UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REACTIVE SURFACES LTD., LLP

Petitioner

v.

TOYOTA MOTOR CORPORATION

Patent Owner

CASE: To Be Assigned

Patent No. 8,252,571 B2

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,252,571 B2

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Ex. 1003 **U.S. Patent No. 6,291,582 B1 to Dordick *et al.* ("Dordick")**

Ex. 1004 **U.S. Patent Publication No. 2007/0282070 A1 of Adams *et al.* ("Adams")**

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Ex. 1014 **Printed Publication of Novick, S. et al., Protein-containing hydrophobic coatings and films, *Biomaterials,* 23: 441-448, 2002**

("Novick")

Ex. 1015 Published PCT Application No. WO2009/155115 A2 of McDaniel; ("McDaniel '115")

I. INTRODUCTION

Pursuant to 35 U.S.C. §311 and 37 C.F.R. §42.100, Reactive Surfaces LTD. LLP ("Petitioner") petitions for *inter partes* review of claims 1-23 of U.S. Pat. No. 8,252,571 B2 ("the '571 Patent," Ex. 1001). The '571 Patent issued from U.S. Patent Application Serial No. 12/434,320 of Wang *et al*., which published as U.S. Patent Application Publication No. 2010/027376 A1 ("the '320 Application", Ex. 1002).

This Petition shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims 1-23 of the '571 Patent. These claims are unpatentable under at least 35 U.S.C. §103. The Office is respectfully requested to institute a trial for *inter partes* review and to cancel claims 1-23 of the '571 Patent.

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8(B)

A. REAL PARTY IN INTEREST

Reactive Surfaces Ltd., LLP is the real party in interest.

B. RELATED MATTERS

Petitioner submits that there are no related judicial or administrative matter that would affect, or be affected by, a decision in the proceeding. The cases identified below, which have been ***dismissed without prejudice***, were previously filed by Petitioner against Patent Owner seeking a declaratory judgment with regards to certain rights in U.S. Patent No. 8,252,571 B2:

1. Cause No. 1-13-CV-1098-LY; *Reactive Surfaces Ltd. LLP v. Toyota Motor Engineering & Manufacturing North America, Inc. et al;* In The United States District Court For The Western District of Texas –Austin Division, and

2. Cause No. 1:14-CV-1009-LY; *Reactive Surfaces Ltd. LLP v. Toyota Motor Corporation*, In The United States District Court For The Western District of Texas –Austin Division.

C. NOTICE OF COUNSEL AND SERVICE INFORMATION

Pursuant to 37 C.F.R. §42.8(b)(3) and 37 C.F.R. §42.10(a), Petitioner designates counsel as indicated in Table 1 below. Please address all correspondence and service to counsel at the address provided in Table 1 below.

Table 1 - DESIGNATION OF COUNSEL

Lead Counsel	**Back-up Counsel**
David O. Simmons Reg. No. 43,124 IVC Patent Agency P. O. Box 26584 Austin, Texas 78755 7637 Parkview Circle Austin, Texas 78731 Ph: (512) 345-9767 Fax: (512) 345-0021	Jonathan D. Hurt Reg. No. 44,790 McDaniel & Associates, PC 300 West Avenue, #1316 Austin, Texas 78701 Ph: (512) 472-8486 Fax: (512) 472-8181 jhurt@technologylitigators.com

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Petitioner consents to electronic service by email for all correspondence at: dsimmons@ivcpatentagency.com, jhurt@technologylitigators.com, and ReactiveSurfaces@wattsguerra.com.

Pursuant to 37 C.F.R. §42.10(b), a Power of Attorney executed by Petitioner for appointing the above-designated counsel is concurrently filed herewith.

D. PAYMENT OF FEES – 37 C.F.R §42.103

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 50-1085 for the fees set in 37 C.F.R §42.15(a) for this Petition and further authorizes payment for additional fees to be charged to this Deposit Account.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW

This Petition complies with all requirements under 37 C.F.R. §42.104.

A. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. §42.104(a), Petitioner hereby certifies that the '571 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging claims of the '571 Patent.

B. IDENTIFICATION OF CHALLENGE

Pursuant to 37 C.F.R. §42.104(b), the precise relief requested is that the Board cancel claims 1-23 of the '571 Patent.

1. Claims Challenged

Claims 1-23 of the ’571 Patent are challenged in this Petition.

2. The Prior Art

The prior art references relied upon are Dordick (Ex. 1003), Adams (Ex. 1004), McDaniel (Ex. 1005), Huynh-Ba (Ex. 1006) and Bonaventura (Ex. 1007) mentioned above in Section II.B. See Exhibit List and Section V.A for detailed description of each prior art reference.

3. Supporting Evidence Relied Upon For The Challenge

The declaration by Dr. Douglas M. Lamb, Ph.D. (Ex. 1008), declaration by Dr. David Rozzell, Ph.D. (Ex. 1009) and other supporting evidence in the Exhibit List are filed herewith.

4. Statutory Ground(s) Of Challenge And Legal Principles

The review of the ’571 Patent is governed by pre-AIA 35 U.S.C. §102 and §103 that were in effect before March 16, 2013. Further, 35 U.S.C. §§311 - 319 that took effect on September 16, 2012 govern this *inter partes* review.

5. Claim Construction

The ’571 Patent is an unexpired patent. In *inter partes* review, a claim in the ’571 Patent “shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. §42.100(b).

6. How Claims Are Unpatentable Under Statutory Grounds

Pursuant to 37 C.F.R. §42.104 (b)(2)

Section VI provides an explanation of how claims 1-23 of the '571 Patent are unpatentable under pre-AIA 35 U.S.C. §103, including the identification of where each element of the claim is found in the prior art patents, published patent applications, and/or printed publications.

IV. OVERVIEW OF THE '571 PATENT

A. PRIORITY DATE OF THE CLAIMS OF THE '571 PATENT

The '320 Application, from which the '571 Patent issued, was filed on May 1, 2009. The '320 Application did not claim priority to any prior-filed application(s). Therefore, the earliest effective filing date for the '571 Patent is the filing date of the '320 Application (*i.e.*, May 1, 2009).

B. SUMMARY OF THE '571 PATENT

The '571 Patent discloses, "Methods according to embodiments of the present invention are provided which include formation of fine emulsion solution that contains bioactive proteins dispersed in a continuous phase containing polymerizable ingredients, such that the proteins are entrapped and crosslinked with polymer upon the formation of the polymer network. The crosslinking of at least some of the protein to the polymer network along with the confinement of the protein in the polymer provides long-lasting activity of the protein ingredient in a coating formed using methods and materials described

herein. A process for preparation of a protein-polymer composite material is provided according to embodiments of the present invention which includes providing an admixture of a polymer resin, a surfactant and a non-aqueous organic solvent. An aqueous solution containing bioactive proteins and substantially free of surfactant, is mixed with the admixture, thereby producing an emulsion. The emulsion is mixed with a crosslinker to produce a curable composition; and the curable composition is cured to produce the protein-polymer composite material." (*Id*. at 1:21-40). "In preferred embodiments of inventive processes, no surfactant is intentionally added to the aqueous bioactive protein solution and the aqueous bioactive protein solution is substantially free of surfactant. The term "substantially free" refers to the total absence or near-total absence of surfactant in the aqueous bioactive protein solution." (*Id*. at 5:59-64). "Processes for preparation of protein-polymer composite materials according to embodiments of the present invention are characterized by dispersion of bioactive proteins in solvent-borne resin prior to curing and in the composite materials, in contrast to forming large aggregates of the bioactive proteins which diminish the functionality of the bioactive proteins and protein-polymer composite materials. In embodiments of the present invention, bioactive proteins are dispersed in the protein-polymer composite material such that the bioactive proteins are unassociated with other bioactive proteins and/or

form relatively small particles of associated proteins. Thus, in embodiments, the average particle size of bioactive protein particles in the protein-polymer composite material is less than 10 μm (average diameter) such as in the range of 1 nm to 10 μm, inclusive." (*Id*. at 3:16-30).

With respect to curing, the '571 Patent discloses: 1.) "Curing modalities are those typically used for conventional curable polymer compositions. Protein-polymer composite materials produced by embodiments of processes of the present invention are optionally thermoset protein-polymer composite materials. For example, thermal curing is used in particular embodiments. A thermal polymerization initiator is optionally included in a curable composition according to embodiments." (*Id*. at 4:60-67); 2.) "Curing may include evaporation of a solvent in particular embodiments. Optionally, a curable composition is cured by exposure to actinic radiation, such as ultraviolet, electron beam, microwave, visible, infrared, or gamma radiation." (*Id.* at 5:23-27); 3.) "Optionally, a crosslinker, 30, is present in the curable protein-polymer composition, 40, depending on the polymer resin used and the curing modality selected. Curing of the composition is performed to produce a cured protein-polymer composite material, 50." (*Id.* at 2:67-3:5); and 4.) "A crosslinker, 80, is added to the emulsion, 75, depending on the polymer resin used and the curing modality selected, producing a curable protein-polymer composition, 90. The curable protein-polymer composition 90 is cured to produce a

protein-polymer composite material, 100." (*Id.* at 3:9-14).

C. SUMMARY OF PROSECUTION FILE HISTORY

Prosecution of the '320 Application included one (1) Non-Final Office Action (*i.e.*, Office Action dated December 13, 2011 ("the '320 OA" - Ex. 1010)), one (1) Examiner Interview on March 13, 2012 ("the Examiner Interview") summarized in an Interview Summary dated March 15, 2012 ("the '320 Interview Summary" – Ex. 1011) and one (1) Office Action Response (*i.e.*, Office Action Response filed April 13, 2012 ("the '320 OAR" – Ex. 1012)). A Notice of Allowability ("the '320 NOA" – Ex. 1013) dated April 30, 2012 was issued following the '320 OAR being filed.

In the '320 OA, as-filed claims 1-21 were indicated as being allowable and claims 22 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Novick (Ex. 1014). In citing Novick, the '320 OA states, "While Applicant's claim that the proteins are dispersed in a "two component solvent borne [taken as 'made from'] polymer resin", there appears to be no discernible difference in the composite material claimed and that taught in Novick et al. Therefore, Claims 22 and 23 are anticipated by the teachings of et al." ('320 OA at pg. 3: ln. 14-21). The '320 OA further states," Novick et al. (as cited above, and Dordick et al. (IDS, which includes Norvick USP 5,914,367) teach aqueous solutions of enzyme in buffer, and surfactant AOT in hexane, but the polymer is added after the enzyme and surfactant are mixed, that is, the polymer is not in the admixture with hexane and surfactant.

Glutaraldehyde is used as a crosslinking regeant." ('320 OA at pg. 4: ln. 4-8).

In regard to conversation with Applicant's attorney (Julie Staple – "JS") during the Examiner Interview, the Examiner (Karen Carlson – "KCC") stated in the '320 Interview Summary that, "JS is considering amending claim 22 to recite that the bioactive protein is not ion-paired. JS pointed to Novick. para. bridging pages 441-442, that the use of surfactants results in ion-pairing of the protien. KCC will have to re-search the art for this limitation. that bioactive proteins are not ion-paired via the method to which they were made". (the '320 Interview Summary at pg. 2: ln. 16-18).

Following the Examiner Interview, in the '320 OAR [Ex. 1012], Applicant in the '320 Application presented the limitation "with the proviso that the bioactive proteins are not ion-paired" (*i.e.*, "the ion-paired limitation") in both amended original Claim 22 ('320 OAR at pg. 4, lines 18-22) and new Claim 24 ('320 OAR at pg. 5, lines 5-9). Additionally, Applicant in the '320 Application made several assertions and admissions regarding the ion-paired limitation. These assertions and admission included: 1.) "The cited Novick et al. reference explicitly states that ion-pairing of enzymes and surfactant is used in their methods to "solubilize enzymes into organic solvents ..." (p.442, left column, first paragraph) Novick et al. states that ion-pairing of enzymes and surfactants allows for "solubility of the enzyme in organic solvents" and "[o]nce the protein is dissolved in a suitable organic solvent,

the polymer can be added ..." (p.442, left column, first paragraph) Figure 1 of Novick et al. diagrammatically shows the use of ion-paired enzyme." ('320 OAR at pg. 6, lines 11-16); 2.) "In contrast, **"direct dispersion" processes are described according to aspects of the present invention in which an aqueous solution of a non-ion-paired enzyme is directly mixed into a polymer-containing admixture (polymer, organic solvent, may or may not contain a surfactant**), see 019-021 and Figures I A and l B, for example. The specification, including 0004-0005, 0010 and independent claims 1, 8 and 14, indicates that **an aqueous solution of enzyme is substantially free of surfactant, *i.e.* non-ion-paired**." ('320 OAR at pg. 6, lines 17-22) [**emphasis added**]; and 3.) "The amendment to claim 22 clarifies that the bioactive proteins in the claimed compositions are not ion-paired." ('320 OAR at pg. 6, lines 23-24).

The '320 NOA included an Examiner's Statement of Reasons for Allowance, which stated:

> The prior art does not appear to teach non-ion-paired bioactive proteins in solvent-borne polymer resins. See art of discussed in the first action on the merits. Also, McDaniel uses surfactants to place bioactive proteins into resins, which pairs ions to the bioactive proteins. ('320 NOA at pg. 4, lines 3-7, where the cited "McDaniel" is McDaniel '115 [Ex. 1015])

Petitioner submits that there is no disclosure in the ‘571 Patent or assertion by the ’320 Application Applicant that enzymes of a polymer-protein composite material thereof cannot have ion-paring via a surfactant. Rather, the ’320 Application Applicant has clarified that the enzyme is not ion paired by a surfactant that is within the aqueous solution. The ’320 Application Applicant has admitted that the admixture into which the aqueous solution is added can include a surfactant (e.g., see ’320 OAR at pg. 6, lines 23-24; ‘571 Patent at Abstract:1-6) and presents no disclosure that would preclude ion-pairing of the enzyme once mixed into the admixture (e.g., ion-pairing as caused by a surfactant that is part of the admixture).

Thus, based on the disclosure in the ’320 Application and the prosecution history of the ’320 Application, Petitioner submits that the claims of the ’320 Application were allow based on the Examiner not identifying prior art that explicitly taught or reasonably suggested: 1.) a process for preparation of a protein-polymer composite material that comprises mixing an aqueous solution of a non-ion-paired enzyme directly into a polymer and organic solvent-containing admixture and/or 2.) a protein-polymer composite material that comprises a two component solvent-borne resin having bioactive proteins dispersed therein by mixing an aqueous solution of a non-ion-paired enzyme directly into a polymer and organic solvent-containing admixture from which the two component solvent-borne resin is formed.

D. PROPOSED CLAIM CONSTRUCTION

Any term not construed herein should be interpreted in accordance with its plain and ordinary meaning under the broadest reasonable construction. See Section III.B(5). Given the different claim construction standards used by the PTO and district courts, Petitioner reserves the right to argue a different construction during litigation for any term recited in the '571 Patent.

1. "**bioactive proteins are not ion-paired"** in Claims 22 and 23: The specification of the '571 Patent is silent on the term "ion-paired", which is recited in claims 22 and 23. As discussed above in Section IV.C, this claim term was introduced during prosecution of the '320 Application by way of amendment of as-filed claim 22 and addition of new claim 24 that became issued claim 23. In view of the specification of the '571 Patent and the prosecution history of the '320 Application, Petitioner submits that the proposed BRI construction for this term is "particles of the bioactive proteins that are not ionically bound with an added surfactant within an aqueous solution, which is then combined with a polymer and organic solvent component of the two component solvent-borne polymer resin." See Lamb Declaration [Ex. 1008], ¶¶44-49.
2. "**the polymerizable composition"** in Claim 8: This claim term lacks proper antecedent basis, as there is no prior recitation of "a polymerizable

composition". Based on the context of this term in Claim 8 in light of the specification, Petitioner submits that the proposed BRI construction for this term is "the curable composition".

3. "**the composite material"** in Claim 8: This claim term lacks proper antecedent basis, as there is no prior recitation of "a composite material". Based on the context of this term in Claim 8 in light of the specification, Petitioner submits that the proposed BRI construction for this term is "the protein-polymer composite material".

In view of the discussion in this section and section IV.C.1 above, Petitioner submits that that the grounds of unpatentability presented herein (See Section V.B below) and the prior art relied upon therein are applicable to multiple reasonable interpretations of "bioactive proteins are not ion-paired", "the polymerizable composition" and/or "the composite material", which includes those claim constructions presented herein.

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '571 PATENT IS UNPATENTABLE

Claims 1-23 are unpatentable under 35 U.S.C. §103(a) for merely reciting predictable and obvious combinations of elements/limitations that were well known many years prior to the filing date for the '571 Patent and that were taught or suggested by the cited prior art in this Petition.

A. IDENTIFICATION OF THE REFERENCES AS PRIOR ART

As detailed below, the cited prior art references relied upon herein are within the same or closely related technical field as the claimed subject matter of the ’571 Patent. All of the cited prior art references relied upon herein were published more than one year prior to the May 1, 2009 earliest effective filing date for the application from the ’571 Patent issued (*i.e.*, ’320 Application) and, therefore, are prior art under 35 U.S.C. §102(b). As prior art under 35 U.S.C. §102(b), the cited references cannot be sworn behind by a declaration under 37 C.F.R. §1.131. In addition, none of the cited references in this Petition were cited and relied upon during original examination of the ’320 Application.

Dordick: ([Ex. 1003] U.S. Patent No.6,291,582 B1, published September 18, 2001) discloses, “the present invention relates to methods for the preparation of protein-containing polymeric materials, such as enzyme-containing polymeric materials. The present invention also relates to protein-containing polymeric materials and use of the materials, for example, as catalytic particles in self-cleaning/non-fouling paints and coatings, as highly active and stable biocatalysts, in chemical/biochemical sensing and in medical applications including implants and in controlled drug release, immobilization, and/or stabilization of therapeutic proteins.” (*Id.* at 1:21-29).

With respect to the organic solution including a polymer resin, Dordick

discloses: 1.) "the process methodologies to make composites in accordance with applicants' inventions can employ two or more surfactants and solvents" (*Id.* at 4:10-12), 2.) "Also the organic phase can actually consist of, consist essentially of, or comprise the polymerizable monomer." (*Id.* at 6:30-31), 3.) "One or more proteins, one or more surfactants, optionally one or more organic solvents, one or more monomers and/or polymers, and optionally one or more crosslinkers may be used" (*Id.* at 6:62-65), 4.) "The polymerizable monomer is selected from any desired polymerizable monomer. Such monomers are well known and readily obtained by those in the field of polymers." (*Id.* at 7:51-53); 5.) "Note if monomer is used as a solvent in step (2), (3) or (4) additional monomer need not be added." (*Id.* at 10:54-55); and 6.) "Of course, in methodologies that employ only already-formed polymers, the polymerization can be omitted because the necessary polymer has already formed. Reactions may still be necessary, however, in situations where cross-linking is desired and/or the protein (such as an enzyme) is to be covalently bound to the polymer." (*Id.* at 11:29-35).

With respect to the surfactant and the organic solution, Dordick teaches: "In accordance with still another aspect of the invention, there are provided methods of preparing a polymer-protein composite comprising ion-pairing a protein in an aqueous phase with a surfactant in a first organic phase to yield a protein-

surfactant ion pair; …" (*Id.* at 3:17-21). FIG. 1 of Dordick "shows how proteins, such as enzymes, are incorporated into polymers according to the present invention." (*Id.* at 4:24-26). For example, in reference to FIG. 1, Dordick discloses, "Two approaches are evident from FIG. 1. In one (left side of FIG. 1), the enzyme is simply extracted into the organic phase by ion-pairing with a surfactant." As shown, the surfactant is not associated with the protein (e.g., an enzyme) within the aqueous phase and the enzyme is then exposed to the surfactant and monomer of the organic media (i.e., phase) when the aqueous phase contacts the organic media. Moreover, FIG. 1 only shows polymers and surfactant associated protein in the organic media after extraction of the protein from the aqueous phase.

Adams ([Ex. 1004] U.S. Appl. Pub. No. 2007/0282070, published December 6, 2007) discloses various aspects of a crosslinkable coating composition that comprises a film-forming binder and a liquid carrier. Adams discloses that, "the binder contains (a) "a crosslinkable film-forming resin (such as an oligomer, polymer or a dispersed gelled polymer) having functional groups that are capable of crosslinking with the isocyanate groups of component (b)" and that component (b) is "a crosslinking portion comprising a urea- and/or biuret-containing polyisocyanate adduct mixture. …" (*Id.* at 0010:5-0012:2). Adams discloses that the crosslinkable film-forming resin can be a Hydroxy-Functional Acrylic Copolymer

(*Id.* at 0125 and Table 5) and that the Hydroxy-Functional Acrylic Copolymer can be a constituent component of an admixture (*i.e.*, Part 1 in Table 5) that further comprises a surfactant (*i.e.*, BYK-358 in Table 5). Adams discloses that crosslinkable film-forming resins thereof can be cross-linked via a polyisocyanate (*Id.* at Table 5 (Part 2): Desmodur N3300A; 0101:1-6, 0104:1-6).

McDaniel ([Ex. 1005] U.S. Appl. Pub. No. 2004/0109853, published June 10, 2004) is directed to compositions and methods for their use as components of surface treatments such as coatings. McDaniel discloses "compositions and methods for incorporating biological molecules into coatings in a manner to retain biological activity conferred by such biological molecule." (*Id*. McDaniel at 0021:4-6). McDaniel discloses that such compositions comprise "a bioactive molecule such as an enzyme composition that retains activity after being admixed with paint." (*Id.* at 0023:2-4).

McDaniel discloses that an aqueous solution thereof can be substantially-free of added surfactant. Specifically, McDaniel discloses: 1.) "In some embodiments, the coating is a multi-pack coating. In particular aspects, the coating is stored in a two to five containers prior to application to the surface. In specific aspects, 0.001% to 100% of the biomolecular com- position, including all intermediate ranges and combinations thereof, is stored in a container of a multipack coating, and at least one additional coating component is stored in another container of a

multipack coating. In some aspects, the container comprising the biomolecular composition further comprises an additional coating component. In particular facets, the additional coating component comprises a preservative, a wetting agent, a dispersing agent, a buffer, a liquid component, a rheological modifier, or a combination thereof. In specific facets, the additional coating component comprises glycerol." (*Id.* at 0083:1-15) and 2.) "In many embodiments, the liquid component comprises water." (*Id.* at 0078:1-2). Thus, the disclosures of McDaniel teach an aqueous solution that can include water and enzyme without any surfactant.

With respect to particle size of bioactive proteins (e.g., enzymes) within a coating formed from a film-forming polymer resin (*i.e.*, a protein-polymer composition), McDaniel discloses: 1.) "As would be known to one of ordinary skill in the art, a coating may comprise insoluble particulate material. Particulate material may comprise a primary particle, an agglomerate, an aggregate, or a combination thereof. A primary particle is a single particle not in contact with a second particle. An agglomerate is two or more particles in contact with each other, and generally can be separated by a dispersion technique, a wetting agent, a dispersant, or a combination thereof. An aggregate is two or more particles in contact with each other, which are generally difficult to separate by a dispersion technique, a wetting agent, a dispersant, or a combination thereof." (*Id.* at 0779:1-12) and 2.) "Of course, processing and purifying techniques may reduce the

particle size by fragmentation of the cell wall and membrane, and it is contemplated that a biomolecule composition of the present invention may be prepared to an average particle size for a specific purpose (e.g., gloss)." (*Id.* at 0788:18-23)

Huynh-Ba ([Ex. 1006] U.S. Patent No. 6,472,493, published October 29, 2002) is directed to "A fast hardening clear coating composition for repairing a clearcoat/colorcoat finish of a vehicle. …" (*Id.* at Abstract:1-2). Huynh-Ba discloses that the coating composition "comprising a film forming binder and an organic liquid carrier, where the binder contains a hydroxyl component comprising a hydroxyl-containing acrylic polymer and a hydroxyl-terminated polyester oligomer, and an organic polyisocyanate crosslinking component, at least portion of which comprises a trimer of isophorone diisocyanate. …" (*Id.* at Abstract:4-10). Huynh-Ba further discloses, "The binder contains two components, a hydroxyl and an organic polyisocyanate crosslinking component, which are capable of reacting with each other to form urethane linkages." (*Id.* at 3:1-4) and that the binder can be a hydroxyl-functionalized acrylate resin (*Id.* at 9:44-10:65).

Bonaventura ([Ex. 1007] U.S. Patent No. 5,998,200, published December 7, 1999) is directed to "a method for preventing fouling of an aquatic apparatus by an aquatic organism which comprises affixing biologically active chemicals to a surface intended for use in contact with an aquatic environment containing said

organism wherein said chemicals possess anti-fouling properties in a bound state." (*Id.* at 2:46-51). To this end, Bonaventura discloses that "The invention involves confinement of a biologically active chemical on or within an inert matrix which is applied to a surface intended for contact with an aquatic environment" (*Id.* at 3:22-25) and that "the attachment and/or growth and development of organisms on a submerged surface may be hindered by use of non-toxic coatings containing combinations of immobilized bioactive species, these being enzymes, enzyme inhibitors, repellants, chelating agents, surfactants or non-metallic toxicants". (*Id.* at 2:51-56). With respect to the inert matrix with which the biologically active chemical is associated, Bonaventura discloses, "When the method of the invention is carried out by affixing the biologically active chemical to the surface by means of a matrix which either incorporates the biologically active material by physically entrapping it in the matrix or which is bound to the biologically active material by a chemical bond (whether a polar interaction, ionic bond or covalent bond), a matrix prepared from a polyurethane polymer is a preferred matrix. Especially preferred are hydrophilic polyurethane prepolymers, since these materials can be used to physically entrap biologically active material by mixing the biologically active material with water by which the prepolymer is polymerized." (*Id.* at 13:20-30).

B. SUMMARY OF GROUNDS OF UNPATENTABILITY

The cited prior art references disclose all the limitations of claims 1-23 of the ’571 Patent and render each claim as a whole obvious and unpatentable under 35 U.S.C. §103(a). Petitioner requests IPR of the claims 1-23 of the ’571 Patent on the grounds set forth in Table 2, shown below, and requests that claims 1-23 be found unpatentable. An explanation of unpatentability under the statutory grounds identified below is provided in the form of detailed descriptions that follow, indicating where each element can be found in the cited prior art, and the relevance of that prior art.

TABLE 2 – GROUNDS OF UNPATENTABILITY

Ground	‘571 Patent	Basis for Invalidity
Ground 1A (G1)	1, 4-6, 14-19, 21	Obvious under §103(a) over Dordick
Ground 1B (G2)	2, 3, 8-11, 13	Obvious under §103(a) over Dordick in view of Adams
Ground 1C (G3)	7, 20, 22, 23	Obvious under §103(a) over Dordick in view of Bonaventura
Ground 1D (G4)	12	Obvious under §103(a) over Dordick in view of Adams and further in view of Bonaventura
Ground 2A (G5)	22, 23	Obvious under §103(a) over McDaniel
Ground 2B (G6)	1-21	Obvious under §103(a) over McDaniel in view of Huynh-Ba

C. DIFFERENT INVALIDITY POSITIONS AGAINST CLAIMS ARE INDEPENDENT, DISTINCTIVE AND NOT REDUNDANT

This Petition uses five (5) references to form two independent and distinct invalidity positions and the grounds of unpatentability thereof against claims 1-23 of the ’571 Patent. The basis of the first invalidity position is Dordick and the basis of the second position is McDaniel. These invalidity positions are selected because they are non-redundant. For example, each one of the invalidity positions provides a uniquely different perspective upon which the patentably distinguishing limitation(s) related to non-ion-pairing of bioactive proteins is taught with respect to other recited limitations. In this respect, these invalidity positions provide the Office and the public with a fuller view of the prior art landscape that was not discussed or duly considered during the original examination of the application from which the ’571 Patent issued (*i.e.*, the ’320 Application).

With regard to the basis of the first invalidity position (*i.e.*, Dordick), the patentably distinguishing “ion-paired limitation” as recited in all of the independent claims is taught by the disclosure of Dordick alone, with additional disclosure of Dordick and at least one other cited reference teaching specific aspects of limitations related to an admixture, an aqueous solution, an emulsion resulting from mixing of the admixture and the aqueous solution, and curing of a curable composition produced by mixing a crosslinker with the emulsion.

With regard to the basis of the second invalidity position (*i.e.*, McDaniel), the patentably distinguishing "ion-paired limitation" as recited in all of the independent claims is taught by the disclosure of McDaniel alone, with additional disclosure of McDaniel and at least one other cited reference teaching specific aspects of limitations related to an admixture, an aqueous solution, an emulsion resulting from mixing of the admixture and the aqueous solution, and curing of a curable composition produced by mixing a crosslinker with the emulsion.

In the spirit of 37 C.F.R. §42.1(b) to facilitate "just, speedy and inexpensive Resolution," Petitioner has diligently minimized the number of references, out of myriad highly relevant references, and the number of invalidity positions. Thus, Petitioner respectfully submits that the invalidity positions presented herein are non-redundant and are the minimum number required to facilitate such just, speedy and inexpensive resolution in this matter.

Rule 37 C.F.R. §42.1(b) also requires just resolution of the unpatentability issues. In this regard, Petitioner respectfully reminds the Office that the absence of full and proper prior art references being cited and applied during the original examination is the underlying reason that led to the issuance of claims 1-23. Claims 1-23 fail to meet the statutory requirements for patentability over available prior art. This Petition is a remedial measure for correcting the mistake in the original examination and is necessitated to prevent the improper enforcement of invalid

patent claims.

Petitioner respectfully submits that the need for just resolution of the unpatentability issues urges the full adoption of all proposed invalidity positions and their associated respective grounds of unpatentability.

VI. DETAILED EXPLANATION OF GROUNDS OF UNPATENTABILITY OF CLAIMS 1-23

A. Basis of Dordick

A POSITA would have been motivated, or would have found it obvious, at the time that the invention was made to combine disclosure (e.g. embodiments) in Dordick with each other and/or the disclosure of Dordick with the disclosure of one or more other references cited in view of Dordick because such disclosures are directed to the same technical field, address similar technical disclosure relating to polymeric coating compositions, and presents motivating and/or suggesting disclosure for such combinations. See Table 2 for specific grounds of unpatentability.

CLAIMS 1 and 8 Preamble [P1] each recite: "A process for preparation of a protein-polymer composite material." Dordick teaches a method of preparing a polymer-protein composite material (Dordick [Ex. 1003] at Abstract:1; 1:20-32; 2:57-60; 3:17-19; 9:44-45; 21:2-3). See Lamb Declaration [Ex. 1008], ¶¶89-99; 122-136.

Element [A1-1] recites, exactly or more broadly: "providing an admixture of a hydroxyl-functionalized acrylate resin, a surfactant and a non-aqueous organic solvent." Dordick teaches an organic solution comprising at least one organic solvent and at a least one surfactant (Dordick [Ex. 1003] at 4:9-12; 6:29-36; 7:19-26; 10:3-5) and teaches that at least one of the one or more solvents can be a non-aqueous organic solvent (*Id*. at 7:39-41; 7:28-34). Dordick also teaches that the organic solution can comprise polymerizable monomer(s) (*Id*. at 6:29-36; 6:62-65; 7:51-53; 7:60-65) and that that a monomer may include an organic solvent or be used as a solvent in the organic solution (*Id*. at 7:23-26; 10:52-56). Furthermore, Dordick teaches that methodologies thereof can employ only already-formed polymers in place of monomers (*Id*. at 11:31-33; 10:54-56; 19:38-46; 19:51-54). Thus, Dordick discloses that the organic solution, which is an admixture, can comprise a polymer, a surfactant and a non-aqueous organic solvent. See Lamb Declaration [Ex. 1008], ¶¶ 62-63.

Claim 8 more broadly recites "a solvent" in the admixture rather than "a non-aqueous organic solvent". The non-aqueous organic solvent taught by Dordick (*Id*. at 7:39-41; 7:28-34) satisfies this broader limitation in Claim 8.

With respect to a polymer of the organic solution being a hydroxyl-functionalized acrylate resin, as recited in Claim 8, Dordick teaches that polymers used in methodologies thereof can contain reactive functional groups

such as carboxylic acids, alcohols, amino groups, or any other suitable reactive group (*Id*. at 20:19-26) and that monomers that are used in the organic solution can be polymerizable acrylates (e.g., methyl methacrylate) (*Id*. at 7:61-8:1). See Lamb Declaration [Ex. 1008], ¶127. The alcohol reactive functional group is well-known to be a hydroxyl functional group when bound to a saturated carbon atom such as that of a polymerized acrylate resin. As previously discussed, Dordick teaches that the organic solution can include polymerized monomers such that the organic solution includes an already-formed polymer (*Id*. at 11:31-33; 10:54-56; 19:38-46; 19:51-54) and that the polymer can be polyacrylate (e.g., poly(methyl)methacrylate, poly(ethylmethacrylate) (*Id*. at 5:22-29; 19:52-55).

Although Dordick discloses such an alcohol reactive functional group and explicitly discloses monomers that are used in the organic solution can be polymerizable acrylates, Dordick does not explicitly teach that the organic solution includes a polymer that is a hydroxyl-functionalized acrylate resin, as recited in Claim 8.

With respect to Claim 8, Adams teaches the polymer resin of curable two component solvent-borne material compositions thereof can be a hydroxyl-functionalized acrylate resin (Adams [Ex. 1004] at 0061:1-12; 0065:1-7; Table 5 (Part 1):hydroxy-functional acrylic copolymer #1). It would have been obvious to

a POSITA at the time that the invention of the '571 Patent was made to modify the polymer of the organic solution taught by Dordick to be a hydroxyl-functionalized acrylate resin as taught by Adams. A motivation for such modification is that Adams teaches that coatings in accordance with the invention thereof are particularly useful as a paint or clearcoat (*Id*. at 0054:1-25) for refinishing automobiles and trucks (*Id*. at 0002:5-6) and Dordick teaches that compositions thereof can be used in paints such as for automobiles (*Id*. at 5:61-66) thereby making it obvious to a POSITA that the Part 1 polymer in the polymeric coating composition of Adams could be substituted for the organic solution polymer of Dordick. See Lamb Declaration [Ex. 1008], ¶¶70, 132-133.

Element [A1-2] of Claim 8 recites: "the solvent having a log P in the range of -0.5-2, inclusive." Dordick teaches that the solvent in the organic solution can be acetone and/or ethyl acetate (*Id*. at 7:28-33). It is well-known that acetone and ethyl acetate both have a respective log P value (i.e., -0.23 and 0.68, respectively) that is within the recited range ('571 Patent [Ex. 1001] at Table 2).

Element [B1] recites: "mixing an aqueous solution containing a bioactive protein with the admixture to produce an emulsion." Dordick discloses an aqueous solution that includes an enzyme (*Id*. at 3:41-43; 9:54-57; 10:13-14; 10:30-31; 9:31-36; Fig. 1) and that the aqueous solution is mixed with the organic solution

to create an emulsion (*Id*. at 10:30-31; 3:40-45; 9:31-36; Fig. 1; 8:37-43; 15:11-31). Dordick teaches that the enzymes within the protein-polymer composites thereof are proteins and that proteins other than enzymes can be used therein (*Id*. at 2:49-56; 5:30-35)

Element [B2] recites: "the aqueous solution is substantially free of surfactant." Dordick teaches an aqueous solution that includes an aqueous buffer solution and enzyme mixed therewith and that does not include any added surfactant that would ionically pair with the enzyme (*e.g.*, *Id*. at FIG. 1 (enzyme in the aqueous phase without any added surfactant); 9:54-57; 11:43-54; 14:13-23; 15:53-63). Moreover, the disclosures of Dordick only disclose inclusion of a surfactant in the organic solution (*e.g.*, *Id*. at FIG. 1; 10:3-8; 11:56-58; 14:23-26; 15:63-64). In fact, Dordick teaches away from there being surfactant in the aqueous solution as an underlying functionality of the methodologies of Dordick is to use surfactant in the organic solution to extract protein from within the aqueous solution (*e.g.*, *Id*. at 10:3-8, 9:54-57, 10:13-14), whereby inclusion of a surfactant in the aqueous solution would be counterproductive to enabling the extraction of the protein from the aqueous phase into the organic solution. See Lamb Declaration [Ex. 1008], ¶¶56, 65-66, 71.

Element [C1] recites, exactly or more broadly: "mixing the emulsion with a polyisocyanate crosslinker to produce a curable composition." Dordick teaches that

the polymer in the organic solution can require cross-linking and that a cross-linker can be used to accomplish such cross-linking (*Id*. at 11:31-35; 10:49-51; 15:11-31; 8:4-14, 6:57-7:6), thereby producing a curable composition. See Lamb Declaration [Ex. 1008], ¶¶29-31, 36-39, 137-138.

Dordick discloses various steps that can be performed after a mixture of the aqueous and organic solutions are mixed (*Id*. at 10:16-62), wherein such mixing would produce the claimed emulsion. However, Dordick explicitly teaches: 1.) the organic solution can include more than one organic solvent (*Id*. at 4:9-12; 6:29; 7:19-26), 2.) the organic solution can include a monomer as one of the solvents (*Id*. at FIG. 1:monomer within organic media(phase), 6:30-35,10:54-56), 3.) polymer can be used in place of the monomer (*Id*. at 11:30-32), 4.) drying the resulting separated enzyme-containing organic phase is optional (*Id*. at 10:38-42), 5.) that it is not practical for all of the aqueous phase to be separated from the organic phase due to incomplete phase separation (*Id*. at 10:16-22), and up to 5% by volume of water can be added to the enzyme-containing organic phase. (*Id*. at 10:49-58). Thus, in view of such teachings of Dordick, a POSITA will understand that even when such separation step is performed, the additional steps of Dordick still yield a mixture of an organic solution including a polymer resin, a surfactant and a non-aqueous organic solvent in combination with an aqueous solution including water and an

enzyme, which when mixed will produce the claimed emulsion. In fact, the '571 Patent explicitly teaches that additional steps can be performed to provide for the addition of one or more additives in at least one of the admixture, the aqueous solution, the emulsion, and the curable composition (*Id*. at 5:28-33)

Accordingly, Petitioner submits that the additional steps taught by Dordick do not preclude a finding of obviousness based on the teachings of Dordick. Tellingly, the transitional term "comprising" in each of the independent claims of the '571 Patent is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("[L]ike the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."); Invitrogen Corp. v. Biocrest Manufacturing, L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); and Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim).

As a separate matter from such additional steps in Dordick not precluding a finding of obviousness based on the teachings of Dordick, a

POSITA would have found it obvious at the time of the invention of the'571 Patent that the need for such separation of the aqueous and organic phases is optional in the case of a methodology that includes already-formed polymer in the organic solution into which the aqueous solution is mixed. For example, in suggesting such a methodology of preparing a protein-polymer composite material without such separation of the of the aqueous and organic phases, Dordick discloses the following: 1.) the organic solution can include more than one organic solvent (*Id*. at 4:9-12; 6:29; 7:19-26), 2.) the organic solution can include a monomer as one of the solvents (*Id*. at FIG. 1:monomer within organic media(phase), 6:30-35,10:54-56), 3.) polymer can be used in place of the monomer (*Id*. at 11:30-32), 4.) when a monomer is used as such a solvent in the organic solution, Dordick's monomer adding step (*Id*. at 10:49-54) can be optional (*Id*. at 10:54-56), and 5.) when polymer is used in place of the monomer, Dordick's polymerizing step (*Id*. at 10:63-11;1) can be omitted (*Id*. at 11:30-32). Thus, even though Dordick does not explicitly teach a method of preparing a protein-polymer composite material without such separation of the aqueous and organic phases, such method would be obvious in view of the teachings of Dordick because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested

in any one or all the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981). See Lamb Declaration [Ex. 1008], ¶¶67-69

With respect to a cross-linker being a polyisocyanate cross-linker, as recited in Claim 8, although Dordick discloses that the cross-linker may be selected from any component that functions to cross-link the polymer-protein composite (*Id*. at 8:4-6; 6:57-7:6), Dordick does not explicitly teach that the cross-linker is a polyisocyanate cross-linker.

Adams teaches the curable two component solvent-borne material compositions thereof can include a polyisocyanate cross-linker (Adams [Ex. 1004] at Table 5 (Part 2): Desmodur N3300A; 0101:1-6, 0104:1-6), that the material compositions thereof can include the presence of other conventional components (Adams at 0054:19-23) and that coating compositions thereof can include usual other additives (*Id*. at 0094:1-16). A POSITA would have recognized at the time of the invention of the ’571 Patent was made that such of other conventional components and/or usual other additives thereof could include proteins and/or enzymes. It would have been obvious to a POSITA at the time that the invention of the ’571 Patent was made to modify the cross-linker mixed with the emulsion taught by Dordick to be a polyisocyanate cross-linker as taught by Adams. A motivation

for such modification is that Adams teaches that coatings in accordance with the invention thereof are particularly useful as a paint or clearcoat (*Id*. at 0054:1-25) for refinishing automobiles and trucks (*Id*. at 0002:5-6) and Dordick teaches that compositions thereof can be used in paints such as for automobiles (*Id*. at 5:61-65) thereby making it obvious to a POSITA that the Part 1 polymer in the polymeric coating composition of Adams could be substituted for the organic solution polymer of Dordick. See Lamb Declaration [Ex. 1008], ¶¶70, 132-133

Element [D1] recites, exactly or equivalently: "curing the polymerizable composition, thereby producing the composite material."

As an initial matter, see Section IV.D.2 regarding Claim 8 lacking proper antecedent basis for the recited term "the polymerizable composition" and see Section IV.D.3 regarding Claim 8 lacking proper antecedent basis for the recited term "the composite material".

Dordick teaches that solvents for use in the organic solution include acetone and ethyl acetate (*Id*. at 7:28-33), both of which are well-known to readily evaporate at or above common ambient temperature (e.g., at or above 70ºF). Dordick also teaches that polymer-protein composites thereof can be used in coatings and that such coatings can be formed directly via the in-situ polymerization (*Id*. at 6:3-6), that a solid polymer material can be formed and that a formation of a solid phase may be helped through use of a crosslinker. (*Id.*

at 6:43-54; 6:58-61; 3:4-10; 6:26-38). With respect to such polymerization, Dordick teaches that polymerization can be initiated by supplying light or electronic beam, radiation, or a combination thereof. (*Id*. at 10:65-11:1). Thus, curing can occur through such evaporation of the solvent in the organic solution of a polymer-protein composite taught by Dordick during use of such polymer-protein composite (e.g., after application of a paint comprising such polymer-protein composite of Dordick) and/or such polymerization and/or crosslinking. See Lamb Declaration [Ex. 1008], ¶¶59

CLAIM 14 Preamble [P1] recites**: "**A process for preparation of a protein-polymer composite material." Dordick teaches a method of preparing a polymer-protein composite material (Dordick [Ex. 1003] at Abstract:1; 1:20-32; 2:57-60; 3:17-19; 9:44-45; 21:2-3). See Lamb Declaration [Ex. 1008], ¶¶89, 100-112.

Element [A1] recites: "providing an admixture of a polymer resin and a non-aqueous organic solvent." Dordick teaches an organic solution comprising at least one organic solvent and at a least one surfactant (Dordick [Ex. 1003] at 4:9-12; 6:29-36; 7:19-26; 10:3-5) and teaches that at least one of the one or more solvents can be a non-aqueous organic solvent (*Id*. at 7:39-41; 7:28-34). Dordick also teaches that the organic solution can comprise polymerizable monomer(s) (*Id*. at 6:29-36; 6:62-65; 7:51-53; 7:60-65) and that that a monomer may include an organic solvent or be used as a solvent in the organic solution (*Id*. at 7:23-26;

10:52-56). Furthermore, Dordick teaches that methodologies thereof can employ only already-formed polymers in place of monomers (*Id*. at 11:31-33; 10:54-56; 19:38-46; 19:51-54). Thus, Dordick discloses that the organic solution, which is an admixture, can comprise a polymer and a non-aqueous organic solvent. See Lamb Declaration [Ex. 1008], ¶¶62-63

Element [B1] recites: "mixing an aqueous solution containing bioactive proteins with the admixture to produce a first component." Dordick teaches an aqueous solution that includes an enzyme (*Id*. at 3:41-43; 9:54-57; 10:13-14; 10:30-31; 9:31-36; Fig. 1) and that the aqueous solution is mixed with the organic solution to create an emulsion (*Id*. at 10:30-31; 3:40-45; 9:31-36; Fig. 1; 8:37-43; 15:11-31). Dordick teaches that the enzymes within the protein-polymer composites thereof are proteins and that proteins other than enzymes can be used therein (*Id*. at 2:49-56; 5:30-35).

Element [B2] recites: "the aqueous solution is substantially free of surfactant." Dordick teaches an aqueous solution that includes only an aqueous buffer solution and enzyme mixed therewith and that does not include any added surfactant that would ionically pair with the enzyme (*e.g.*, *Id*. at FIG. 1 (enzyme in the aqueous phase without any added surfactant); 9:54-57; 11:43-54; 14:13-23; 15:53-63). Moreover, Dordick teaches inclusion of a surfactant in the organic solution (*e.g.*, *Id*. at FIG. 1; 10:3-8; 11:56-58; 14:23-26; 15:63-64). In fact,

Dordick teaches away from there being surfactant in the aqueous solution as an underlying functionality of the methodologies of Dordick is to use surfactant in the organic solution to extract protein from within the aqueous solution (*e.g.*, *Id*. at 10:3-8, 9:54-57, 10:13-14), whereby inclusion of a surfactant in the aqueous solution would be counterproductive to enabling the extraction of the protein from the aqueous phase into the organic solution. See Lamb Declaration [Ex. 1008], ¶¶56, 65-66, 71

Element [C1] recites: "providing a second component comprising a crosslinker." Dordick teaches that the polymer in the organic solution can require cross-linking and that a cross-linker can be used to accomplish such cross-linking (*Id*. at 11:31-35; 10:49-51; 15:11-31; 8:4-14, 6:57-7:6).

Element [D1] recites: "mixing the first component with the second component to produce a curable composition." Dordick teaches that the polymer in the organic solution can require cross-linking and that a cross-linker can be used to accomplish such cross-linking (*Id*. at 11:31-35; 10:49-51; 15:11-31; 8:4-14, 6:57-7:6), thereby producing a curable composition. See Lamb Declaration [Ex. 1008], ¶¶29-31 36-39, 70. See also the discussion above in reference to Claims 1 and 8 relating to 1.) Dordick teaching various steps that can be performed after a mixture of the aqueous and organic solutions are mixed to create an emulsion and 2.) omission of one or more of such various steps.

Element [E1] recites: "curing the curable composition, thereby producing the protein-polymer composite material." Dordick teaches that solvents for use in the organic solution include acetone and ethyl acetate (*Id*. at 7:28-33), both of which are well-known to readily evaporate at or above common ambient temperature (e.g., at or above 70ºF). Dordick also teaches that polymer-protein composites thereof can be used in coatings and that such coatings can be formed directly via the in-situ polymerization (*Id*. at 6:3-6), that a solid polymer material can be formed and that a formation of a solid phase may be helped through use of a crosslinker. (*Id.* at 6:43-54; 6:58-61; 3:4-10; 6:26-38) With respect to such polymerization, Dordick teaches that polymerization can be initiated by supplying light or electronic beam, radiation, or a combination thereof. (*Id*. at 10:65-11:1). Thus, curing can occur through such evaporation of the solvent in the organic solution of a polymer-protein composite taught by Dordick during use of such polymer-protein composite (e.g., after application of a paint comprising such polymer-protein composite of Dordick) and/or such polymerization and/or crosslinking. See Lamb Declaration [Ex. 1008], ¶¶59

CLAIMS 22 and 23 Preamble [P1] each recite, exactly or more broadly: "A curable protein-polymer composite material." Dordick teaches polymer-protein composites that are curable (Dordick [Ex. 1003] at 3:61-4:3; 4:13-17; 5:51-6:13; 8:44-9:30; 6:3-6; 6:43-54; 6:58-61; 3:4-10; 6:26-38; 10:65-11:1). The preamble

of Claim 22 more broadly recites "a protein-polymer composite material" rather than "a curable protein-polymer composite material". The curable protein-polymer composite material taught by Dordick satisfies this broader preamble in Claim 22. See Lamb Declaration [Ex. 1008], ¶¶152-171.

Element [A1] recites, exactly or more broadly: "bioactive proteins dispersed in a curable two component solvent-borne polymer resin[1]." Dordick teaches polymer-protein composites (*Id*. at 3:60-66; 4:13-17; 5:50-6:25; 8:44-9:31). Dordick also teaches that the enzymes within the protein-polymer composites thereof are proteins and that proteins other than enzymes can be used therein (*Id*. at 2:49-56; 5:30-35). Furthermore, Dordick teaches that such polymer-protein composites can comprise an organic solution comprising at least one organic solvent and at a least one surfactant (*Id*. at 4:9-12; 6:29-36; 7:19-26; 10:3-5) and that at least one of the one or more solvents can be a non-aqueous organic solvent (*Id*. at 7:39-41; 7:28-34). Dordick also teaches that the organic solution can comprise polymerizable monomer(s) (*Id*. at 6:29-36; 6:62-65; 7:51-53; 7:60-65) and that that a monomer may include an organic solvent or be used as a solvent in the organic solution (*Id*. at 7:23-26; 10:52-56). Still further, Dordick teaches that

[1] In view of the specification of the '571 Patent, this term is believed to be construed as "a solvent-borne material having a first component, which includes a polymer resin, and a second component that interacts with the first component to alter a characteristic of the polymer resin."

methodologies thereof can employ only already formed polymers in place of monomers (*Id*. at 11:31-33; 10:54-56; 19:38-46; 19:51-54). Thus, Dordick discloses that the organic solution, which is an admixture, can comprise a polymer and a non-aqueous organic solvent. See Lamb Declaration [Ex. 1008], ¶¶62-63, 159, 164-165. See also the discussion above in reference to Claims 1 and 8 relating to 1.) Dordick teaching various steps that can be performed after a mixture of the aqueous and organic solutions are mixed to create an emulsion and 2.) omission of one or more of such various steps.

In regard to the protein-polymer composite material being curable, Dordick teaches that the polymer in the organic solution can require cross-linking and that a cross-linker can be used to accomplish such cross-linking (*Id*. at 11:31-35; 10:49-51; 15:11-31; 8:4-14, 6:57-7:6), thereby producing a curable composition. Moreover, Dordick teaches that solvents for use in the organic solution include acetone and ethyl acetate (*Id*. at 7:28-33), both of which are well-known to readily evaporate at or above common ambient temperature (e.g., at or above 70ºF). Thus, polymer-protein composites as taught by Dordick can be curable through such evaporation of the solvent in the organic solution and/or via the in-situ polymerization (*Id*. at 6:3-6) and formation of a solid polymer material can be aided through use of a crosslinker. (*Id.* at 6:43-54; 6:58-61; 3:4-10; 6:26-38). See Lamb Declaration [Ex. 1008], ¶¶29-31, 36-39.

Element [B1] recites: "the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive." Although Dordick teaches protein particles in the curable protein-polymer composites thereof (*Id.* at 2:49-56; 3:60-66; 4:13-17; 5:30-35; 5:50-6:25; 8:44-9:31), Dordick does not explicitly disclose the average particle size of such protein particles in the curable protein-polymer composite material being in the range of 1 nm to 10 μm (average diameter), inclusive.

However, Bonaventura teaches confinement of a biologically active chemical on or within an inert matrix (e.g., a matrix prepared from a polyurethane polymer) that is applied to a surface of a structure (Bonaventura [Ex. 1007] at 3:22-25; 13:20-37), that acetone or water may be used in preparation of the matrix (*Id.* 19:3-9), and that the biologically active chemical can be an enzyme (*Id*. at 2:51-56; 3:28-33; 4:66-5:2) and that particles of protease (i.e., an enzyme) in a coating thereof has an approximate diameter of 40 angstroms, which equates to a diameter of approximately 4 nm (*Id*. at 5:33-43). Bonaventura also teaches that, in addition to the enzyme, the inert matrix can include a surfactant (*Id*. at 2:51-56; 13:44-48; 34:57-61; 35:55-57). See Lamb Declaration [Ex. 1008], ¶¶50-54, 152, 170-171 and Rozzell Declaration [Ex. 1009], ¶¶50-51

It would have been obvious to a POSITA at the time that the invention of the '571 Patent was made to modify (e.g., perform in a particular manner) one or more

of process steps taught by Dordick (e.g., mixing the aqueous solution, mixing the organic solution, mixing the aqueous solution with the organic solution, selection of constituent component(s) of such step(s)) using modern dispersion techniques well known in the art to arrive at the particle size teaching of Bonaventura (i.e., particle size diameter of approximately 4 nm). A motivation for modifying of Dordick in view of Bonaventura in this manner is that both Dordick (Dordick at 1: 21-26; 18:64-19:8) and Bonaventura (Bonaventura at 5:34-39; 5:42-46; 9:9:-4; 9:14-17; 9:26-29; 6:44-48; Table 2: Presettlement Adhesives– protein & polysaccharide) have an objective or reducing fouling at a surface of a substrate and Bonaventura teaches that particle size of enzyme within a protein-poly matrix thereof influences spacing of enzyme molecules and thus availability for reaction with a fouling organism. See Lamb Declaration [Ex. 1008], ¶¶50-54, 170-171.and Rozzell Declaration [Ex. 1009], ¶¶52-53

Element [C1] recites: "with the proviso that the bioactive proteins are not ion-paired." Dordick teaches an aqueous solution that includes only an aqueous buffer solution and enzyme mixed therewith and that does not include any added surfactant that would ionically pair with the enzyme (*e.g.*, *Id*. at FIG. 1 (enzyme in the aqueous phase without any added surfactant); 9:54-57; 11:43-54; 14:13-23; 15:53-63). Moreover, the disclosures of Dordick only provide for inclusion of a surfactant in the organic solution (*e.g.*, *Id*. at FIG. 1; 10:3-8; 11:56-58; 14:23-26;

15:63-64). In fact, Dordick teaches away from there being surfactant in the aqueous solution as an underlying functionality of the methodologies of Dordick is to use surfactant in the organic solution to extract protein from within the aqueous solution (*e.g.*, *Id*. at 10:3-8, 9:54-57, 10:13-14), whereby inclusion of a surfactant in the aqueous solution would be counterproductive to enabling the extraction of the protein from the aqueous phase into the organic solution. See Lamb Declaration [Ex. 1008], ¶¶56, 65-66, 71

Thus, Dordick teaches that particles of the biomolecules (e.g., proteins and/or enzymes) thereof, which are not ionically bound with an added surfactant within the aqueous solution, are combined with a polymer resin component of the two component solvent-borne polymer resin thereof.

See proposed claim construction in Section IV.D.1 for "bioactive proteins are not ion-paired".

CLAIM 2 recites: "the polymer resin is a hydroxyl-functionalized acrylate resin." See the discussion above for **Element A1-1 of Claim 8** in regard to a polymer of the organic solution being a hydroxyl-functionalized acrylate resin.

CLAIM 3 recites: "the crosslinker is a polyisocyanate." Although Dordick discloses that the cross-linker may be selected from any component that functions to crosslink the polymer-protein composite (*Id*. at 8:4-6; 6:57-7:6), Dordick does not explicitly teach that the cross-linker is a polyisocyanate cross-

linker.

Adams teaches the curable two component solvent-borne material compositions thereof can include a polyisocyanate cross-linker (Adams at Table 5 (Part 2): Desmodur N3300A; 0101:1-6, 0104:1-6). It would have been obvious to a POSITA at the time that the invention of the '571 Patent was made to modify the cross-linker mixed with the emulsion taught by Dordick to be a polyisocyanate cross-linker as taught by Adams. A motivation for such modification is that Adams teaches that coatings in accordance with the invention thereof are particularly useful as a paint or clearcoat (*Id*. at 0054:1-25) for refinishing automobiles and trucks (*Id*. at 0002:5-6) and Dordick teaches that compositions thereof can be used in paints such as for automobiles (*Id*. at 5:61-65), thereby making it obvious to a POSITA that the Part 1 polymer in the polymeric coating composition of Adams could be substituted for the organic solution polymer of Dordick. See Lamb Declaration [Ex. 1008], ¶¶70, 143-144.

CLAIMS 4, 9 and 17 each recite: "the bioactive protein is an enzyme." Dordick teaches that the enzymes within the protein-polymer composites thereof are proteins and that proteins other than enzymes can be used therein (*Id*. at 2:49-56; 5:30-35).

CLAIMS 5, 10 and 18 each recite: "the bioactive protein is selected from the group consisting of: a lectin, an antibody and a receptor." Dordick teaches that,

besides or in addition to enzymes, any other proteins, such as hormones, toxins, antibodies, antigens, lectins, structural proteins, signal proteins, transport proteins, receptors, blood factors, and others can be used in the present invention (*Id*. at 5:30-35).

CLAIMS 6, 11 and 19 each recite: "addition of one or more additives to at least one of: the admixture, the aqueous solution, the emulsion, and the curable composition." Dordick teaches that, besides or in addition to enzymes and any other proteins, additives may be added to the polymer-protein composite (i.e. to the curable composition), and additives can be added during the preparation of the aqueous solution (e.g., a buffer) (*Id*. at 5:30-35, 6:3-6; 9:54-57) and/or the organic solution (e.g., $CaCl_2$) (*Id*. at 5:30-35, 6:3-6; 10:3-29). See Lamb Declaration [Ex. 1008], ¶¶40-43.

CLAIMS 7, 12 and 20 each recite: "the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive." Although Dordick teaches enzymes within protein-polymer composite materials (*Id.* at 2:49-56; 3:60-66; 4:13-17; 5:30-35; 5:50-6:25; 8:44-9:31), Dordick does not expressly teach that the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive. However, Bonaventura teaches confinement of a biologically active chemical on or within an inert matrix

(e.g., a matrix prepared from a polyurethane polymer) that is applied to a surface of a structure (Bonaventura [Ex. 1007] at 3:22-25; 13:20-37), that acetone or water may be used in preparation of the matrix (*Id.* 19:3-9), and that the biologically active chemical can be an enzyme (*Id*. at 2:51-56; 3:28-33; 4:66-5:2) and that particles of protease or other enzyme in a coating thereof have spacing on the surface of up to 1,000 angstroms (100 nm), given a radius for the particles of protease or other enzyme of approximately 20 angstroms, which equates to a diameter of approximately 4 nm (*Id*. at 5:33-46), which is within the recited range in Claims 7, 12 and 20 of the ' 571 Patent. Bonaventura also teaches that, in addition to the enzyme, the inert matrix can include a surfactant (*Id*. at 2:51-56; 13:44-48; 34:57-61; 35:55-57). See Lamb Declaration [Ex. 1008], ¶¶50-54, 152, 176-177, 181 and Rozzell Declaration [Ex. 1009], ¶¶50-51.

It would have been obvious to a POSITA at the time that the invention of the '571 Patent was made to modify one or more of the process steps taught by Dordick (e.g., mixing the aqueous solution, mixing the organic solution, mixing the aqueous solution with the organic solution, selection of constituent component(s) of such step(s)) using modern dispersion techniques well known in the art to arrive at the particle size teaching of Bonaventura (i.e., particle size diameter of approximately 4 nm). A motivation for modifying of Dordick in view of Bonaventura in this manner is that both Dordick (Dordick at 1: 21-26; 18:64-19:8) and Bonaventura

(Bonaventura at 5:34-39; 5:42-46; 9:9:-4; 9:14-17; 9:26-29; 6:44-48; Table 2: Presettlement Adhesives – protein & polysaccharide) have an objective or reducing fouling at a surface of a substrate and Bonaventura teaches that particle size of enzyme within a protein-poly matrix thereof influences spacing of enzyme molecules and thus availability for reaction with a fouling organism. See Rozzell Declaration [Ex. 1009], ¶¶52-53

Separate from the above application of obviousness of Dordick in view of Bonaventura, Petitioner submits that the recitation of dependent Claims 7, 12 and 20 of the'571 Patent is an inherent result of the recited process of the independent claims from which such dependent claims depend (i.e., Claims 1, 8, and 14, respectively). For particular bioactive protein used as a constituent component of a process, the particle size of bioactive protein in a resulting protein-polymer composite material will be dictated by constituent components of such protein-polymer composite material (e.g., polymer resin, surfactant, solvent, etc.) and the manner in which the bioactive protein is dispersed into such constituent components. Thus, without a patentably distinguishing step of a process causing the particle size within the protein-polymer composite material to be achieved and/or a patentably distinguishing bioactive protein or constituent component(s) thereof causing the particle size within the protein-polymer composite material to be achieved, the resulting particle size of the bioactive protein within the protein-polymer composite

material will be inherent to such process, bioactive protein and/or constituent component(s). The '571 Patent presents no such patentably distinguishing step of a process or patentably distinguishing bioactive protein or constituent component(s) and, thus, the language of "the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive" as recited in dependent Claims 7, 12 and 20 of the '571 Patent is inherent to the recited processed in the respective independent claim.

Furthermore, the recitation of "the protein-polymer composite material" in independent Claims 1, 8 and 14 and dependent Claims 7, 12 and 20 finds antecedent basis only in the preamble. As the recited range of average particle size of bioactive protein particles is that in the protein-polymer composite material, the recited language of dependent Claims 7, 12 and 20 only states a result of the claimed process and, thus, does not limit the claim. See *Hoffer v. Microsoft Corp*., No. 04- 1103 (Fed. Cir. Apr. 22, 2005) [affirmed the construction of a "whereby" clause, which "generally states the result of a patented process" and generally does not limit claims.] and *Minton v. Nat'l Ass'n of Secs. Dealers, Inc*., 336 F.3d 1373, 1381 (Fed. Cir. 2003) [holding that "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."]

CLAIMS 13 and 21 each recite: "applying the curable composition to a substrate prior to curing the curable composition." Dordick teaches that protein-

polymer composite materials thereof can be used in paints and coatings (*Id*. at 4:13-17; 6:3-6; 17:53-57; 5:38-49), which are well known to be applied to a substrate prior to curing such paints or coatings.

CLAIM 15 recites: "the curing comprises thermal curing." Dordick teaches that polymer-protein composites thereof can be used in coatings and that such coatings can be formed directly via in-situ polymerization (*Id*. at 6:3-6). With respect to such polymerization, Dordick teaches that polymerization can be initiated by supplying heating (*Id*. at 10:65-67). It would have been well-known by a POSITA at the time that the invention of the '571 Patent that such polymerization initiated by heating would be a method to achieve thermal curing of a curable composition, and such supplying of heat will cause evaporation of non-aqueous organic solvent within the polymer-protein composite. See Lamb Declaration [Ex. 1008], ¶117.

CLAIM 16 recites: "the curing comprises curing using actinic radiation." Dordick teaches that polymer-protein composites thereof can be used in coatings and that such coatings can be formed directly via in-situ polymerization (*Id*. at 6:3-6). With respect to such polymerization, Dordick teaches that polymerization can be initiated by supplying light or electronic beam, radiation, or a combination thereof. (*Id*. at 10:65-11:1). Sources of actinic radiation are well-known to include light and electron beam sources. It would have been well-

known by a POSITA at the time that the invention of the '571 Patent that curing of a curable composition can occur by such actinic radiation, and such actinic radiation (e.g., infrared) will cause evaporation of non-aqueous organic solvent within the polymer-protein composite. See Lamb Declaration [Ex. 1008], ¶119.

B. Basis of McDaniel

A POSITA would have been motivated, or would have found it obvious, at the time that the invention was made to combine disclosure (e.g. embodiments) in McDaniel with each other and/or the disclosure of McDaniel with the disclosure of one or more other references cited in view of McDaniel because such disclosures are directed to the same technical field, address similar technical disclosure relating to polymeric coating compositions, and presents motivating and/or suggesting disclosure for such combinations. See Table 2 for specific grounds of unpatentability.

CLAIMS 1 and 8 Preamble [P1] each recite: "A process for preparation of a protein-polymer composite material." McDaniel teaches a method of preparing a polymer-protein composite material (McDaniel [Ex. 1005] at 0021:3-6; 0023:1-6; 285:1-11; 0083:1-14; 0089:1-4; 0299:1-17). See Lamb Declaration [Ex. 1008], ¶¶199-222.

Element [A1-1] recites, exactly or more broadly: "providing an admixture of a hydroxyl-functionalized acrylate resin, a surfactant and a non-aqueous organic

solvent." McDaniel teaches a coating whose components are provided in a multi-pack format wherein at least one coating component is stored in at least one other container than a container having a biomolecular composition such as a microorganism based particulate material (*Id*. at 0032:5-7; 0083:1-15; 0100:1-18; 0101:1-12; 0359:28-34; Claims 251-255, Claim 307). More specifically, McDaniel teaches a three-pack coating wherein the first container and the second container contain coating components separated to reduced film formation during storage and a third container comprises microorganism based particulate material (*Id*. at 0299:36-42) and wherein the components of such a multi-pack coating are admixed prior to and/or during application (*Id*. at 0299: 2-7). With respect to coating components in the first container, McDaniel teaches that a coating can comprise components such as a binder, a liquid component, a colorizing agent, an additive, or a combination thereof (*Id.* at 0046:5-7; 0297:1-9), and that the binder from which a film can be formed includes various polymer resins such as acrylate binders that have a respective hydroxyl-functionalized group (*Id*. at 0379:1-4, 0454:1-6, 0510:2-5, 0510:10-17, 0512:2-8), that the liquid component can comprise a non-aqueous organic solvent (*Id.* at 0047:9-13; 0051:1-2; 0069:1-6; 0072:1-5; 0072:38-45; 0298:1-5) and the additive can be a surfactant (Id. at 0082:1-5; 0082:12). Thus, as was well-known by a POSITA at the time of the invention in the '571 Patent, McDaniel teaches that

the container of the multi-pack coating that contains the binder can also contain a non-aqueous organic solvent and a surfactant, which together form an admixture comprising a polymer resin, a surfactant and a non-aqueous organic solvent. McDaniel teaches that storing the coating components in separate containers is done to reduce film formation during storage for certain types of coatings (*Id*. at 0299:5-7) and to reduce damage to the microorganism-based particulate material of the present invention by a coating component (*Id*. at 0299:17-21). McDaniel further teaches that film formation can occur by crosslinking of one of a plurality of binders (*Id.* at 0047:19-21; 0454:1-8; 0504:1-8), and that reactive binders may be separated in a two-pack coating until application (*Id.* 0512:1-17), and that a coating may comprise a cross-linker *(Id.* at 0517:7-10). Thus, in the case of a polymer resin that is acted on by a cross-linker to promote film formation, it would be well-known to a POSITA at the time of the invention of the '571 Patent for the polymer resin and the cross-linker to be stored in separate containers (i.e., the polymer resin in the first container and the cross-linker in the second container). See Lamb Declaration [Ex. 1008], ¶205.

Claim 8 more broadly recites "a solvent" in the admixture rather than "a non-aqueous organic solvent". The non-aqueous organic solvent taught by McDaniel (*Id*. at 0072:1-5) satisfies this broader limitation in Claim 8.

Claim 1 more broadly recites "a polymer resin" in the admixture rather

than "a hydroxyl-functionalized acrylate resin". The hydroxyl-functionalized acrylate resin taught by McDaniel (*Id*. at 0379:1-4, 0454:1-6, 0510:2-5, 0510:10-17, 0512:2-8) satisfies this broader limitation in Claim 1.

Element [A1-2] of Claim 8 recites: "the solvent having a log P in the range of -0.5-2, inclusive." McDaniel teaches that the solvent in the first container of the multi-pack coating can be acetone and/or ethyl acetate (*Id*. at 0072:1-3; 0072:17; 0072:36-38). It is well-known that acetone and ethyl acetate both have a respective log P value (i.e., -0.23 and 0.68, respectively) that is within the recited range (e.g., see the '571 Patent [Ex. 1001] at Table 2).

Element [B1] recites: "mixing an aqueous solution containing a bioactive protein with the admixture to produce an emulsion." McDaniel teaches that the biomolecular composition such as a microorganism based particulate material used in coating thereof can be a biomolecule (*Id*. at 0032:5-7; 0090:1-4; 0091:1-4) and that protein and enzymes are examples of such a biomolecule (*Id*. at 0027:1-7; 0023:1-6; 0116:1-13; 0289:1-18). McDaniel also teaches that such the dedicated container of a multi-pack coating in which the microorganism based particulate material is contained also includes a liquid component (*Id*. at 0032:5-7; 0083:8-14; 0299:23-29) and that the liquid component can comprise water (*Id*. at 0078:1-2).

McDaniel explicitly teaches a bioactive molecule such as an enzyme

composition being admixed with paint (*Id*. at 0023:2-4), teaches a three-pack coating, as discussed above in reference to the admixture (*Id*. at 0299:36-43), and teaches that the components of such a multi-pack coating are admixed prior to and/or during application (*Id*. at 0299:2-7; 0299:36-43). McDaniel teaches that the three-pack coating enables mixing of the coating components thereof prior to and/or during application (*Id*. at 0299: 6-7; 0299:36-43).

As discussed above, in the case of a polymer resin that is acted on by a cross-linker to promote film formation, it would be well-known to a POSITA at the time of the invention of the '571 Patent for the polymer resin and the cross-linker to be stored in separate containers (i.e., the polymer resin in the first container and the cross-linker in the second container). With respect to a specific order in which the contents of the containers are mixed together, it would be well-known to a POSITA at the time of the invention of the '571 Patent to mix the polymer resin containing component of the three-pack coating (i.e., the first container) with the container comprising the microorganism based particulate material and water (i.e., the third container) for allowing an emulsion to be produced. See Lamb Declaration [Ex. 1008], ¶211.

Element [B2] recites: "the aqueous solution is substantially free of surfactant." McDaniel teaches that the dedicated container of a multi-pack coating in which the microorganism based particulate is contained also includes

a liquid component (*Id*. at 0032:5-7; 0083:8-14; 0299:23-29) and that the liquid component can comprise water (*Id*. at 0078:1-2). McDaniel presents no disclosure that a surfactant must be added to the dedicated container of the multi-pack coating in which the microorganism based particulate material (i.e., biomolecular composition) and water are contained. Moreover, it would be well-known to a POSITA at the time of the invention of the '571 Patent for a biomolecular composition such as an enzyme or other protein to be in an aqueous solution that consists of only water or only water and a buffer. See Lamb Declaration [Ex. 1008], ¶214.

Element [C1] recites, exactly or more broadly: "mixing the emulsion with a polyisocyanate crosslinker to produce a curable composition."

McDaniel teaches that the three-pack coating, as discussed above in reference to the admixture and aqueous solution (*Id*. at 0299:36-43), enables mixing of the coating components thereof prior to and/or during application (*Id*. at 0299:2-7; 0299:36-43). As discussed above, in the case of a polymer resin that is acted on by a cross-linker to promote film formation, it would be well-known to a POSITA at the time of the invention of the '571 Patent for the polymer resin and the cross-linker to be stored in separate containers (i.e., the polymer resin in the first container and the cross-linker in the second container). With respect to a specific order in which the contents of the containers are mixed together, it

would be well-known to a POSITA at the time of the invention of the '571 Patent to mix the cross linker with the emulsion formed by mixing of the first container and the third container for allowing a cross-linked/curable composition to be produced.

McDaniel teaches a composition having an isocyanate moiety (i.e., cross-linker) is reactive (e.g., crosslinkable) with a binder moiety (i.e., a polymer resin) comprising a chemically reactive hydrogen such as a hydroxyl moiety, and that acrylate binders may be hydroxyl functionalized (*Id*. at 0448:1-17; 0454:1-6, 0510:2-5, 0510:10-17, 0512:2-8) and that such isocyanate moiety can be a polyisocyanate (*Id*. at 0449:3-25). However, McDaniel does not explicitly teach that the hydroxyl functionalized binder moeity (i.e., a polymer resin) and the isocyanate moiety (i.e., a cross-linker) as separate parts of a two-part polymer resin system (i.e., held in two separate containers of a multi-pack coating).

Huynh-Ba teaches that the polymer resin of curable two component solvent-borne material compositions thereof can be a hydroxyl-functionalized acrylate resin (Huynh-Ba [Ex. 1006] at 9:44-10:65; 7:46-55) and that the curable two component solvent-borne material compositions thereof can include a polyisocyanate cross-linker (*Id*. at 11:1-13 (Desmodur N3300A); 5:24-45) that is a separate part of a two-part polymer resin system that is added to the hydroxyl-functionalized acrylate resin (i.e., Part 1 and Part are mixed together). (*Id*. at 11:14-16) Huynh-Ba

also teaches that the coating compositions thereof can include usual other additives (*Id*. at 7:46-55), which a POSITA would have recognized at the time of the invention included proteins and/or enzymes. It would have been obvious to a POSITA at the time that the invention of the '571 Patent was made to combine the two-part mixing methodology of Huynh-Ba with the multi-moiety composition teaching and multi-pack coating teaching of McDaniel. A motivation for such modification is that a POSITA would seek a simple yet effective approach for maintaining the separation of an admixture comprising the hydroxyl-functionalized acrylate resin from the polyisocyanate crosslinker. See Lamb Declaration [Ex. 1008], ¶¶220-221.

Claim 1 more broadly recites "a crosslinker" being mixed with the admixture rather than "a polyisocyanate crosslinker". The polyisocyanate cross-linker taught by Huynh-Ba (*Id*. at 11:1-13 (Desmodur N3300A); 5:24-45) satisfies this broader limitation in Claim 1.

Element [D1] recites, exactly or equivalently: "curing the polymerizable composition, thereby producing the composite material." McDaniel teaches promoting film formation (i.e., curing, cure) of coatings thereof, including by irradiation such as by an ultraviolet and/or infrared electromagnetic radiation source (*Id*. at 0301:1-7, 0301:16-19, 0047:1-22; 0303:23-32).

CLAIM 14 Preamble [P1] recites**: "**A process for preparation of a protein-

polymer composite material." McDaniel teaches a method of preparing a polymer-protein composite material (McDaniel [Ex. 1005] at 0021:3-6; 0023:1-6; 285:1-11; 0083:1-14; 0089:1-4; 0299:1-17). See Lamb Declaration [Ex. 1008], ¶¶199-222.

Element [A1] recites: "providing an admixture of a polymer resin and a non-aqueous organic solvent." See all of the discussion above for **Element A1-1 of Claims 1 and 8**.

Element [B1] recites: "mixing an aqueous solution containing bioactive proteins with the admixture to produce a first component." See all of the discussion above for **Element B1 of Claims 1 and 8**.

Element [B2] recites: "the aqueous solution is substantially free of surfactant." See all of the discussion above for **Element B2 of Claims 1 and 8**.

Element [C1] recites: "providing a second component comprising a crosslinker." See the discussion above for **Element C1 of Claims 1 and 8** regarding McDaniel teaches a composition having an isocyanate moiety is reactive with a binder moiety comprising a chemically reactive hydrogen such as a hydroxyl moiety, and that acrylate binders may be hydroxyl functionalized and that such isocyanate moiety can be a polyisocyanate.

Element [D1] recites: "mixing the first component and the second component to produce a curable composition." See all of the discussion above for

Element C1 of Claims 1 and 8.

Element [E1] recites: "curing the curable composition, thereby producing the protein-polymer composite material." See all of the discussion above for **Element D1 of Claims 1 and 8**.

CLAIMS 22 and 23 Preamble [P1] each recite, exactly or more broadly: "A curable protein-polymer composite material." McDaniel teaches curable composite materials that comprise a polymeric composition such as a paint that has a biomolecular composition such as a proteinaceous molecule dispersed therein (McDaniel [Ex. 1005] at 0003:1-6; 0023:1-6; 0089:1-4; 0032:5-7, 0027:1-7; 0033:1-7; 0289:1-18; 0083:1-14, 0299:1-23; 0299:36-43; 0301:1-4). The preamble of Claim 22 more broadly recites "a protein-polymer composite material" rather than "a curable protein-polymer composite material". The curable protein-polymer composite material taught by McDaniel satisfies this broader preamble in Claim 22. See Lamb Declaration [Ex. 1008], ¶¶186-195.

Element [A1] recites, exactly or more broadly: "bioactive proteins dispersed in a curable two component solvent-borne polymer resin." McDaniel teaches a coating whose components are provided in a multi-pack format (*Id*. at 0032:5-7; 0083:1-15; 100:1-18; 0101:1-12; 0359:28-34; Claims 251-255, Claim 307). More specifically, McDaniel teaches a three-pack coating wherein the first container and the second container contain coating components separated to reduced film

formation during storage and a third container comprises microorganism based particulate material (*Id*. at 0299:36-42) and wherein the components of such a multi-pack coating are admixed prior to and/or during application (*Id*. at 0299:2-7; 0299:36-43). McDaniel teaches curable composite materials that comprise a polymeric composition such as a paint that has a proteinaceous molecule dispersed therein (*Id*. at 0003:1-6; 0023:1-6; 0047:1-4; 0089:1-4; 0032:5-7, 0027:1-7; 0033:1-7; 0289:1-18; 0083:1-10; 0299:1-23; 0299:36-43; 0301:1-4) and that the biomolecular composition such as a microorganism based particulate material used in coating thereof can be a biomolecule (*Id*. at 0032:5-7; 0090:1-4; 0091:1-4) and that proteinaceous molecules such as protein and enzymes are examples of such a biomolecule (*Id*. at 0027:1-7; 0023:1-6; 0116:1-13; 0289:1-18).

Furthermore, McDaniel teaches that the dedicated container of a multi-pack coating in which the biomolecular composition such as a microorganism based particulate material is contained also includes a liquid component (*Id*. at 0032:5-7; 0083:8-14; 0299:23-29) and that the liquid component can comprise water (*Id*. at 0078:1-2). McDaniel presents no disclosure that a surfactant must be added to the dedicated container of the multi-pack coating in which the biomolecular composition and water are contained. Moreover, it would be well-known to a POSITA at the time of the invention of the ’571 Patent for a microorganism based particulate material such as an enzyme or other protein to

be in an aqueous solution that consists of only water or only water and a buffer.

Element [B1] recites: "the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive." McDaniel teaches that insoluble particulate material within a coating may comprise a primary particle, an agglomerate, an aggregate, or a combination thereof (*Id*. at 0779:1-12), that the size of particulate matter in a coating can affect gloss, with smaller particle size generally more conducive for a higher gloss property of a coating and/or film (*Id*. at 0788:9-11), and that a high gloss coating has a dispersion of particulate material of 7.5 Hu to 8.0 Hu where a particle size of 6 μm to $3\mu m$ and $3\mu m$ to 0.1 μm is associated with a dispersion of 7.5 Hu to 7.75 Hu and 7.75 Hu to 8.0 Hu, respectively (*Id*. at 0788:32-36)), and that purified proteinaceous molecules may be used in the composition (*Id*. at 0289:1-18). See Lamb Declaration [Ex. 1008], ¶¶194-195.

Element [C1] recites: "with the proviso that the bioactive proteins are not ion-paired." McDaniel teaches that the dedicated container of a multi-pack coating in which the biomolecular composition such as a microorganism based particulate material is contained also includes a liquid component (*Id*. at 0032:5-7; 0083:8-14; 0299:23-29) and that the liquid component can comprise water (*Id*. at 0078:1-2). McDaniel presents no disclosure that a surfactant must be added to the dedicated container of the multi-pack coating in which the biomolecular

composition and water are contained. Moreover, it would be well-known to a POSITA at the time of the invention of the '571 Patent for a microorganism based particulate material such as an enzyme or other protein to be in an aqueous solution that consists of only water or only water and a buffer.

Thus, McDaniel teaches that particles of the biomolecules (e.g., proteins and/or enzymes) thereof, which are not ionically bound with an added surfactant within the aqueous solution, are combined with a polymer resin component of the two component solvent-borne polymer resin thereof.

See proposed claim construction in Section IV.D.1 for "bioactive proteins are not ion-paired".

CLAIM 2 recites: "the polymer resin is a hydroxyl-functionalized acrylate resin." McDaniel teaches various polymer resins such as acrylate binders that have a respective hydroxyl-functionalized group (*Id*. at 0379:1-4; 0454:1-6, 0510:2-5, 0510:10-17, 0512:2-8).

CLAIM 3 recites: "the crosslinker is a polyisocyanate." McDaniel teaches a composition having an isocyanate moiety (i.e., cross-linker) that is reactive (e.g., crosslinkable) with a binder moiety (i.e., a polymer resin) comprising a chemically reactive hydrogen such as a hydroxyl moiety (*Id*. at 0448:1-17; 0454:1-6, 0510:2-5, 0510:10-17, 0512:2-12) and that such isocyanate moiety can be a polyisocyanate (*Id*. at 0449:3-25).

CLAIMS 4, 9 and 17 each recite: "the bioactive protein is an enzyme." McDaniel teaches curable composite materials that comprise a polymeric composition such as a paint that has a biomolecular composition such as a proteinaceous molecule dispersed therein (*Id*. at 0003:1-6; 0023:1-6; 0089:1-4; 0032:5-7, 0027:1-7; 0033:1-7; 0289:1-18; 0083:1-14; 0299:1-23; 0299:36-43; 0301:1-4) and that the biomolecular composition such as a microorganism based particulate material used in coating thereof can be a biomolecule (*Id*. at 0032:5-7; 0090:1-4; 0091:1-4) and that proteinaceous molecules such as protein and enzymes are examples of such a biomolecule (*Id*. at 0027:1-7; 0023:1-6; 0116:1-13; 0289:1-18).

CLAIMS 5, 10 and 18 each recite: "the bioactive protein is selected from the group consisting of: a lectin, an antibody and a receptor." McDaniel teaches curable composite materials that comprise a polymeric composition such as a paint that has a biomolecular composition such as a proteinaceous molecule dispersed therein (*Id*. at 0003:1-6; 0023:1-6; 0089:1-4; 0083:1-10; 0299:1-23; 0299:36-43) and that biomolecular composition such as a the microorganism based particulate material used in coating thereof can be a biomolecule (*Id*. at 0032:5-7; 0090:1-4; 0091:1-4) and that proteinaceous molecules such as protein and enzymes are examples of such a biomolecule (*Id*. at 0027:1-7; 0116:1-13; 0289:1-18). McDaniel also teaches that biomolecules thereof can be receptors and antibodies (*Id*. at 0033:1-7;

0034:1-8).

CLAIMS 6, 11 and 19 each recite: "addition of one or more additives to at least one of: the admixture, the aqueous solution, the emulsion, and the curable composition." McDaniel teaches that coatings thereof are curable compositions (*Id*. at 0301:1-7, 0301:16-19, 0047:19-22; 0303:23-32), which can include one or more additives (*Id*. at 0046:5-7; 0082:1-14; 0083:8-15). McDaniel also teaches that the container of a multi-pack coating that contains protein and/or enzyme (i.e., biomolecular composition) thereof can include one or more additives (*Id*. at 0083:8-15; 0089:1-4; 0116:1-13; 0299:23-29).

CLAIMS 7, 12 and 20 each recite: "the average particle size of bioactive protein particles in the protein-polymer composite material is in the range of 1 nm to 10 μm (average diameter), inclusive." McDaniel teaches that insoluble particulate material within a coating may comprise a primary particle, an agglomerate, an aggregate, or a combination thereof (*Id*. at 0779:1-12), that the size of particulate matter in a coating can affect gloss, with smaller particle size generally more conducive for a higher gloss property of a coating and/or film (*Id*. at 0788:9-11), and that a high gloss coating has a dispersion of particulate material of 7.5 Hu to 8.0 Hu where a particle size of 6 μm to 3μm and 3μm to 0.1 μm is associated with a dispersion of 7.5 Hu to 7.75 Hu and 7.75 Hu to 8.0 Hu, respectively (*Id*. at 0788:32-36), and that purified proteinaceous molecules may be used in the composition (*Id*.

at 0289:1-18).

CLAIMS 13 and 21 each recite: "applying the curable composition to a substrate prior to curing the curable composition." McDaniel teaches applying coatings thereof to surfaces (*Id*. at 0300:1-12) followed by curing of such coatings (*Id*. at 0301:1-4).

CLAIM 15 recites: "the curing comprises thermal curing." McDaniel discloses thermal curing of coatings thereof (*Id*. at 0301:1-19)

CLAIM 16 recites: "the curing comprises curing using actinic radiation." McDaniel teaches promoting film formation of coatings thereof by irradiation such as by an ultraviolet and/or infrared electromagnetic radiation source (*Id*. at 0301:1-7; 0301:16-19; 0047:19-22; 0303:23-32). Such sources of actinic radiation are well-known in the art promote cure of coatings (e.g., UV radiation or infrared radiation).

VII. CONCLUSION

This Petition demonstrates a reasonable likelihood that Petitioner will prevail in its challenge of patentability for claims 1-23 of the '571 Patent. It is respectfully requested that a trial for *inter partes* review of the '571 Patent be instituted and claims 1-23 thereof be canceled. This would prevent Patent Owner from claiming technology already known in the prior art before its belated patent filing, and from asserting invalid patent claims to exclude others.

Dated: January 4, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

Pursuant to 37 C.F.R. §42.24 *et seq*., the undersigned certifies that this Petition complies with the 14,000-word type-volume limitation. This Petition contains 13922 words, excluding the parts of the Petition exempted.

Dated: January 4, 2017

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *inter partes* review of U.S. Patent No. 8,252,571, including all Exhibits, was served on January 4, 2017 via United States Postal Service Express delivery directed to the firm of record for the '571 patent as shown in USPTO PAIR at the following address:

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