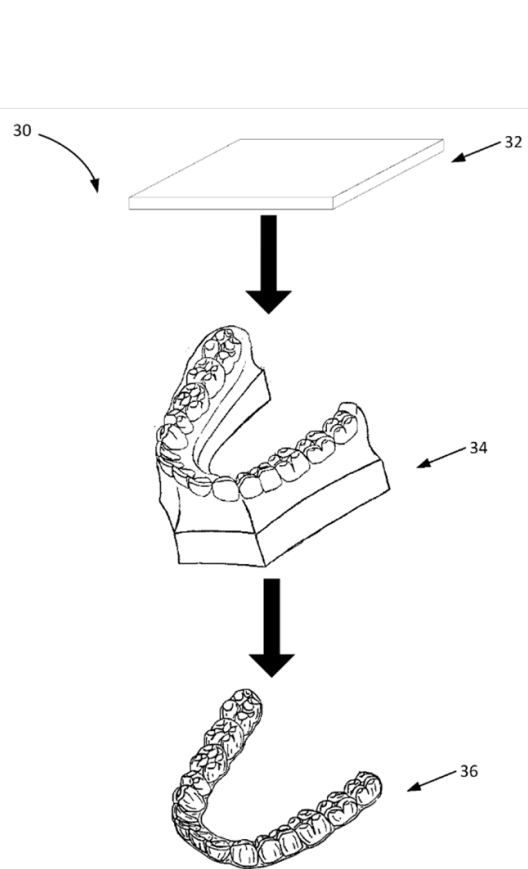


FIG. 3

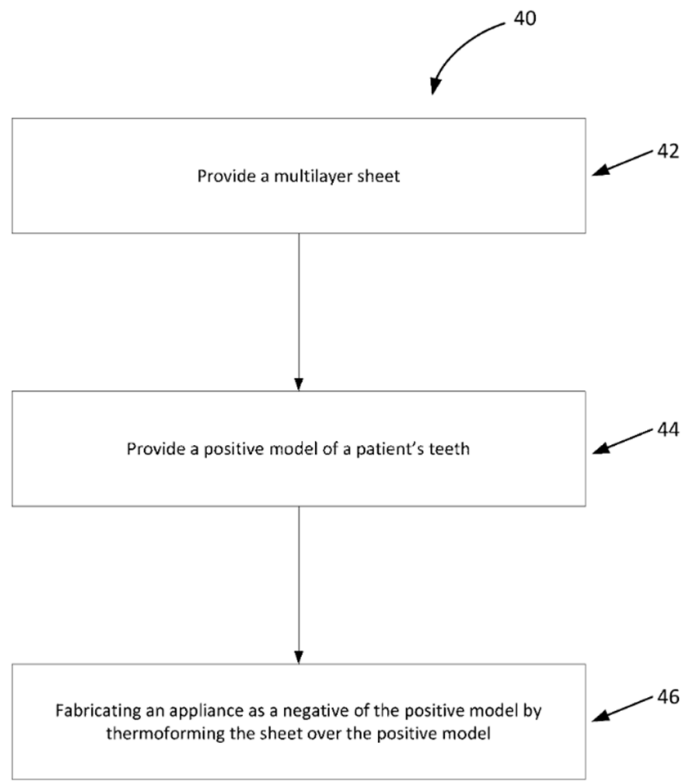


FIG. 4

(Li, 7:4-20, 7:36-50, Figs. 3-4.)

169. A POSA would have recognized from the interrelated teachings of Li and Chen that Li's soft-hard-soft multilayer sheet is a configuration with beneficial features for dental aligners (e.g., improved durability, mechanical properties, and material performance) and, according to Chen, that Li's soft-hard-soft sheet should be formed to "suit the modulus and application requirements" for a dental aligner. (Chen, 5:29-31.) Chen teaches a dental aligner "is made of a material that has a predetermined modulus" and that "the modulus can be predetermined to match the

compliance required to reposition the teeth,” with a preferred modulus of “about 0.8 GPa to 1.5 GPa.” (Chen, 3:22-33.) A POSA would therefore have followed Chen’s express teaching of the preferred predetermined modulus for a dental aligner, and would have been motivated to construct Li’s soft-hard-soft multilayer sheets such that they had a predetermined preferred modulus of about 800 MPa to 1,500 MPa for repositioning a patient’s teeth, which is the application of a dental aligner. (Chen, 1:10-11 (“An alternative to braces includes the use of aligner-type dental appliances for realigning teeth”); Li, 1:40-41 (“each aligner exerts force on the teeth and elastically repositions the teeth”), 1:48-50 (“aligners that can, for example, produce more continuous force and better bring a patient's teeth into a desired occlusion”).)

170. Boronkay expressly teaches further improvement of the properties of a multilayer dental aligner by utilizing stiff/hard “innermost” and “outermost” layers that serve “to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like.” (Boronkay, [00144] (“Alternatively or in combination, the outermost layer can have a greater stiffness and/or hardness than the outer shell, e.g., in order to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like.”), [00145] (“For example, the appliance can include an innermost layer coupled to an inner surface of the inner structure, and the

innermost layer can be stiffer and/or harder than the inner structure, e.g., to protect the inner structure from abrasion, wear, staining, biological interactions, and the like.”); *see also* Boronkay, [00135] (“In some embodiments, a stain resistant protective layer may be formed on a surface of the aligner.”)

171. In my opinion, given the teachings of Li, a POSA also would have recognized that Boronkay’s suggested hard protective or stain-resistant coating layers would further enhance the properties of the soft-hard-soft multilayer aligners taught and disclosed by Li. Li notes that “aligners that include multilayer sheets can, for example, provide increased durability of the aligners so that they can better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment.” (Li, 3:5-10.) A POSA would have understood that the addition of Boronkay’s hard protective coating layers on the outside of a soft-hard-soft multilayer aligner would enhance and bolster the appliance’s durability and wear resistance while adding the additional benefit of improved stain resistance because Boronkay expressly teaches that such additional layers further serve “to protect the appliance, against abrasion, wear, staining, biological interactions (e.g., reduce plaque or biological growth), and the like.” (Boronkay, [00144]-[00145]; *see also* Boronkay, [00135].)

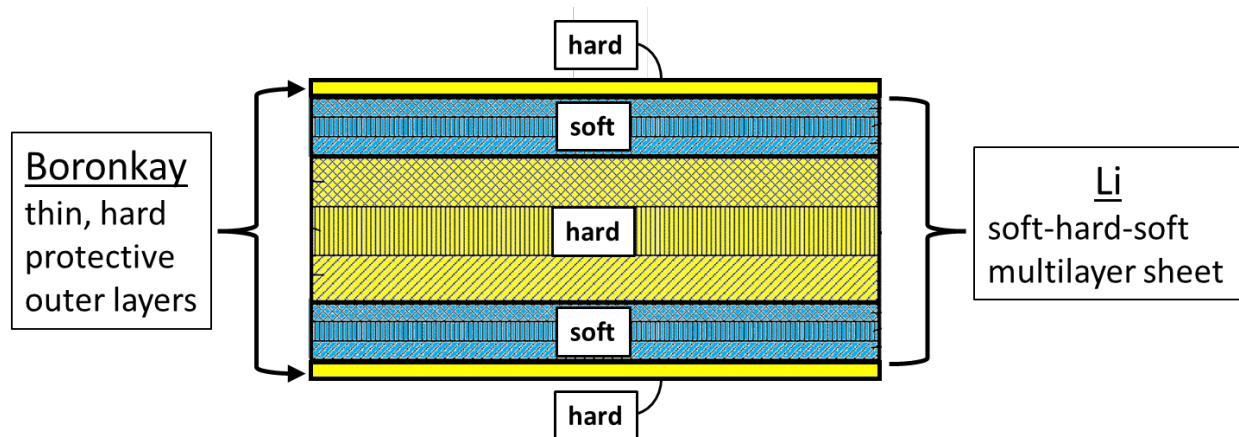
172. A POSA would not have been dissuaded from applying Boronkay’s

teaching of relatively thin hard protective layers on the outer sides of the multilayer aligners of Li. To the contrary, a POSA would have expected that the benefits of Boronkay's thin and hard protective layers would provide Li's multilayer aligners with enhanced resistance to abrasion, wear, staining, and biological interactions without negating or substantially contributing to the "overall properties" of the multilayer aligner appliance taught by Li. For instance, a POSA would understand that the "improved elastic properties" of Li's multilayer aligners would remain even with the addition of Boronkay's thin, hard protective layers since such an appliance would maintain Li's soft polymeric layers that provide elasticity to the appliance. Plus, Boronkay also teaches that "multiple protective layers may be used. For example, a stain resistant protective layer may be formed over a wear resistant protective layer," (Boronkay, [00138]), and a POSA would therefore have understood that the protective layers can provide additional beneficial features to an aligner beyond wear resistance, such as stain resistance, without detracting from the orthodontic efficacy of the appliance.

173. Boronkay further expressly teaches that the protective or stain resistant layers "can be formed as a material layer or a coating" and that they should be "thinner" than the other layers "in order to reduce the contributions of the outermost/innermost layer to the overall properties of the appliance." (Boronkay,

[00134], [00144], [00145].) A POSA would understand from Boronkay's express disclosures that the protective, stain-resistant layers on the outside of a device should be relatively thin, so as to provide the stated benefits while only minimally changing the "overall properties of the appliance."

174. Based on the foregoing, a POSA would have been motivated from the express teaching of Boronkay to add thin, hard protective coating layers to the outer sides of Li's soft-hard-soft multilayer sheets for making a thermoformed aligner such that the aligner would have the added beneficial properties gained by having such hard protective layers (outer yellow layers, below), resulting in the following overall hard-soft-hard-soft-hard configuration:



175. As described above, a POSA would have been motivated to ensure that the obvious hard-soft-hard-soft-hard multilayer sheet according to the combined teachings of Li and Boronkay would have a modulus that satisfied Chen's preferred

range of about 800-1,500 MPa for a dental aligner.

2. Reasonable Expectation of Success

176. A person of ordinary skill in the art would have known how to (and therefore would have had a reasonable expectation of success to) make the hard-soft-hard-soft-hard multilayer polymeric sheet according to the combined disclosures and teachings of Li, Boronkay, and Chen.

177. I have been informed that because Li is a patent, Li's disclosures are presumptively enabled under the law. Although I do not believe this presumption is necessary, that presumption is correct here since a POSA would have understood how to make the expressly disclosed multilayer sheets with hard and soft layers disclosed by Li. In that regard, Li expressly discloses a soft-hard-soft multilayer sheet, such as in reference to Figures 2 and 3, with a three-layer structure. (Li, 5:13-18; 7:8-10 ("The multilayer sheet **32**, as depicted, can include three layers: a hard polymer layer disposed between two soft polymer layers.").) A POSA would also have understood that Li and Boronkay expressly disclose the same polymers suitable for hard and soft layers in a multilayer sheet, such that selecting adequate materials for each layer would be routine. For instance, both Li and Boronkay identify the exact same polymers for use in the hard polymer layers of a multilayer aligner, including "a polyester, a co-polyester, a polycarbonate, a thermoplastic

polyurethane,” among others. (*Compare* Li, 5:34-46 (“[s]uitable polymeric materials for the hard polymer layer can include a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane”) with Boronkay, [00176] (“relatively rigid portions of the orthodontic appliance can be formed . . . using one or more of the following materials: a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane”).) Li and Boronkay also identify the exact same polymers for use as soft polymer layers. (*Compare* Li, 6:1-9 with Boronkay, [00177].) A POSA would therefore have reasonably expected to be able to successfully form a five layer hard-soft-hard-soft-hard multilayer sheet because Li already indicates that the hard and soft polymeric materials of Li (which are identical to those disclosed in Boronkay) can be formed into multilayer sheets, thereby indicating that the soft and hard layer polymers are suitable for creating multilayered sheets.

178. A POSA also would have recognized that Boronkay expressly teaches that “[t]he protective layer can be formed as a material layer or as a coating deposited on the compliant inner structure,” further confirming a reasonable expectation of success. (Boronkay, [00134].) Accordingly, POSA would have known that adding Boronkay’s suggested thin, hard outer layers to Li’s soft-hard-soft multilayer structure could be achieved using routine methods well known in the art such as, for

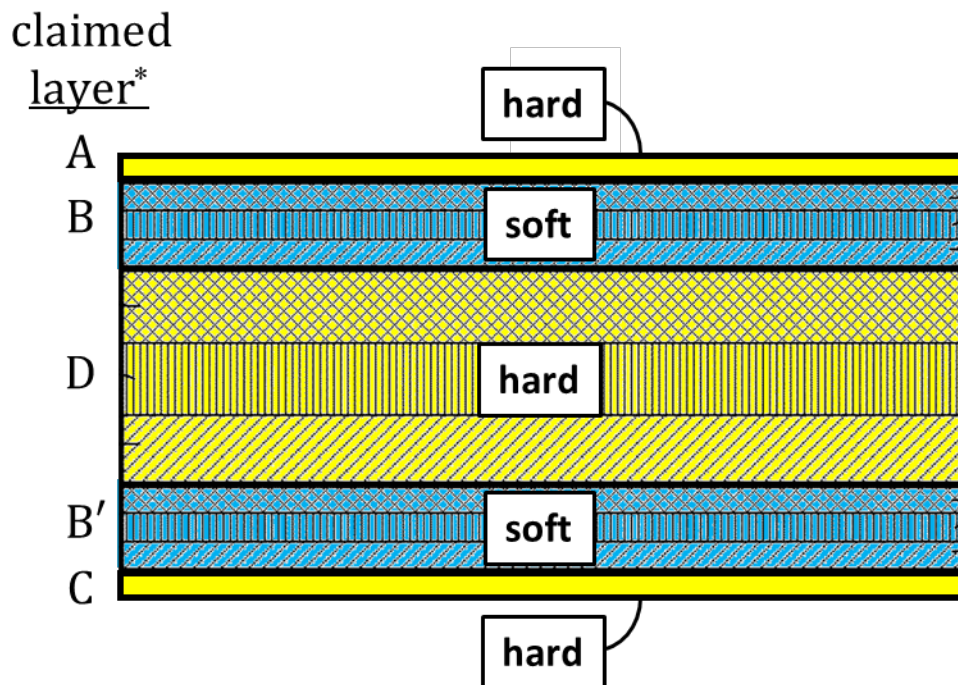
example, co-extrusion, calendaring, or lamination processes using the same methods used by Li or other standard methods known in the art to create multilayer polymer sheets. (See also, e.g., Ex.1133 (Drobny), 64-65 (“sheet extrusion” and “co-extrusion”), 138 (“Polymer sheets and films made by the usual techniques, such as extrusion, casting, and calendaring . . .”); Ex.1134 (Pehlert), 25:23-27 (“The plastic film according to the invention can be produced by means of co-extrusion or double lamination The production of multi-layer plastic films by means of co-extrusion is known to a person skilled in the art.”).) The ’263 patent admits these are methods known to a POSA for making multilayer polymeric sheets: “Multilayer sheets may be prepared by a number of means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or *other known methods*.” (Ex.1101, 15:15-19 (emphasis added).)

179. A POSA would further have known that the modulus of a multilayer polymeric sheet, similar to the sheet’s flexural modulus, is a function of and can be calculated from the thickness and modulus of the individual layers that make up the polymeric sheet. (See Ex.1116 (Osswald Decl.), ¶38.) Accordingly, a POSA would have understood that individual layer thickness and individual layer modulus are the result-effective variables of the overall modulus of a multilayer sheet. A POSA would therefore have been able to optimize the individual layer thicknesses and

select polymeric materials with suitable modulus according to the express teachings of Li and Boronkay to achieve configurations that result in hard-soft-hard-soft-hard polymeric sheets within Chen's preferred modulus of 800-1,500 MPa.

3. Independent Claim 11

180. As explained in Section IX above, Patent Owner has accused Petitioner's five-layer product of infringing claim 11 in the district court litigation. As illustrated below, the five-layer hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay satisfies the layer stacking of claim 11 under Patent Owner's infringement positions:



* per Patent Owner's infringement allegations

This obvious hard-soft-hard-soft-hard configuration for a multilayer sheet according to the express disclosures of Li and Boronkay for layer thicknesses and material properties, designed to achieve the preferred 800-1,500 MPa modulus of Chen, satisfies all elements of claim 11.

a. Claim 11[pre]: “[a] polymeric sheet composition comprised of”

181. To the extent the preamble is limiting, it is satisfied by the obvious combination of Li and Boronkay. As noted above, Li discloses a three-layer soft-hard-soft polymeric sheet and Boronkay expressly discloses the benefits of adding thin, hard outer polymeric layers to this sheet. (*See, e.g.*, Li, 5:13-18 (“As shown, a multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 and two soft polymer layers 22, 26.”); Boronkay, [00144]-[00145].) The obvious five-layer hard-soft-hard-soft-hard polymeric sheet according to Li and Boronkay is a “polymeric sheet composition.” (*Id.*) Thus, Ground 4 satisfies 1[pre].

b. Claim 11[a]: “at least two rigid or hard outer layers A and C, at least two soft inner layers B and B’, and at least a rigid or hard inner layer, D”

182. Under Patent Owner’s interpretation, the obvious hard-soft-hard-soft-hard polymeric sheet according to the combined teachings of Li and Boronkay satisfies claim element 11[a]. Boronkay expressly discloses that the “stiffer and/or harder” protective or stain-resistant outer layers “can have a hardness greater than

or equal to about 70 Shore D or about 90 Shore D.” (Boronkay, [00144]-[00145].)

A POSA would recognize that these thin, hard outer layers suggested by Boronkay are “two rigid or hard outer layers A and C.”

183. Li discloses a multilayer sheet with “a hard polymer layer disposed between two soft polymer layers.” (Li, 7:8-10.) Li further discloses that the inner “hard polymer layer” can have a tensile and/or flexural modulus “greater than about 150,000 psi” (i.e., 1,034 MPa) and that “the soft polymer layers” can have “a hardness of about 60 A to about 85 D” and “flexural modulus of greater than about 35,000 psi” (i.e., 241 MPa). (Li, 5:50-67, 6:1-26.) A POSA would recognize that Li’s disclosed “soft polymer layers” are “two soft inner layers B and B” and Li’s “hard polymer layer” is “a rigid or hard inner layer, D” in the context of the hard-soft-hard-soft-hard sheet of this Ground.

184. Accordingly, Ground 3 satisfies claim element 11[a].

c. Claim 11[b]: “wherein the rigid or hard layers, A, C and D, individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and”

185. Li discloses that the inner “hard polymer layer,” which corresponds to rigid or hard layer D of claim 11, can have a tensile modulus “greater than about 150,000 psi” (i.e., greater than 1,034 MPa). (Li, 5:57-63.) While Li does not expressly disclose an upper limit on the modulus of the “hard polymer layer,” a

POSA would recognize that there would be an upper limit on the modulus value of Li's hard inner layer under this Ground imposed by Chen's preferred 800-1,500 MPa modulus range for the overall sheet, as I explain below.

186. In the broadest layer thicknesses expressly disclosed, Li states that the "hard polymer layer can have a thickness in a range from about 400 μm to about 1100 μm " and the "soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm ." (Li, 5:21-27.) These thickness ranges teach that the inner "hard" layer of Li's soft-hard-soft sheet is between about 67-96% of the overall sheet thickness—i.e., $400(\text{hard})/(100(\text{soft})+400(\text{hard})+100(\text{soft}))=0.67$ for the thinnest disclosed hard layer (400 μm) with the thickest disclosed soft layers (100 μm) or $1100(\text{hard})/(25(\text{soft})+1100(\text{hard})+25(\text{soft}))=0.96$ for the thickest disclosed hard layer (1100 μm) and thinnest disclosed soft layers (25 μm). Accordingly, since Li teaches that the majority of the thickness of the overall sheet is in the "hard" middle layer, a POSA would understand the modulus of this "hard" middle layer would be the dominant contributor to the sheet's overall modulus and that it would contribute at least 67% (and up to 96%) of its individual modulus to the overall modulus of Li's soft-hard-soft sheet. Thus, a POSA would have recognized that to obtain an overall sheet modulus that does not exceed 1,500 MPa—i.e., above Chen's preferred modulus range of 800-1500 MPa—the maximum modulus of the inner hard layer

for *any* combination of Li's layer thicknesses within a hard-soft-hard-soft-hard multilayer sheet with Boronkay's thin hard outer layers would necessarily have to be less than a maximum value of about 2,250 MPa (i.e., $2,250 \text{ MPa} \times 0.67$ (fraction of thickness attributable to hard layer) = 1,500 MPa).

187. Thus, according to the express teachings of Chen's preferred overall sheet modulus together with Li's minimum "hard" layer modulus of 1,034 MPa, a POSA would have understood that the obvious combination under this Ground requires Li's inner "hard polymer layer" would have to have a modulus of between 1,034-2,250 MPa when following Li's express teachings. This range falls entirely within and therefore satisfies the claimed "modulus of from about 1,000 MPa to 2,500 MPa" for rigid or hard layer D.

188. Boronkay discloses that the "stiffer and/or harder" protective outer layers, which correspond to hard layers A and C of claim 11 in Ground 3 herein, "can have a hardness greater than or equal to about 70 Shore D or about 90 Shore D." (Boronkay, [00144]-[00145].) The '263 patent discloses, correctly, that "Shore hardness and modulus are generally correlated and can be converted by approximation if only one value is known by methods described in the art." (Ex.1101, 6:67-7:2.) Following this teaching, Shore hardness 70D and 90D correspond to converted modulus values of approximately 243 MPa and 2,812 MPa,

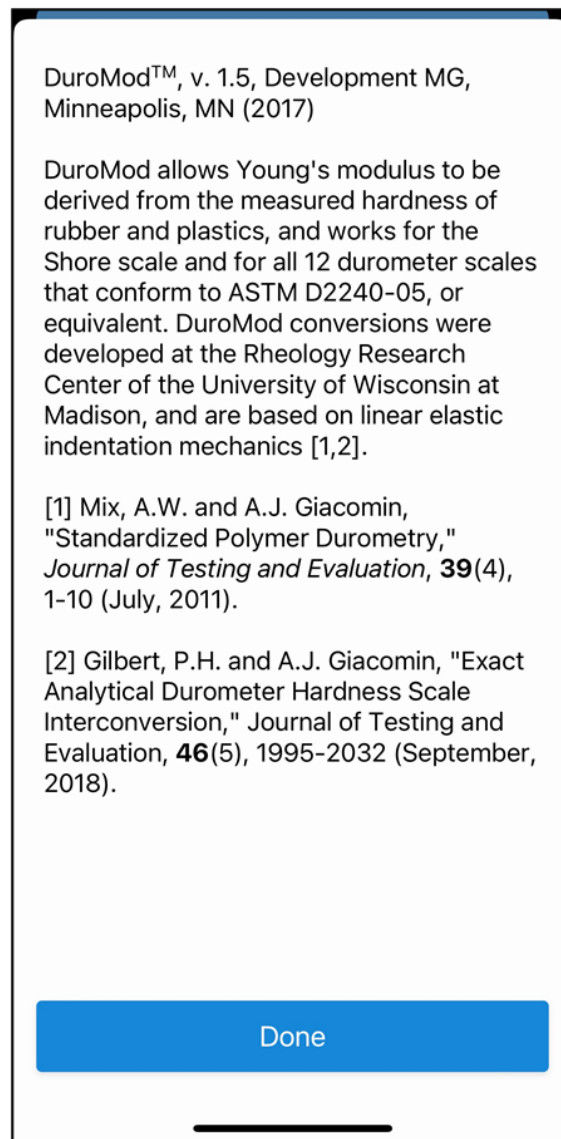
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respectively (as shown by my method from the prior art that can be calculated using
the DuroMod app that I helped to create):

The screenshot shows the DuroMod app interface. At the top is a blue header with the text "DuroMod™" and a link "about". Below the header is a white box with the title "CONVERSION TO YOUNG'S MODULUS". Inside this box, there are two input fields: "Reading" with the value "70" and "Scale" with a dropdown menu showing "D". Below these fields, the result "243.0 MPa" is displayed in large blue text.

The screenshot shows the DuroMod app interface. At the top is a blue header with the text "DuroMod™" and a link "about". Below the header is a white box with the title "CONVERSION TO YOUNG'S MODULUS". Inside this box, there are two input fields: "Reading" with the value "90" and "Scale" with a dropdown menu showing "D". Below these fields, the result "2812 MPa" is displayed in large blue text.

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(See Ex.1136 (Mix & Giacomini); see also Ex.1137 (Qi).)

189. Accordingly, a POSA would recognize that Boronkay's general teaching of thin, hard outer protective layers with a hardness greater than or equal to about 70D or 90D is referring to a polymer with modulus in the range of approximately 243 MPa to 2,812 MPa, which overlaps the claimed "modulus of

from about 1,000 MPa to 2,500 MPa” for rigid or hard layers A and C.

190. Additionally, Boronkay also teaches that the hard outer protective layers “can have a greater stiffness and/or hardness than the outer shell,” wherein the “outer shell” refers to a “stiff” layer “that generates the force and/or torque” on the teeth by the aligner. (See Boronkay, [00144]-[00145], [0008] (“the appliance comprises a stiff outer shell that generates the force and/or torque”).) A POSA would have recognized that this express teaching, under the hard-soft-hard-soft-hard sheet taught by the combination of Li and Boronkay, suggests that Boronkay’s hard protective outer layers should have “greater stiffness and/or hardness” than Li’s “hard” inner layer that generates the force to reposition the teeth.

191. Boronkay therefore teaches a POSA that the hard outer protective layers, when applied to the exterior of Li’s hard-soft-hard multilayer sheet, should have a stiffness and/or hardness at least greater than Li’s minimum of 1,034 MPa for the “inner” hard layer (such that the hard outer protective layers are stiffer/harder than Li’s inner hard layer). Accordingly, Boronkay’s further teaching in combination with Li would have led a POSA to a modulus for the hard outer protective layers of a polymer with at least greater than 1,034 MPa, which falls within and teaches an overall range (up to the 2,812 MPa value of a material with hardness of 90D described above) that closely overlaps with and, in my opinion,

renders obvious rigid or hard layers A and C having “a modulus of from about 1,000 MPa to 2,500 MPa.”

192. Additionally, both Li and Boronkay disclose the same materials for use as the rigid or hard layers, including a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane. (Li, 5:34-46; Boronkay, [00176].) Both Li and Boronkay disclose that their dental appliances can be made by thermoforming. (Li, 6:60-64, Figs. 3-4; Boronkay, [00146], [00159].) A POSA would understand that the rigid or hard layers of the combination of Li and Boronkay to achieve Chen’s preferred modulus under Ground 3 would be thermoplastic polymers to be suitable for thermoforming. Ground 3 therefore satisfies the “hard layers, A, C and D, individually comprise a thermoplastic polymer.”

193. Thus, Ground 3 satisfies claim element 11[b].

d. Claim 11[c]: “the soft inner layers B and B’ individually comprise an elastomeric material having a hardness from about A 60 to D 85”

194. Li discloses that “the soft polymer layers” can have “a hardness of about 60 A to about 85 D,” exactly as claimed. (Li, 6:18-21.) A POSA would recognize that Li’s disclosed “soft polymer layers” are “two soft inner layers B and B’” in the five-layer hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay in view of the preferred modulus of Chen. Thus,

Ground 3 satisfies claim element 11[c].

195. Claim 11 is obvious under Ground 4.

F. Ground 5: Obviousness of Claims 12-14, 16, and 18 Based on Ground 4 further in view of Stewart

196. Ground 5 relies on the same hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay of Ground 4. Whereas Ground 4 focuses solely on optimizing the “modulus” according to Chen’s preferred 800-1,500 MPa range, Ground 5 adds Stewart’s preferred “flexural modulus” range of 1,000-3,000 MPa as a second property of the multilayer sheet to be optimized (along with Chen’s preferred “modulus”).

1. Motivation to Combine and Reasonable Expectation of Success

197. Stewart is in the same field as Li, Boronkay, and Chen—i.e., multilayer polymeric sheets for creating dental aligners. (*See* Stewart, 1:12-13 (“In orthodontic procedures, the objective is to change the relative positions of two or more teeth.”); 3:15-18 (“this invention provides a sheet of polymeric composition for use in . . . thermoforming the sheet around a physical model of the teeth”); 13:19-20 (“[t]he sheet is a laminate having two or more layers of different polymeric compositions”).) Stewart expressly discloses and incorporates by reference the same Align Technology patents as those cited and/or incorporated by reference in Li, Boronkay,

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and Chen. (*Compare* Stewart, 1:18-20 (“Reference may be made for example to US 5,975,893(Chishti) and US7,220,122(Chishti), the entire disclosure of each of which is incorporated herein by reference”) *with* Li, 1:18-28, 4:8-15; Boronkay, [0088]; Chen. 2:60-3:3.) In my opinion, a POSA would therefore have been motivated to look to the interrelated teachings of Stewart for use within the combination of Li, Boronkay, and Chen, for additional desirable design considerations for a dental aligner, including specifically for the flexural modulus of a dental aligner.

198. Stewart discloses that for an “orthodontic appliance [i.e., a dental aligner], *it is desirable to use* a polymeric sheet which, before being thermoformed, is 0.5 to 0.8 mm thick and for the polymeric composition to have a *flexural modulus* between 1000-3000 MPa.” (Stewart, 20:21-24.) A POSA would therefore have been motivated to design a multilayer sheet for use in creating a dental aligner that satisfied Stewart’s expressly disclosed “desirable” flexural modulus of between 1000-3000 MPa. A POSA would have recognized that Stewart’s desirable thickness for a dental aligner of 0.5 to 0.8 mm falls within the range of thicknesses generally taught by Li. (*See*, Li 5:27-31 (“Multilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 500 μm to about 1200 μm . . .”).)

199. Li teaches that both the hard polymer layer and the soft polymer layers

of an appliance can have a variety of physical properties that can “improve treatment options.” (Li, 5:50-52, 6:13-14.) Li further explains that the physical properties of the materials such as tensile modulus (i.e., “modulus”) and flexural modulus, among others, “can each be specifically tailored for a particular application.” (Li, 5:52-56, 6:14-18.) While suggested in the context of the individual layers of a multilayer sheet, a POSA would have understood that Li’s teaching would equally apply to the overall multilayer sheet—i.e., tailoring both the modulus and the flexural modulus of the multilayer sheet could improve treatments options for dental aligners. Thus, in my opinion, a POSA would also have been motivated to design the hard-soft-hard-soft-hard multilayer sheets taught by Li and Boronkay for use in dental aligners such that those sheets simultaneously satisfied both Chen’s “preferabl[e]” modulus of 800-1,500 MPa and Stewart’s “desired” flexural modulus range of 1000-3000 MPa.

200. As noted in Ground 4, a POSA would have reasonably expected to be able to successfully design a hard-soft-hard-soft-hard multilayer sheet according to the teachings of Li and Boronkay to achieve Chen’s preferred 800-1,500 MPa modulus. A POSA would further have has no problem (and therefore would have reasonably expected success) in designing such a multilayer sheet that also achieved Stewart’s desired flexural modulus range of 1000-3000 MPa.

201. First, a POSA would have recognized that there is substantial overlap in between Chen's preferred modulus range and Stewart's flexural modulus range. In the district court litigation, Patent Owner's expert, Dr. Osswald, stated that the "[f]lexural modulus is fundamentally equivalent to the elastic modulus of a material, but the two properties can, and often do, hold slightly different values when it comes to polymeric materials." (Ex.1116 (Osswald Decl.), ¶30.) Patent Owner's expert referred to the foregoing statement in the context of his analysis of Petitioner's accused multilayer product, stating: "as I explained in section V.B, *the flexural modulus would be expected to be similar to the elastic modulus* and the two can be related using specific equations." (*Id.*, ¶109 ("the *elastic modulus of the composite sheet is calculated to be $E = 1247 \text{ MPa}$, which is similar to the calculated flexural modulus* and").) A POSA therefore would have expected a multilayer sheet could be designed such that the modulus and flexural modulus properties of are "similar" enough to have a reasonable expectation of success in achieving both Chen's preferred modulus and Stewart's desirable flexural modulus values.

202. Second, individual layer thickness and elastic modulus of each individual layer are the result-effective variables for both the overall modulus and overall flexural modulus of a multilayer film. Both the modulus and flexural modulus of a multilayer sheet can be calculated by different equations based on the

thickness and modulus of each individual layer. (See Ex.1116 (Osswald Decl.), ¶38.) Accordingly, it would have been a matter of routine selection from within the express teachings of Li and Boronkay of appropriate individual layer thicknesses and materials with appropriate modulus properties for a POSA to design a hard-soft-hard-soft-hard multilayer sheet with both Chen’s preferred modulus (800-1,500 MPa) and Stewart’s desirable flexural modulus (1000-3000).

2. Dependent Claim 12

203. Claim 12 recites: “The polymeric sheet composition of claim 11, wherein the polymeric sheet composition has a combined thickness of from 250 microns to 2,000 microns and a flexural modulus of from 500 MPa to 1,500 MPa.” These limitations are satisfied by hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay.

a. “a combined thickness of from 250 microns to 2,000 microns”

204. Li discloses that the “[m]ultilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 500 μm to about 1200 μm ” (Li, 5:27-31.) Adding the thin hard protective outer layers taught by Boronkay to the outer sides of the multilayer sheets of Li to create a hard-soft-hard-soft-hard sheet would still fall well within claim 12’s thickness range. Boronkay emphasizes that the outer protective

layers should be thinner than the other layers of the appliance to reduce or minimize their contributions to the overall properties of the appliance. (Boronkay, [00144]-[00145].) Li teaches that “the soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm .” (Li, 5:24-26.) Thus, a POSA following Boronkay’s teaching would recognize that the thin hard protective layers would at least have to be less than 25-100 μm such that the hard-soft-hard-soft-hard multilayer sheet taught by the combination of Li and Boronkay would always satisfy the claimed 250-2,000 μm range.

b. “a flexural modulus of from 500 MPa to 1,500 MPa”

205. Stewart discloses a “desirable” flexural modulus range for a polymeric sheet of 1000-3000 MPa, which overlaps with and, in my opinion, satisfies the claimed range.

206. Furthermore, a POSA would have been motivated to optimize the material properties of a multilayer sheet to satisfy both Chen’s preferred modulus of 800-1500 MPa *and* Stewart’s desirable flexural modulus of 1000-3000 MPa. As noted above in claim element 11[b], the combination of Li and Boronkay teaches a hard-soft-hard-soft-hard multilayer sheet configured with a predominantly thick hard middle layer, relatively thin inner soft layers, and even thinner protective hard outer layers. A POSA would have understood that the hard-soft-hard-soft-hard

multilayer sheet taught by Li and Boronkay has a configuration wherein the flexural modulus would be generally similar to the elastic modulus because it predominantly consists of a hard middle layer. (See Ex.1116 (Osswald Decl.) ¶109 (“the flexural modulus would be expected to be similar to the elastic modulus”).) A POSA would have recognized that optimizing the obvious hard-soft-hard-soft-hard sheet according to Li and Boronkay to attain both Chen’s preferred modulus and Stewart’s desirable flexural modulus would essentially occur within or close to their similar overlapping values—i.e., from about 1,000-1500 MPa. Consequently, a POSA would have been motivated towards the lower end of Stewart’s stated desirable flexural modulus because the hard-soft-hard-soft-hard multilayer sheets of Li and Boronkay would not be able to satisfy both Chen’s preferred modulus range *and* Stewart’s desirable modulus range when the flexural modulus of a multilayer sheet is substantially greater than their overlapping values. A POSA would therefore understand that the effective operative range of Stewart’s flexural modulus under this Ground is essentially 1000-1,500 MPa, which closely overlaps with and satisfies the recited “flexural modulus of from 500 MPa to 1,500 MPa” of claim 12.

207. The following exemplary multilayer sheets demonstrate the similar values for modulus and flexural modulus, as well as the ability of a POSA to readily optimize the modulus and flexural modulus properties of a hard-soft-hard-soft-hard

multilayer sheet according to the teachings of Li and Boronkay to achieve both the preferred modulus range of Chen (800-1,500 MPa (“ E ”)) and the desirable flexural modulus range of Stewart (1000-3000 MPa (“ E_f ”)) based on the result-effective variables of individual layer thickness and layer elastic modulus:

Example 1

claimed layer*	A	$h_1 = 25 \mu$	$E_1 = 1,550 \text{ MPa}$
	B	$h_2 = 100 \mu$	$E_2 = 241 \text{ MPa}$
	D	$h_3 = 1,100 \mu$	$E_3 = 1,500 \text{ MPa}$
	B'	$h_4 = 100 \mu$	$E_4 = 241 \text{ MPa}$
	C	$h_5 = 25 \mu$	$E_5 = 1,550 \text{ MPa}$

$E = 1,315 \text{ MPa}$
 $E_f = 1,062 \text{ MPa}$

Example 2

claimed
layer*

A		$h_1 = 25 \mu$	$E_1 = 1,550 \text{ MPa}$
B		$h_2 = 50 \mu$	$E_2 = 241 \text{ MPa}$
D		$h_3 = 400 \mu$	$E_3 = 1,500 \text{ MPa}$
B'		$h_4 = 50 \mu$	$E_4 = 241 \text{ MPa}$
C		$h_5 = 25 \mu$	$E_5 = 1,550 \text{ MPa}$

$$E = 1,276 \text{ MPa}$$

$$E_f = 1,051 \text{ MPa}$$

Example 3

claimed
layer*

A	$h_1 = 25 \mu$	$E_1 = 1,550 \text{ MPa}$
B	$h_2 = 75 \mu$	$E_2 = 241 \text{ MPa}$
D	$h_3 = 750 \mu$	$E_3 = 1,500 \text{ MPa}$
B'	$h_4 = 75 \mu$	$E_4 = 241 \text{ MPa}$
C	$h_5 = 25 \mu$	$E_5 = 1,550 \text{ MPa}$

$$E = 1,304 \text{ MPa}$$

$$E_f = 1,056 \text{ MPa}$$

(See Attachments B-1, B-2, and B-3.) Of course, the foregoing are mere examples. Because a POSA would have known that the individual layer thickness and elastic modulus values are the result-effective variables, a POSA would be able to follow the teachings of Li and Boronkay to construct countless different multilayer sheets through judicious selection of layer thickness and elastic modulus from the teachings of Li and Boronkay to achieve Chen's preferred modulus *and* Stewart's preferred flexural modulus. Essentially any of these sheet constructions would, in my opinion,

render claim 12 obvious.

208. Accordingly, claim 12 is obvious under Ground 5.

3. Dependent Claim 13

209. Claim 13 recites: “The polymeric sheet composition of claim 12, wherein the rigid or hard layers, A, C and D individually comprise one or more of a polyester, a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane,” and various other polymers. Both Li and Boronkay identify these exact same polymeric materials for use in “hard” or “rigid” layers of a multilayer appliance. Li discloses that “[s]uitable polymeric materials for the hard polymer layer can include a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, . . .” and Boronkay discloses that “relatively rigid portions of the orthodontic appliance can be formed . . . using one or more of the following materials: a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, . . .” (Li, 5:34-46; Boronkay, [00176].) Thus, claim 13 is obvious under Ground 3.

4. Dependent Claim 14

210. Claim 14 recites: “The polymeric sheet composition of claim 12, wherein the soft inner layers B and B' individually comprise one or more of a polyurethane elastomer, . . .” and various other polymers. Both Li and Boronkay

expressly disclose the use of polyurethane elastomer as a suitable for the “soft” polymer layers of a multilayer sheet, as well as many of the other recited polymers of claim 14. (Li, 6:1-12, 8:12-14 (“In some examples, the hard polymer layer was disposed between thermoplastic polyurethane elastomer soft polymer layers.”), claim 1; Boronkay, [00177].) Thus, claim 14 is obvious under Ground 3.

5. Dependent Claim 16

211. Claim 16 recites: “The polymeric sheet composition of claim 14, wherein the rigid or hard layers, A, C and D have a combined thickness of from 100 microns to about 750 microns.” As noted with respect to claim element 1[a] above, Li’s “hard polymer layer” corresponds to rigid or hard inner layer D and the claimed rigid or hard layers A and C are satisfied by Boronkay’s teaching of thin, hard outer protective layers on the outside of a multilayer appliance.

212. Li discloses that “the hard polymer layer can have a thickness in a range from about 400 μm to about 1100 μm . . . or about 550 μm to about 750 μm ” and further discloses examples “having a hard polymer layer with thicknesses ranging from about 580 μm to about 715 μm .”¹³ (Li, 5:21-24; 8:7-10.) In turn, Boronkay

¹³ Consistent with Li, Boronkay discloses that “the stiff portion can have a thickness of about 0.5 mm, or within a range from about 0.2 mm to about 1 mm.” (Boronkay,

emphasizes that the protective outer layers can be thinner than the other non-protective layers of the appliance “in order to reduce their contributions to the appliance’s overall properties.” (Boronkay, [00144]-[00145].) In this regard, Li teaches that “the soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm .” (Li, 5:24-26.) A POSA following Boronkay’s teaching that the hard protective layers should be thinner than the other layers of a multilayer device would recognize that such layers should be thinner than the 25-100 μm “soft layers” disclosed by Li—i.e., less than 25-100 μm in thickness—to reduce their contributions to the appliance’s overall properties.

213. Accordingly, the combined teachings of Li and Boronkay, disclose an inner hard layer D with a thickness of from about 400-1100 μm or about 550-750 μm and outer layers A and C that are thinner than 25-100 μm . The combined thickness of the rigid or hard layers, A, C and D under Ground 3 is therefore less than about 450 μm (thinnest) to less than about 1300 μm (thickest), which overlaps and thereby satisfies the claimed range of “from 100 microns to about 750 microns.” Thus, claim 16 is obvious under Ground 3.

[0096].)

6. Dependent Claim 18

214. Claim 18 recites “A dental appliance conformal to one or more teeth comprising a polymeric sheet composition according to claim 12.” I understand from the district court litigation that Patent Owner (and Dr. Osswald) has taken the position that claim 18 can be met by any pre-thermoformed polymeric sheet that satisfies all limitations of claim 12 that is then thermoformed into a dental appliance. (Ex.1135, 212:19-213:2.) While I do not agree that this is an appropriate interpretation of claim 18, since polymeric sheets thin upon thermoforming, under Patent Owner’s interpretation the claims are plainly satisfied under this Ground. As discussed above, the combination of Li and Boronkay teaches a five-layer hard-soft-hard-soft-hard polymeric sheet that renders the claimed “polymeric sheet composition” of claim 12 obvious. Li discloses that such a multilayer sheet can be made into a dental appliance by thermoforming. (*E.g.* Li, Figs. 3-4.) Thus, claim 18 is obvious under Ground 3.

VIII. SECONDARY CONSIDERATIONS

215. As explained in **Section III.B**, I understand that “secondary considerations” may be used as indicia of non-obviousness, provided that any such consideration has a *nexus* to the merits of and is commensurate in scope with the invention claimed.

216. I understand that, in the district court litigation, the Patent Owner has asserted some secondary considerations. (*See* Ex.1115, pp.11-12.) My understanding is that Patent Owner contended the existence of secondary considerations only with respect to three-layer hard-soft-hard sheets and did not assert any secondary indicia with respect to claim 11 or its dependent claims. I therefore reserve the right to respond to any secondary considerations that may later be proffered by patent owner with respect to claim 11 and to its dependent claims.

217. The Patent Owner contends that “the claimed inventions unexpectedly provide greatly improved properties . . . and have had great commercial success.” (*Id.*) Counsel has asked me to opine briefly on the Patent Owner’s arguments regarding secondary considerations. In my opinion, the Patent Owner’s assertions cannot overcome the strong case of obviousness because they were either already disclosed by Hinz (and therefore not “unexpected”) or not commensurate with the scope of the Challenged Claims.

218. Hinz discloses “a multilayer dental splint” “having two hard outer layers and having a soft inner layer embedded between the hard layers[,]” wherein the dental splints “have improved mechanical properties and are to be inserted into and removed from patients easily.” (Hinz, 2:54-3:78.) Hinz teaches that “[t]he dental splint according to the invention has increased breaking strength and better

insertion and removal behavior due to increased elasticity of the dental splint, which is caused by the internal soft layer having higher elasticity.” (*Id.*) Hinz further teaches that the hard outer layers made of polyester “are stable against discoloration and enable a crystal-clear appearance.” (*Id.*, 3:82-83.) In my opinion, a skilled artisan would have understood that any assertion by the Patent Owner that a hard-soft-hard multilayer film or dental appliance (i.e., splint) with improved properties, such as mechanical properties, tear strength, elasticity, easier insertion or removal, and stain resistance would not be “unexpected” because such improved features were already disclosed expressly by Hinz.

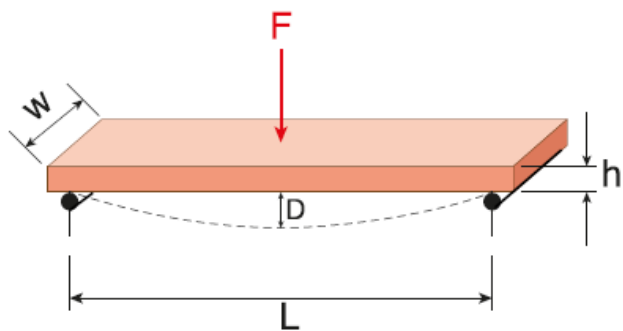
219. For example, dependent claim 9 of the ’630 patent recites “[a] dental appliance . . . comprising a polymeric sheet composition, ” and Hinz’s dental splint is a “dental appliance” that already discloses various improved properties, which the Patent Owner cannot contend are “unexpected” in the context of Zendura FLX.

220. Additionally, in my opinion, the Patent Owner’s allegations of improved properties and commercial success of its Zendura FLX product do not support non-obviousness. I understand that assertions of non-obviousness based on an embodiment of a claim must be commensurate in scope with the challenged patent claims. Here, Zendura FLX is, at best, but a single hard-soft-hard embodiment that is not commensurate with the broadly recited challenged claims that require only

“one . . . of the outer layers A and C is a polyester or co-polyester having a flexural modulus of from about 1,000 MPa to 2,500 MPa” (*see* claim element 1[b]), and therefore Zendura FLX cannot support the non-obviousness of the full scope of the Challenged Claims as there are no “unexpected results” that have been shown where only one of the outer layers A and C has a flexural modulus of from about 1,000 MPa to 2,500 MPa.

IX. DERIVATION OF OVERALL FLEXURAL MODULUS FOR A MULTILAYER SHEET

221. In the district court, the Patent Owner submitted an expert declaration from Dr. Osswald that included a “Technological Background” section in which he



describes a calculation method, employing equations used together to compute the *flexural modulus* of a multilayer polymeric sheet composition. (Ex.1010, ¶¶35-47; *id.*, ¶39 (“The flexural modulus of a multilayer polymeric sheet composition... can be computed using the thickness (h_i) and elastic modulus (E_i) of each layer i ,....”).) In this section of his declaration, Dr. Osswald explains, and I agree, that the flexural modulus of a multilayer polymeric sheet composition (in the direction perpendicular to the layers of the sheet) can be “calculated based on the modulus and thickness of

each individual layer.” (Ex.1010, ¶38.) This calculation would be a “tangent” flexural modulus as it is based on the tangent elastic moduli of the component layers.

222. As Dr. Osswald confirmed at his deposition, his calculation method for flexural modulus is based on “just basic mechanics.” (Ex.1020, 228:3 (testifying that the equations he cites are “just basic mechanics”).) Specifically, as Dr. Osswald confirmed at his deposition, his calculation method involves “an elastic bending analysis of a beam,” and relies on the well-known “parallel axis theorem[.]” (*Id.*, 252:13-14, 253:3-5.)

223. While I agree generally with the calculation method for flexural modulus as provided by Dr. Osswald at ¶¶38-47 of his declaration (Ex.1010), one of the equations he provides contains a key error, which is shown easily. At ¶42 of his declaration, he provides an equation for the “location of the neutral axis” as the following:

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum h_i}$$

(Ex.1010, ¶42.)

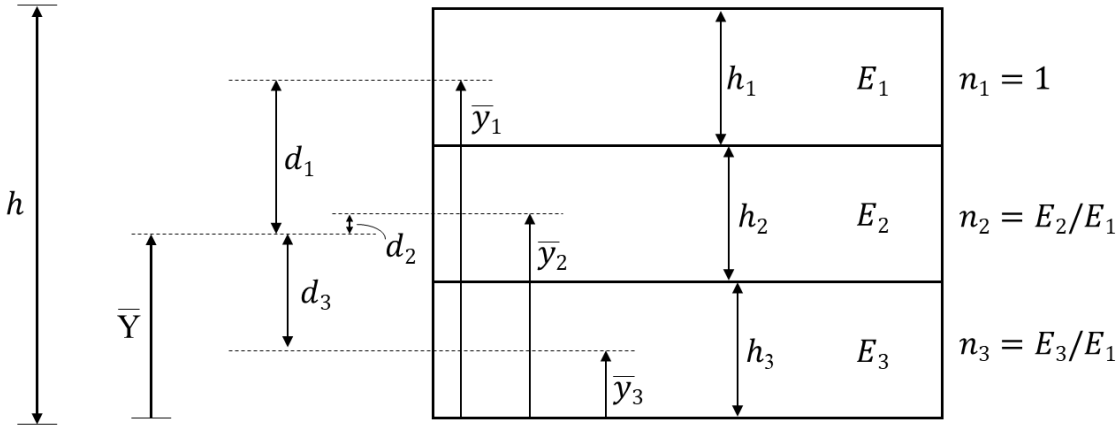
224. This equation, for deriving the “neutral axis,” is incorrect. Specifically, the denominator is missing the key term, n_i . My corrections to this equation are thus:

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum n_i A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum n_i h_i}$$

(See Ex.1138 (Beer, *Mechanics of Materials* (2001), p.231 (“[T]he resistance to bending of the bar would remain the same if both portions were made of the first material, provided that the width of each element of the lower portion were multiplied by the factor n .”) (emphasis added (i.e., underlining of quote from Beer))).)¹⁴

225. With my foregoing correction, the following figure depicting a 3-layer sheet and the associated equations permit the calculation of the flexural modulus for the overall multilayer sheet (E_f) based on the thickness (h_i) and elastic modulus (E_i) of each layer ($i = 1, 2, 3$), wherein $\bar{y}_i$ is the distance to the midpoint of layer i from a coordinate surface of the overall sheet:

¹⁴ Beer is the same textbook cited by Dr. Osswald in whole as Exhibit E of his declaration.



$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum n_i A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum n_i h_i} = \frac{n_1 h_1 \bar{y}_1 + n_2 h_2 \bar{y}_2 + n_3 h_3 \bar{y}_3}{n_1 h_1 + n_2 h_2 + n_3 h_3}$$

$$d_i = |\bar{Y} - \bar{y}_i|$$

$$d_1 = |\bar{Y} - \bar{y}_1| \quad d_2 = |\bar{Y} - \bar{y}_2| \quad d_3 = |\bar{Y} - \bar{y}_3|$$

$$E_f = \left(\frac{12E_1}{h^3} \right) \left[(n_1 h_1 d_1^2 + n_2 h_2 d_2^2 + n_3 h_3 d_3^2) + \frac{1}{12} (n_1 h_1^3 + n_2 h_2^3 + n_3 h_3^3) \right]$$

(See Ex.1116, ¶¶39-46.)

226. The errors in Dr. Osswald’s equation for “neutral axis,” from ¶42 of his declaration, is shown easily. As he observes correctly: “In a symmetric multi-layer system and in a single layer system, the neutral axis is at the center of the sheet.” (Ex.1116, ¶42.) However, without the term n_i in the denominator, his equation would not provide a neutral axis “at the center of the sheet” for symmetric multilayer systems. To illustrate using a simple 3-layer system, in which each layer is 0.1 mm

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thick, and in which the modulus of the middle layer is half of that of the outer layers,
such that:

- $h_1 = 0.1; n_1 = 1$
- $h_2 = 0.1; n_2 = 0.5$
- $h_3 = 0.1; n_3 = 1$

The neutral axis for this system, as would be intuitive, is “at the center of the sheet,”
i.e., $\bar{Y} = 0.15$ mm for a symmetrical 3-layer sheet with a total thickness of 0.3 mm.
However, if one were to use Dr. Osswald’s equation, one would get $\bar{Y} = 0.125$ mm.
This is clearly incorrect, because 0.125 mm from the bottom of the sheet is not “the
center of the sheet.” (Ex.1116, ¶42.)

227. The methodology provided above for calculating the flexural modulus
for a 3-layer sheet can also be extended to a 5-layer sheet, as explained by Dr.
Osswald according to the following:

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39. The flexural modulus of a multilayer polymeric sheet composition, such as shown in the figure below for a 5-layer system, can be computed using the thickness (h_i) and elastic modulus (E_i) of each layer i , where i varies from 1 to n (total number of layers, which in the figure below is 5).

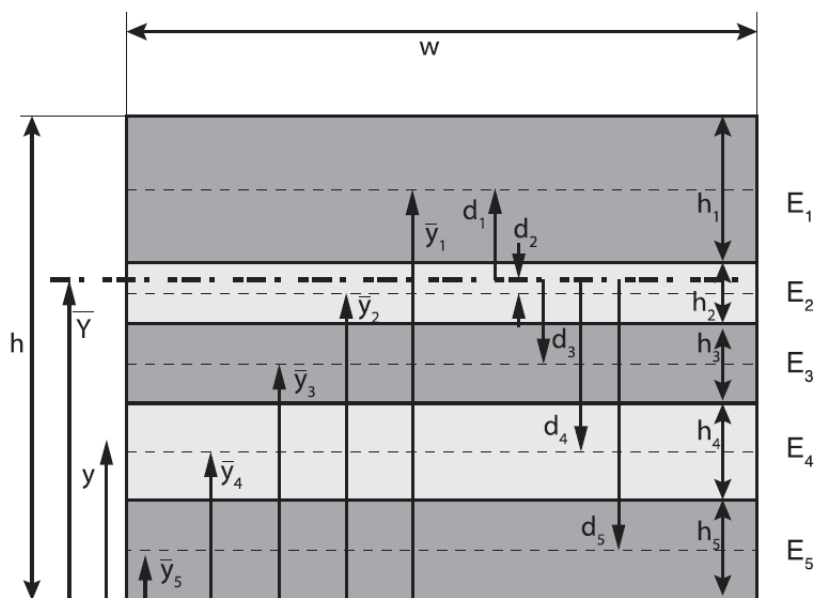
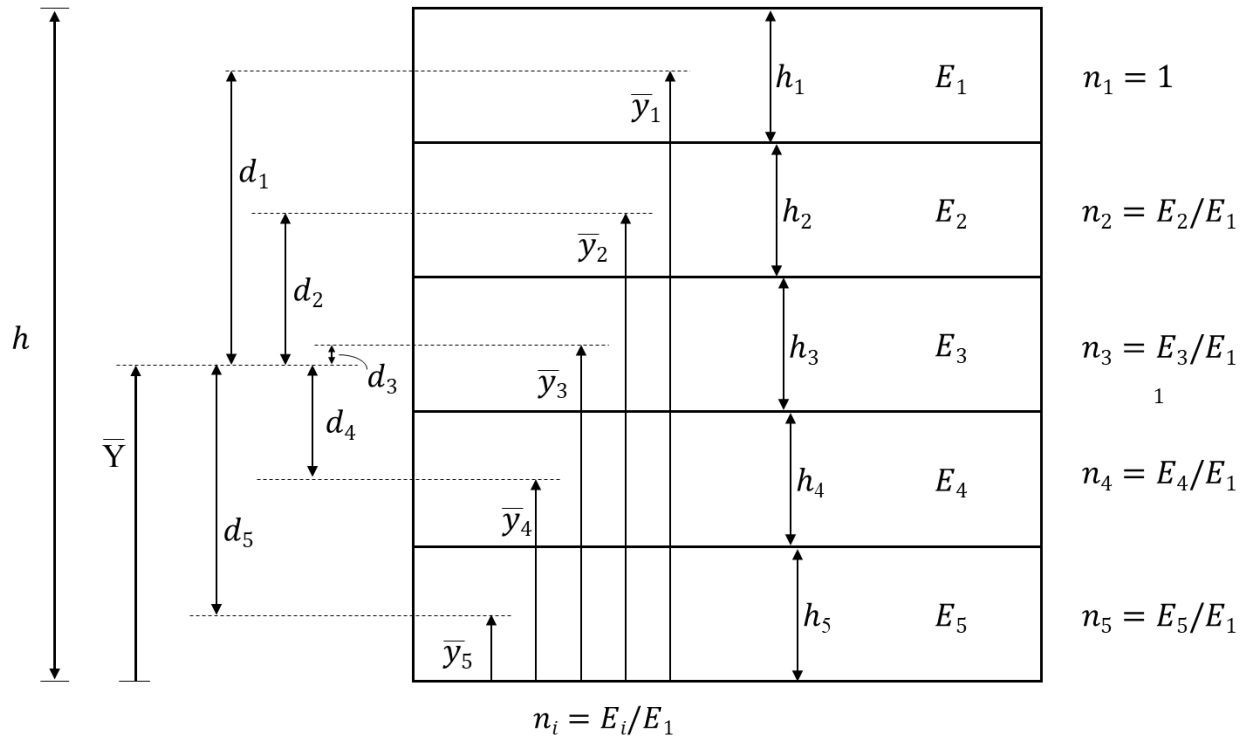


Figure 5: Multi-layer polymeric sheet

(Ex.1116, ¶42.)

228. Accordingly, for a 5-layer sheet, the flexural modulus for the overall multilayer sheet (E_f) based on the thickness (h_i) and elastic modulus (E_i) of each layer ($i = 1, 2, 3, 4, 5$), wherein $\bar{y}_i$ is the distance to the midpoint of layer i from a coordinate surface of the overall sheet, can be calculated as follows:

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$$n_1 = 1 \qquad n_2 = E_2/E_1 \qquad n_3 = E_3/E_1 \qquad n_4 = E_4/E_1 \qquad n_5 = E_5/E_1$$

$$\bar{Y} = \frac{\sum n_i A_i \bar{y}_i}{\sum n_i A_i} = \frac{w \sum n_i h_i \bar{y}_i}{w \sum n_i h_i} = \frac{n_1 h_1 \bar{y}_1 + n_2 h_2 \bar{y}_2 + n_3 h_3 \bar{y}_3 + n_4 h_4 \bar{y}_4 + n_5 h_5 \bar{y}_5}{n_1 h_1 + n_2 h_2 + n_3 h_3 + n_4 h_4 + n_5 h_5}$$

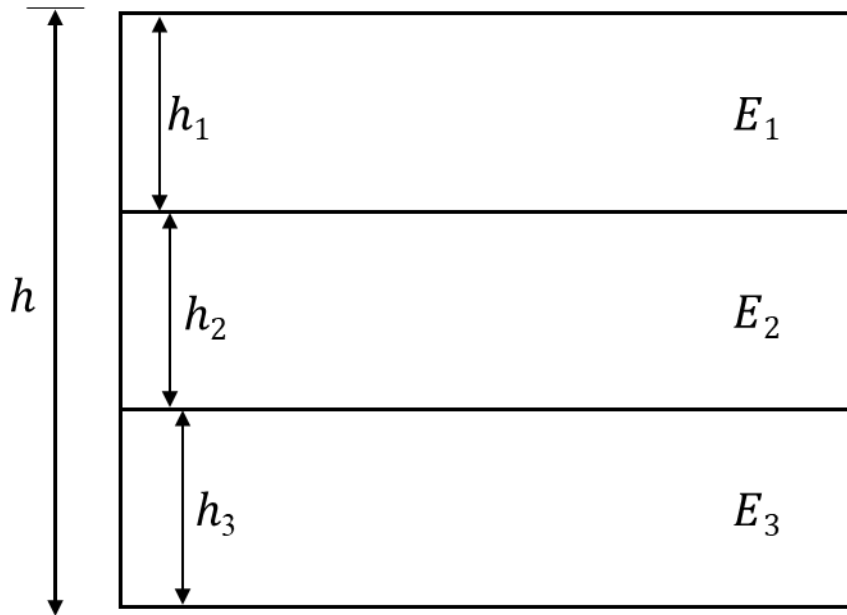
$$d_i = |\bar{Y} - \bar{y}_i|$$

$$d_1 = |\bar{Y} - \bar{y}_1| \quad d_2 = |\bar{Y} - \bar{y}_2| \quad d_3 = |\bar{Y} - \bar{y}_3| \quad d_4 = |\bar{Y} - \bar{y}_4| \quad d_5 = |\bar{Y} - \bar{y}_5|$$

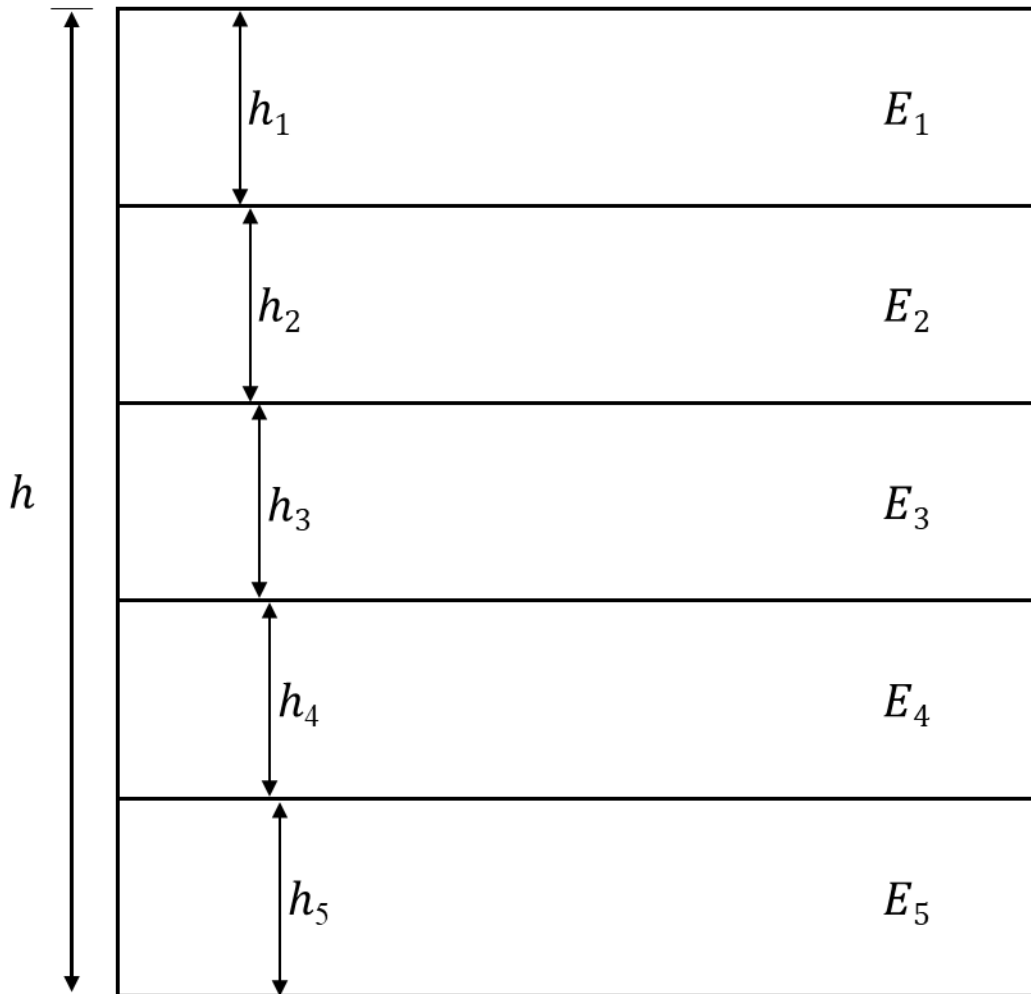
$$E_f = \left(\frac{12E_1}{h^3}\right) \left[(n_1 h_1 d_1^2 + n_2 h_2 d_2^2 + n_3 h_3 d_3^2 + n_4 h_4 d_4^2 + n_5 h_5 d_5^2) \right. \\ \left. + \frac{1}{12} (n_1 h_1^3 + n_2 h_2^3 + n_3 h_3^3 + n_4 h_4^3 + n_5 h_5^3) \right]$$

X. DERIVATION OF OVERALL (ELASTIC) MODULUS FOR A MULTILAYER SHEET

229. The elastic modulus (E) of a multilayer sheet, depicted for a three layer or a five layer sheet, can be estimated from the following equations:



$$E = \frac{\sum E_i h_i}{h} = \frac{E_1 h_1 + E_2 h_2 + E_3 h_3}{h} = E_1 \left(\frac{h_1}{h} \right) + E_2 \left(\frac{h_2}{h} \right) + E_3 \left(\frac{h_3}{h} \right)$$



$$E = \frac{\sum E_i h_i}{h} = \frac{E_1 h_1 + E_2 h_2 + E_3 h_3 + E_4 h_4 + E_5 h_5}{h}$$

XI. CONCLUSION

230. I reserve the right to offer opinions relevant to the validity of the '263 patent claims at issue or offer testimony in support of the Declaration.

231. In signing this Declaration, I recognize that the Declaration will be filed

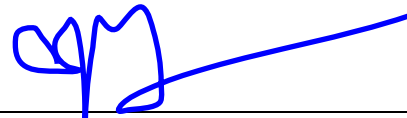
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as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case. If required, I will appear for cross-examination at the appropriate time.

232. 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 18 U.S.C. § 1001.

Dated: December 5, 2022

Respectfully submitted,



Alan Jeffrey Giacomini, Ph.D.

Attachment A

Flexural Modulus (Ef) calculation for PETG-Durasoft(0.2 mm)-TPU-Durasoft(1.0 mm)-PETG-Durasoft (0.8 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	2200	1.9	1	0.38	0.2	1.156492	0.26749494	0.008
TPU-Durasoft	2	1	172	1.3	0.078182	0.101636364	0.078182	0.556492	0.024211643	0.0781818
PETG-Durasoft	3	0.8	2200	0.4	1	0.32	0.8	0.343508	0.094397971	0.512
sum (i=1,2,3)		2.0				0.801636364	1.078182		0.386104553	0.5981818

$$\bar{Y} = 0.743508$$

$$E_f = 1439$$

Flexural Modulus (Ef) calculation for Copolyester-Imprelon(0.2 mm)-TPU-Durasoft(1.0 mm)-Copolyester-Imprelon (0.8 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	1624	1.9	1	0.38	0.2	1.142539	0.261079062	0.008
TPU-Durasoft	2	1	172	1.3	0.105911	0.137684729	0.105911	0.542539	0.031174845	0.1059113
PETG-Durasoft	3	0.8	1624	0.4	1	0.32	0.8	0.357461	0.102222707	0.512
sum (i=1,2,3)		2.0				0.837684729	1.105911		0.394476615	0.6259113

$$\bar{Y} = 0.757461$$

$$E_f = 1088$$

Flexural Modulus (Ef) calculation for PETG-Durasoft(0.2 mm)-TPU-Durasoft(1.3 mm)-PETG-Durasoft (0.2 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	2200	1.6	1	0.32	0.2	0.75	0.1125	0.008
TPU-Durasoft	2	1.3	172	0.85	0.078182	0.086390909	0.101636	1.11E-16	1.25276E-33	0.1717655
PETG-Durasoft	3	0.2	2200	0.1	1	0.02	0.2	0.75	0.1125	0.008
sum (i=1,2,3)		1.7				0.426390909	0.501636		0.225	0.1877655

$$\bar{Y} = 0.85$$

$$E_f = 1293$$

Flexural Modulus (Ef) calculation for Copolyester-Imprelon(0.2 mm)-TPU-Durasoft(1.3 mm)-Copolyester-Imprelon(0.2 mm)

material	layer	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i) y-bar(i)	n(i) h(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
PETG-Durasoft	1	0.2	1624	1.6	1	0.32	0.2	0.75	0.1125	0.008
TPU-Durasoft	2	1.3	172	0.85	0.105911	0.11703202	0.137685	1.11E-16	1.6971E-33	0.2326872
PETG-Durasoft	3	0.2	1624	0.1	1	0.02	0.2	0.75	0.1125	0.008
sum (i=1,2,3)		1.7				0.45703202	0.537685		0.225	0.2486872

$$\bar{Y} = 0.85$$

$$E_f = 975$$

Attachment B-1

Worksheet for modulus and flexural modulus calculations for 5-layer hard-soft-hard-soft-hard sheet according to teachings of Li and Boronkay (Grounds 4, 5)

Li disclosure for thickness of hard layers: 400 - 1100 μm (Li, 5:21-24)

Li disclosure for thickness of soft layers: 25 - 100 μm (Li, 5:24-27)

Li disclosure for overall thickness of multilayer sheet: 500 - 1200 μm (Li, 5:27-31)

Li modulus of hard layer: greater than about 150,000 psi (1034 MPa) (Li, 5:62-63)

Li modulus of soft layers: greater than about 35,000 psi (241 MPa) (Li, 5:62-63)

Boronkay with protective outer layers harder than and thinner than other layers

Claim Layer	thickness (μm)	disclosed thickness per Li + Boronkay	e-modulus (MPa)	disclosed e-modulus
A	25	thinnest (Boronkay)	1550	hardest (Boronkay)
B	100	25-100 (Li)	241	at least 241 MPa (Li)
D	1100	400-1100 (Li)	1500	at least 1,034 MPa (Li)
B'	100	25-100 (Li)	241	at least 241 MPa (Li)
C	25	thinnest (Boronkay)	1550	hardest (Boronkay)
overall	1350			

Determination of Elastic Modulus (E) for 5-layer sheet acc'd to Li + Boronkay to achieve Chen's preferred modulus (800-1500 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	h(i) * E(i)
1	hard (Boronkay)	25	0.025	1550	38.75
2	soft (Li)	100	0.100	241	24.1
3	hard (Li)	1100	1.100	1500	1650
4	soft (Li)	100	0.100	241	24.1
5	hard (Boronkay)	25	0.025	1550	38.75
sum (i=1,2,3,4,5)		1350	1.350		1775.7

Chen's preferred modulus

E (modulus)= 1315 MPa

800-1500 MPa

Determination of Flexural Modulus (Ef) for 5-layer Li+Boronkay to achieve Stewart's preferred modulus (1000-3000 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i)	y-bar(i)	n(i) h(i)	h(i) E(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
1	hard (Boronkay)	25	0.025	1550	1.3375	1.000	0.0334	0.0250	38.75	0.6625		0.0110	0.0000
2	soft (Li)	100	0.100	241	1.275	0.155	0.0198	0.0155	24.1	0.6		0.0056	0.0002
3	hard (Li)	1100	1.100	1500	0.675	0.968	0.7185	1.0645	1650	0		0.0000	1.2881
4	soft (Li)	100	0.100	241	0.075	0.155	0.0012	0.0155	24.1	0.6		0.0056	0.0002
5	hard (Boronkay)	25	0.025	1550	0.0125	1.000	0.0003	0.0250	38.75	0.6625		0.0110	0.0000
sum (i=1,2,3,4,5)		1350	1.350				0.7733	1.1456	1775.7			0.0331	1.2884

Y-bar= 0.675

E_f (flexural mod)= 1062 MPa

Stewart flex mod

1000-3000 MPa

Attachment B-2

Worksheet for modulus and flexural modulus calculations for 5-layer hard-soft-hard-soft-hard sheet according to teachings of Li and Boronkay (Grounds 4, 5)

Li disclosure for thickness of hard layers: 400 - 1100 μm (Li, 5:21-24)

Li disclosure for thickness of soft layers: 25 - 100 μm (Li, 5:24-27)

Li disclosure for overall thickness of multilayer sheet: 500 - 1200 μm (Li, 5:27-31)

Li modulus of hard layer: greater than about 150,000 psi (1034 MPa) (Li, 5:62-63)

Li modulus of soft layers: greater than about 35,000 psi (241 MPa) (Li, 5:62-63)

Boronkay with protective outer layers harder than and thinner than other layers

Claim Layer	thickness (μm)	disclosed thickness per Li + Boronkay	e-modulus (MPa)	disclosed e-modulus
A	25	thinnest (Boronkay)	1550	hardest (Boronkay)
B	50	25-100 (Li)	241	at least 241 MPa (Li)
D	400	400-1100 (Li)	1500	at least 1,034 MPa (Li)
B'	50	25-100 (Li)	241	at least 241 MPa (Li)
C	25	thinnest (Boronkay)	1550	hardest (Boronkay)
overall	550			

Determination of Elastic Modulus (E) for 5-layer sheet acc'd to Li + Boronkay to achieve Chen's preferred modulus (800-1500 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	h(i) * E(i)
1	hard (Boronkay)	25	0.025	1550	38.75
2	soft (Li)	50	0.050	241	12.05
3	hard (Li)	400	0.400	1500	600
4	soft (Li)	50	0.050	241	12.05
5	hard (Boronkay)	25	0.025	1550	38.75
sum (i=1,2,3,4,5)		550	0.550		701.6

Chen's preferred modulus

E (modulus)= 1276 MPa

800-1500 MPa

Determination of Flexural Modulus (Ef) for 5-layer Li+Boronkay to achieve Stewart's preferred modulus (1000-3000 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i)	y-bar(i)	n(i) h(i)	h(i) E(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
1	hard (Boronkay)	25	0.025	1550	0.5375	1.000	0.0134	0.0250	38.75	0.2625	0.0017	0.0000	
2	soft (Li)	50	0.050	241	0.5	0.155	0.0039	0.0078	12.05	0.225	0.0004	0.0000	
3	hard (Li)	400	0.400	1500	0.275	0.968	0.1065	0.3871	600	0	0.0000	0.0619	
4	soft (Li)	50	0.050	241	0.05	0.155	0.0004	0.0078	12.05	0.225	0.0004	0.0000	
5	hard (Boronkay)	25	0.025	1550	0.0125	1.000	0.0003	0.0250	38.75	0.2625	0.0017	0.0000	
sum (i=1,2,3,4,5)		550	0.550				0.1245	0.4526	701.6		0.0042	0.0620	

Y-bar= 0.275

E_f (flexural mod)= 1051 MPa

Stewart flex mod

1000-3000 MPa

Attachment B-3

Worksheet for modulus and flexural modulus calculations for 5-layer hard-soft-hard-soft-hard sheet according to teachings of Li and Boronkay (Grounds 4, 5)

Li disclosure for thickness of hard layers: 400 - 1100 μm (Li, 5:21-24)

Li disclosure for thickness of soft layers: 25 - 100 μm (Li, 5:24-27)

Li disclosure for overall thickness of multilayer sheet: 500 - 1200 μm (Li, 5:27-31)

Li modulus of hard layer: greater than about 150,000 psi (1034 MPa) (Li, 5:62-63)

Li modulus of soft layers: greater than about 35,000 psi (241 MPa) (Li, 5:62-63)

Boronkay with protective outer layers harder than and thinner than other layers

Claim Layer	thickness (μm)	disclosed thickness per Li + Boronkay	e-modulus (MPa)	disclosed e-modulus
A	25	thinnest (Boronkay)	1550	hardest (Boronkay)
B	75	25-100 (Li)	241	at least 241 MPa (Li)
D	750	400-1100 (Li)	1500	at least 1,034 MPa (Li)
B'	75	25-100 (Li)	241	at least 241 MPa (Li)
C	25	thinnest (Boronkay)	1550	hardest (Boronkay)
overall	950			

Determination of Elastic Modulus (E) for 5-layer sheet acc'd to Li + Boronkay to achieve Chen's preferred modulus (800-1500 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	h(i) * E(i)
1	hard (Boronkay)	25	0.025	1550	38.75
2	soft (Li)	75	0.075	241	18.075
3	hard (Li)	750	0.750	1500	1125
4	soft (Li)	75	0.075	241	18.075
5	hard (Boronkay)	25	0.025	1550	38.75
sum (i=1,2,3,4,5)		950	0.950		1238.65

Chen's preferred modulus

E (modulus)= 1304 MPa

800-1500 MPa

Determination of Flexural Modulus (Ef) for 5-layer Li+Boronkay to achieve Stewart's preferred modulus (1000-3000 MPa)

layer No.	Material	thickness (μm)	h(i) (cm)	e-modulus (MPa)	y-bar(i)	n(i)	n(i) h(i)	y-bar(i)	n(i) h(i)	h(i) E(i)	d(i)	n(i) h(i) d(i)^2	n(i) h(i)^3
1	hard (Boronkay)	25	0.025	1550	0.9375	1.000	0.0234	0.0250	38.75	0.4625	0.0053	0.0000	
2	soft (Li)	75	0.075	241	0.8875	0.155	0.0103	0.0117	18.075	0.4125	0.0020	0.0001	
3	hard (Li)	750	0.750	1500	0.475	0.968	0.3448	0.7258	1125	0	0.0000	0.4083	
4	soft (Li)	75	0.075	241	0.0625	0.155	0.0007	0.0117	18.075	0.4125	0.0020	0.0001	
5	hard (Boronkay)	25	0.025	1550	0.0125	1.000	0.0003	0.0250	38.75	0.4625	0.0053	0.0000	
sum (i=1,2,3,4,5)		950	0.950				0.3796	0.7991	1238.65		0.0147	0.4084	

Y-bar= 0.475

E_f (flexural mod)= 1056 MPa

Stewart flex mod

1000-3000 MPa