UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner

v.

CHUGAI PHARMACEUTICAL CO., LTD.,
Patent Owner

Inter Partes Review No. IPR2017-01357
Patent No. 7,332,289 B2
Issued: February 19, 2008
Filed: March 11, 2002

Title: METHOD OF PURIFYING PROTEIN

DECLARATION OF TODD M. PRZYBYCIEN, Ph.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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LIST OF EXHIBITS

Exhibit	Description
1001	Takeda et al., U.S. Patent No. 7,332,289 B2, "Method of Purifying Protein," (issued Feb. 19, 2008) ("the '289 patent")
1003	International Publication No. WO 95/22389 to Shadle et al. ("WO '389")
1004	European Application No. 02703958.5, published as EP 1380589 ("EP '589")
1005	Excerpts from the Prosecution File History of U.S. Patent No. 7,332,289
1006	Excerpts from the Prosecution File History of European Application No. 02703958.5, published as EP 1380589
1007	Formulas and Calculations Appendix prepared by Todd M. Przybycien on May 15, 2017
1008	Shadle et al., U.S. Patent No. 5,429,746, "Antibody Purification" (issued Jul. 4, 1995) ("the '746 patent")
1009	Robert K. Scopes, Protein Purification: Principles and Practice, 21-71, 236-252 (1987) ("Scopes")
1010	Jerry M. Martin et al., "Cartridge Filtration for Biotechnology," in Bioprocessing Engineering: Systems, Equipment and Facilities (Bjorn K. Lydersen et al., eds.) 317-370 (1994) ("Martin")
1013	Alexander Apelblat and Josef Barthel, "Conductance Studies on Aqueous Citric Acid," Z. Naturforsch 46(a):131-140 (1991) ("Apelblat I")
1015	Gerald D. Fasman, Practical Handbook of Biochemistry and Molecular Biology, 545-549, 554 (1989) ("Fasman")
1018	CRC, Handbook of Chemistry and Physics, 61st Edition, F-118 (1980) ("CRC Handbook")

I, Todd M. Przybycien, Ph.D., hereby declare as follows:

I. INTRODUCTION

1. My name is Todd M. Przybycien, and I have been retained by counsel for Pfizer, Inc. ("Petitioner") in connection with its request for *inter partes* review of U.S. Patent No. 7,332,289 B2 ("the '289 patent"). I submit this declaration to address the issue of whether claims 1-8 and 13 of the '289 Patent (the "Challenged Claims") are invalid in light of disclosures in the prior art.

A. Education and experience

2. I am a chemical engineer with more than 25 years of experience in bio-processing and applied biophysics. At present, I am a Professor in the Departments of Chemical Engineering and Biomedical Engineering at Carnegie Mellon University. My education and professional experience are outlined below.

3. I received my B.S. in Chemical Engineering and A.B. in Chemistry from Washington University in St. Louis in 1984. I attended California Institute of Technology for graduate education, receiving M.S. and Ph.D. degrees in chemical engineering in 1986 and 1989. My Ph.D. thesis work involved investigation of protein precipitation as a purification technique and involved the extensive study of the serine protease chymotrypsin, with associated protease inhibition assays, in both solution and precipitate phases. I worked for about two years in the Purification Process Development Group at Monsanto Agricultural Company as a Senior Research

Engineer, before joining Rensselaer Polytechnic Institute as an Assistant Professor in 1991. I came to Chemical Engineering at Carnegie Mellon in 1998 as an Associate Professor with Tenure, was promoted to the rank of Professor in 2002 and served as the (founding) Head of Biomedical Engineering from 2002-2008.

4. My research group's current interests include several research projects in the area of the downstream bioprocessing of recombinant therapeutic proteins. These projects include the development of new protein A affinity chromatography media with enhanced specificity for monoclonal antibodies (mAbs), the development of new modes of operation of Protein A affinity chromatography to purify mAb subspecies, or variants, which vary in their distribution of charged residues or carbohydrate modifications, and the development of new continuous precipitation technologies for the capture of high concentration recombinant therapeutic proteins such as mAbs. Prior bioprocessing-related projects have included work on protein behavior in chromatographic, precipitation and filtration processing environments. My other research interests include drug delivery technologies, water purification technologies and medical device development for the early detection of bedsores.

5. Of my nearly 60 regular journal papers, I have published 20 papers related to the downstream bioprocessing and purification of proteins by chromatographic, precipitation and filtration techniques. I have also delivered 59 invited

presentations, out of a total of nearly 130 invited presentations, related to the downstream processing of proteins at national and international technical conferences, at biotechnology companies and at universities around the world; I have a similar number of contributed presentations to national and international conferences.

6. I currently serve on the editorial boards of *Chemical Engineering Progress* and *Separation Science and Technology* and was previously an Associate Editor for *Biotechnology and Bioengineering*. I have consulted for eleven different national and multi-national biotechnology companies. I hold an Adjunct Professor appointment at the Department of Biotechnology at the Instituto Tecnologico y de Estudios Superiores de Monterrey (ITESM), Monterrey, Mexico and have been an Erskine Fellow in the Department of Chemical and Process Engineering at the University of Canterbury, Christchurch, New Zealand. I am currently a member of the governing board of the Recovery of Biological Products Conference Series, a member of the managing board of the Society for Biological Engineering, and a member of the executive committee of the Division of Biochemical Technology of the American Chemical Society. In 2004, I served as chair of the Food, Pharmaceutical and Biochemical Engineering division of the American Institute of Chemical Engineers. I have co-organized three international conferences on downstream bioprocessing.

7. I have been recognized for my professional achievements by election as a Fellow of the American Institute of Chemical Engineers and the American Institute for Medical and Biological Engineering. I received a Faculty Early Career Development Award from the National Science Foundation and the Camille Dreyfus Teacher-Scholar Award from the Dreyfus Foundation.

8. My *curriculum vitae* is attached hereto and marked as attachment A.

B. Scope of work

9. The opinions expressed in this report are based upon my knowledge of biochemical engineering. I have also reviewed the ’289 patent, its prosecution history, and other documentation referenced in this declaration.

10. I am being compensated at my usual rate of $750 per hour for my independent review and analysis of the ’289 patent, the prior art, and certain other documents. My compensation is in no way contingent on the substance of my opinions or the outcome of this proceeding.

II. SUMMARY OF OPINIONS

11. The alleged invention of the ’289 patent is a method of removing DNA contaminants in an antibody-containing sample that comprises the following four purification steps: (1) applying affinity chromatography on Protein A or G; (2) eluting the antibody with an acidic aqueous solution of low conductivity that has a molarity of 100 mM or less; (3) neutralizing the eluate to form particles by adding a

buffer to raise the pH to 4–8, where the molarity of the neutralized eluate is 100 mM or less; and (4) removing the particles to thereby remove DNA contaminants. *See* Ex. 1001, 12:48-58. Each of these steps and process conditions was known, described, and/or present in prior art purification methods before 2001.

12. As discussed in further detail below, every element of the claimed invention was disclosed, either expressly and/or inherently, in a single prior art reference published in 1995, which thus anticipates claims 1–8, and 13 of the ’289 patent. Independently, each of claims 1–8, and 13 of the ’289 patent would have been obvious to a person of ordinary skill in the art (“POSA”) before the 2001 effective filing date of the claimed invention.

13. Claims 1-8 and 13 are anticipated by International Publication No. WO 95/22389 to Shadle et al. (“WO ’389,” Ex. 1003). The very first Example IA in WO ’389 anticipates the claims of the ’289 patent because it teaches to a POSA a process of purifying antibody proteins by removing DNA contaminants that either expressly or inherently discloses each of the four claimed purification steps of the ’289 patent.

14. Claims 1–8, and 13 are also rendered obvious by the teachings of WO ’389. Based on the disclosure of the purification process in WO ’389, it would have been obvious to a POSA to practice and arrive at each of the claimed process steps recited in the ’289 patent with a reasonable expectation of success. This is because

the claims of the ’289 patent do no more than recite conducting a known process at known parameters to achieve a predictable result.

III. LEGAL STANDARDS USED IN MY ANALYSIS

15. I am not a patent attorney, nor have I independently researched patent law. Counsel for Petitioner have explained certain legal standards to me that I have relied upon in forming my opinions set forth in this declaration.

A. Prior art

16. I have been informed that the law provides certain categories of information, known as prior art, that may be used to invalidate a patent claim. I have also been informed that the reference materials I discuss in this declaration are prior art to the ’289 patent, at least because they would have been available to members of the public as of March 9, 2001. In fact, I understand that the prior art references on which I have relied in forming my opinions were published more than one year before March 9, 2001, and were thus available to a POSA as of March 9, 2000 (what I understand to be referred to as the “critical date” for the ’289 patent). I also understand that, in certain circumstances, references cited to show a universal fact need not be available as prior art before applicant’s filing date. I understand that such facts include the characteristics and properties of a material or a scientific truism.

B. Anticipation

17. I have been informed and understand that, pursuant to 35 U.S.C. § 102, a person is not entitled to a patent if the proposed invention was patented or described

in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for a patent in the United States.

18. I have been informed and understand that a patent claim is invalid as anticipated if each and every element set forth in the claim is found, either expressly or inherently, in a single prior art reference. An anticipatory prior art reference must also be enabling such that it provides a description to a POSA for practicing the claimed invention based on the reference, without undue experimentation.

19. I have been informed and understand that a prior art reference may anticipate without expressly disclosing every limitation of the claimed invention if any limitation that is not expressly disclosed is nonetheless necessarily present, or inherent, in that reference. Additional references or evidence may be used to confirm the contents of the anticipating prior art reference. A reference may anticipate even when the relevant properties of the missing limitation were not appreciated at the time.

20. I have been informed and understand that, in judging the enablement of an anticipatory prior art reference, courts presume that both prior art publications and patents are enabled. That presumption may be overcome by a patentee by providing persuasive evidence of non-enablement. Factors relevant for analyzing whether experimentation is undue, called the Wands Factors, include: (a) the breadth

of the subject matter that must be enabled, (b) the nature of the invention, (c) the state of the prior art, (d) the level of ordinary skill in the art, (e) the level of predictability in the art, (f) the amount of direction provided by the inventor, (g) the existence of working examples, and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

C. Obviousness

21. I understand from counsel that even if every element of a claim is not found explicitly or implicitly in a single prior art reference, and thus anticipated, U.S. patent law (specifically, 35 U.S.C. § 103) forbids the issuance of a patent when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the claimed invention was made to a person having ordinary skill in the art to which said subject matter pertains. For purposes of obviousness, I understand that a POSA may rely on a single prior art reference, or multiple references in combination.

22. I also understand that obviousness is a factual inquiry, where the following factors guide the analysis:

(a) determining the scope and content of the prior art;

(b) determining the differences between the prior art and the claimed invention;

(c) resolving the level of ordinary skill in the art; and

(d) considering any secondary considerations of non-obviousness.

23. I further understand that the issue of obviousness is determined with reference to a hypothetical person having "ordinary" skill in the art. The POSA is not the inventor, but an imaginary being possessing "ordinary skill in the art."

24. I additionally understand that a POSA is not an automaton, but a person of ordinary creativity in his or her field. He or she generally thinks along the line of conventional wisdom in the art during the time period an invention took place. He or she is assumed to be aware of all relevant prior art at the time an invention took place. The POSA would have also understood and considered design incentives and market forces that would prompt a person to seek variations of a product known to have a particular utility in his or her area of expertise.

25. I also understand that rationales that may support a conclusion of obviousness include, among others: (a) simple substitution of one known element for another to obtain predictable results; (b) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (c) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (d) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

26. Finally, I understand that evidence of secondary considerations should be considered when offered in an obviousness analysis. Secondary considerations of nonobviousness include commercial success, long-felt but unsolved needs, failure of others, copying, unexpected results, industry acclaim, and skepticism of others. To overcome a *prima facie* case of obviousness, the patentee must first establish a factual basis for the secondary considerations, and then establish a nexus between the secondary considerations and the claimed invention. There is no nexus unless the offered secondary consideration actually results from something that is both claimed and novel in the claim.

D. Person of Ordinary Skill in the Art (POSA)

27. It is my understanding that the ’289 patent claims priority to Japanese Application No. 2001-067111, which was filed on March 9, 2001. Without conceding that this priority claim is valid, I am using March 9, 2001, as the relevant date for analysis of the level of skill and knowledge of a POSA. My opinions would not materially change if the relevant date for analyzing the skill and knowledge of a POSA were March 9, 2000.

28. The fields of study relevant to the ’289 patent include those concerning protein purification and other related purification processes. By 2001, protein purification was well-practiced for many years, and as such was a mature field. Such purification processes typically can involve the collaborative work of professionals

in many disciplines, including biochemistry, process chemistry, protein chemistry, chemical engineering and biochemical engineering, among others.

29. Individuals who routinely work in the area of protein purification typically have a high level of graduate and/or post-graduate education in their given discipline. The POSA relevant to the '289 patent would have a corresponding high level of education, at least a graduate degree, such as a Ph.D., and several years of postgraduate training or practical experience in a relevant discipline such as biochemistry, process chemistry, protein chemistry, chemical engineering and/or biochemical engineering, among others, and an appreciation of the various scientific and practical factors that relate to the protein purification process. Such a person would also understand that protein purification is a multidisciplinary field, and could take advantage of the specialized skills of others using a collaborative approach. I satisfy this definition of a POSA, and also satisfied that definition as of March 2000 and March 2001.

IV. STATE OF THE ART AS OF MARCH 2001

30. Due to advances in gene recombinant technology by 2001, it was possible to prepare and develop specific proteins for use in recombinant antibody drugs. *See* Ex. 1001, 1:13-17. Generally, to produce the recombinant product, genes encoding proteins such as antibodies may be cloned by incorporating DNA sequences coding for the desired regions of the polypeptide into a recombinant DNA vehicle

(e.g., vector) and transforming or transfecting suitable prokaryotic or eukaryotic hosts. Ex. 1003, 7. The vector directs the production of the product encoded by the DNA sequence of interest in the host cell. *Id.* at 8. Such recombinant techniques were well known to a POSA decades before March 2001. *Id.* at 7.

31. After the recombinant product is produced, it is desirable to recover the product. *Id.* at 9. The goal of protein purification is to provide a protein product that is essentially free of other proteins, and also to eliminate or reduce to acceptable levels other undesired materials—host cell contaminants, protein aggregates, mis-folded species, DNA, RNA, potential pyrogens and the like. *Id.* Specifically for host DNA and contaminant DNA associated with viral contamination, under existing World Health Organization ("WHO") criteria, it was understood before March 2001 that the amount of DNA in biological drugs should not exceed 100 pg DNA/dose. Ex. 1001, 1:18-24. Commonly used methods to purify recombinant proteins while removing contaminants included filtration and column chromatography (*e.g.*, affin-ity chromatography, hydrophobic interaction chromatography, and ion exchange chromatography) process steps. Ex. 1003, 15.

32. Preliminary separation processes such as depth prefilters, centrifuges, cross-flow microfilters, settling, or even immobilized cell bioreactors, are used to remove cell debris but are typically not capable of producing a sterile or cell- and debris-free effluent in recombinant production processes. Ex. 1010, Martin at 27,

30. Secondary filtration later in the purification process is required to further clarify and sterilize the collected sample by removing residual cells, cell debris, bacterial contaminants, and particulate impurities. *Id.* at 27. Absolute removal of particulate solids from the process stream, including sterile filtration, also serves as an essential prefiltration/protection step for downstream chromatography and ultrafiltration steps. *Id.* Filtration can extend the service life and protect more costly tangential flow microfiltration ("TFF") and ultrafiltration ("UF") membrane systems and chromatography columns. *Id.* at 30. Solvents, buffer solutions, and other fluids entering a bioprocess must be sterile filtered to maintain aseptic conditions, and particulate impurities must be removed to prevent premature plugging. *Id.* In most cases, a 0.2-μm-rated sterilizing-grade membrane filter is employed as the fluid filter. *Id.*

33. Affinity chromatography is used to purify a protein of interest from other proteins produced in a cell. Affinity chromatography exploits a reversible interaction between the target protein and a specific ligand (i.e., a molecule that is able to bind to a complementary site in the target protein by weak interactions such as ionic bonds, hydrogen bonds, Van der Waals interactions, and hydrophobic effects) that is coupled to a chromatography matrix in a column. Protein A is a cell wall protein from the bacterium *Staphylococcus aureus* that binds with high affinity to

the Fc (fragment crystallizable) region of antibodies. Protein A affinity chromatography was well-established as a standard purification method for antibodies in industry for decades prior to March 2001.

34. During protein A affinity chromatography, protein A that has been immobilized on a column is used to capture target proteins that have a C_H2/C_H3 region. The captured proteins are separated from the other cellular proteins, which do not have a C_H2/C_H3 region, and therefore can be washed away. The captured proteins are then extracted from the column by elution. Elution is the process of extracting one material from another by washing with a solvent. The solvent used to separate materials in elution is known as an eluent. The captured protein is collected in the eluate, which is the solution of the absorbed material in the eluent that emerges from the chromatography column during the process of elution.

35. Other common column chromatography process steps include hydrophobic interaction chromatography ("HIC"), which separates protein molecules using the properties of hydrophobicity, the physical property of a molecule that is seemingly repelled from a mass of water. Ex. 1003, 5. In this method, proteins containing both hydrophilic and hydrophobic regions are applied under high salt buffer conditions to an HIC column that has hydrophobic ligands attached to a matrix. *Id.* The salt in the buffer (usually ammonium sulfate) reduces the solvation of sample solutes and exposes the hydrophobic regions along the surface of the protein

molecule. This facilitates the adsorption of these hydrophobic regions to the hydrophobic areas on the solid support and precipitates proteins out of the solution. *Id.*

36. In ion exchange chromatography, charge-charge interactions between proteins and the charges immobilized on resin in a column are exploited. *Id.* at 4. Ion exchange chromatography can be subdivided into cation exchange chromatography, in which positively charged ions bind to a negatively charged resin; and anion exchange chromatography, in which the binding ions are negative, and the immobilized functional group is positive. *Id.*

V. THE '289 PATENT

37. The '289 Patent issued on February 19, 2008, from U.S. Application No. 10/471,374 ("the '374 Application"), which is the U.S. National Stage Application of International Application No. PCT/JP02/02248 filed on March 11, 2002. The '374 Application's national stage entry date under 35 U.S.C. § 371 was September 9, 2003. The '374 Application claims priority to a foreign application, Japanese Application No. 2001-067111 ("JP '111 Application"), which was filed on March 9, 2001. European Application No. 02703958.5, published as EP 1380589 ("EP '589") (Ex. 1004), among other foreign counterparts, also claims priority to the JP '111 Application. The inventors listed for each of these applications and patents are Kozo Takeda and Norimichi Ochi.

38. Each of these applications and patents appear to be assigned to Chugai Seiyaku Kabushiki Kaisha ("Chugai"), also known as Chugai Pharmaceutical Co., Ltd. The assignment of the '374 Application by the inventors to Chugai is located at reel/frame 015129/0599 of the U.S. Patent & Trademark Office's patent assignment database.

A. Claims

39. The '289 patent contains 13 claims directed to purification methods for removing contaminant DNA from antibody containing samples. Claim 1 is the sole independent claim, and claims 2-8 and 13 ultimately depend from claim 1. Claim 1 is reproduced below:

> 1. A method for removing contaminant DNA in an antibody-containing sample, which comprises the followings steps:
> 1) applying the antibody-containing sample to affinity chromatography on Protein A or Protein G;
> 2) eluting the antibody with an acidic aqueous solution of low conductivity having a molarity of 100 mM or less;
> 3) neutralizing the eluate from step (2) to form particles by addition of a buffer to raise the pH to 4 to 8, wherein the molarity of the neutralized eluate is 100 mM or less; and
> 4) removing the particles to thereby remove contaminant DNA from the antibody-containing sample.

Ex. 1001, 12:45-58.

40. Claim 2 further recites that "the acidic aqueous solution of low conductivity has a molarity of 50 mM or less." *Id.* at 12:59-61. Claim 3 further recites that "the acidic solution of low conductivity is selected from the group consisting of aqueous solutions of hydrochloric acid, citric acid and acetic acid." *Id.* at 12:62-65. Claim 4 depends on claim 3 and further recites that "the acidic aqueous solution has a pH of 1.5 to 3.9." *Id.* at 12:66-67. Claim 5 further recites that "the contaminant DNA is present at a DNA concentration of 22.5 pg/ml or less in the treated sample containing an antibody." *Id.* at 13:1-3. Claim 6 further recites that "the buffer is an aqueous solution of Tris." *Id.* at 13:4-5. Claim 7 further recites that "the buffer is added to raise the pH to 4.3 to 7.5." *Id.* at 13:6-7. Claim 8 further recites that "the antibody is a humanized monoclonal antibody." *Id.* at 13:8-9. Claim 13 further recites that "the particles are removed by filtration through a filter." *Id.* at 14:9-10.

B. Specification

41. The specification of the '289 patent describes a protein purification method where "a sample containing a physiologically active protein is converted into an acidic aqueous solution of low conductivity, preferably by eluting the sample from Protein A/G affinity chromatography with an acidic aqueous solution of low conductivity." Ex. 1001, 5:23-27. The specification describes an "acidic aqueous solution of low conductivity" as follows:

> an aqueous solution of pH 1.5 to pH 3.9, preferably-of pH 2.0 to pH 3.9, more preferably of pH 2.0 to pH 3.0, which has a molarity of 0 to

> 100 mM, preferably 0 to 50 mM, more preferably 0 to 30 mM, or has an ionic strength of 0 to 0.2, preferably 0 to 0.12, or has a conductivity of 0 to 300 mS/m, preferably 0 to 200 mS/m, more preferably 0 to 150 mS/m.

Id. at 5:29-35. The specification further states that "[t]he acidic aqueous solution may be selected from aqueous solutions of hydrochloric acid, citric acid, acetic acid and other acids." *Id.* at 5:35-37. Next, the resulting sample is neutralized by addition of a buffer to raise the pH to a neutral level. *Id*. at 5:45-46. The '289 patent further explains that "[a] neutral level will vary depending on the type of physiologically active protein or antibody to be purified," and "[i]t usually ranges from pH 4 to pH 8, preferably pH 4.3 to pH 7.5, and more preferably pH 4.5 to pH 7.5." *Id.* at 5:54-58. According to the specification of the '289 patent, the range of conditions identified above will result in the production of particles. *Id.* at 6:4-7 ("[T]he solution neutralized to a neutral pH level in the above stage, in turn, produces particles (i.e., becomes clouded)."); 1:62-67 (after neutralization, the solution is "then filtered through a filter to remove the resulting particles."); 4:60 ("removing the resulting particles").

42. The '289 patent also explains how the particles that will form in the buffer solution contain DNA contaminants:

> Without being bound by any particular theory, the inventors of the present invention estimate that each of these particles is a conjugate formed

> between physiologically active protein and DNA. Particle removal by filtration results in a small loss of physiologically active protein because it is removed in the form of DNA-physiologically active protein conjugates.

Id. at 6:16-19.

43. The specification of the ’289 patent further describes how the formed particles with DNA contaminants are removed by the use of a filter, resulting in the removal of DNA from the protein sample:

> These particles may be removed by filtration through a filter to ensure efficient removal of contaminant DNA. Examples of a filter available for filtration include, but are not limited to, a 1.0-0.2 μm Cellulose Acetate Filter System (Corning) or TFF.

Id. at 6:5-22.

C. Relevant prosecution history

1. The ’289 patent prosecution history

44. Applicant Chugai (“Applicant”) submitted the ’374 Application to the USPTO on September 9, 2003. In an Office Action dated October 10, 2007, the Examiner rejected the pending claims as invalid under 35 U.S.C. § 102(b) (Tsuchiya et al. (EP 1020522), Sun et al. (US Patent No. 5,777,085) or Gourlie et al. (US Patent No. 5,808,033)), and under 35 U.S.C. § 103(a) (Tsuchiya et al. in view of Shibuya et al. (US. Patent No. 6,406,909), or Sato et al. (US Patent No. 6,903,194)). *Id.* at 46-52.

45. In response, Applicant amended the claims to read as follows:

> 3. A method for removing contaminant DNA in an antibody-containing sample, which comprises the followings [*sic*] steps:
>
> 1) applying the antibody-containing sample to affinity chromatography on Protein A or Protein G to elute the antibody with an acidic aqueous solution of low conductivity having a molarity of 0 to 100mM;
>
> 2) neutralizing the resulting elate [*sic*] by addition of a buffer to raise the pH to ~~a neutral level~~ 4 to 8, wherein the molarity of the neutralized solution is 0 to 100mM; and
>
> 3) removing the resulting particles.

Id. at 31-32. Applicant concurrently argued:

> [S]ome of the characteristic features of the present invention for removing contaminant DNA from an antibody-containing sample are that an acidic aqueous solution of low conductivity having a molarity of 0 to 100 mM is used, and the resulting eluate is neutralized by addition of a buffer to raise the pH to 4 to 8 and the molarity of the neutralized solution is 0 to 100mM. Thus, satisfying each of the limitations, namely the conductivity and the pH range, is critical to the present invention . . . .

Id. at 35 (emphasis in original). Applicant further distinguished the prior art cited and relied on by the Examiner by arguing that none of the references "disclose or make obvious the critical feature of the present invention that the molarity of the

neutralized solution must be 0 to 100 mM." *See id.* at 40. More specifically, Applicant argued that "[t]hus, it is recognized that no DNA particle was precipitated in this [prior art Tsuchiya] example because of its higher conductivity, i.e. of a molarity of over 0.1M . . . . Applicants submit that no such particles are formed during the procedure of Tsuchiya because the conditions described in the disclosure and carried out in the examples are fundamentally different from those stipulated in applicants' claims and required according to the present invention." *See id.* at 37-38.

46. In a Final Rejection dated May 2, 2007, the Examiner withdrew the prior art-based rejections, but rejected the claims under 35 U.S.C § 112, first and second paragraphs. *Id.* at 26-30. In response, Applicant amended the claims by changing the molarity limitations to "100 mM or less." *Id.* at 15. In subsequent interviews and communications discussing claim amendments proposed by the Examiner, Applicant responded:

> In step (3) of the examiner's newly proposed claim, "neutralized solution" is amended to "buffer", and as a result, the limitation of molarity 100mM or less is directed to a buffer used in the step. However, we believe that the molarity of the buffer should not be limited to 100mM or less.
>
> As we explained in the comments we provided for responding to previous official actions, an important feature of the present invention is to adjust the pH value of the solution, the eluate, to from 4 to 8 while

> maintaining the molarity of the solution at 100 mM or less, whereby DNA contaminants can be effectively removed as particles.
>
> The purpose of the use of a buffer is to adjust the pH of the solution, and since the amount of the buffer used is very small compared with that of the solution to which the buffer is added, the effect of the molarity of the buffer to the molarity of the whole solution is extremely small. In connection with this point, we would like to point out that use of a small amount of a buffer solution to modulate a pH value of a solution of a relatively large volume is well known in this technical field.
>
> Therefore, the molarity of the buffer solution itself is not critical in the present invention as long as the molarity of the solution is 100mM or less.

Id. at 12-13 (emphasis in original). The Examiner allowed the application on October 5, 2007. *Id.* at 5-8. The '289 patent was issued on February 19, 2008.

47. On July 10, 2008, several months after the '289 patent issued, Chugai submitted a one-page letter informing the USPTO that it had received a communication from the European Patent Office ("EPO") on April 16, 2008, regarding a third party submission in the corresponding European Patent application. *Id.* at 1. Chugai informed the USPTO that the document cited by the third party submission was WO95/22389 and attached a copy of only the first page of WO '389. *Id.* at 1-2.

2. The EP ’589 prosecution history

48. Currently pending European Application No. 02703958.5, filed on March 11, 2002 and published as EP ’589, is a foreign counterpart of the ’289 patent. EP ’589 is entitled “Protein Purification Method,” and the applicant is also Chugai.

49. On April 4, 2008, during the examination of EP ’589, a third party filed Third Party Observations drawing the attention of the EPO to an additional prior art document, WO ’389, which had not been cited previously. Ex. 1006, 49. The Third Party Observations explained in detail how all pending claims of EP ’589 were not novel or inventive because WO’ 389 anticipated each step of the pending claims, including claim 3, which recited:

> 3. A method for removing contaminant DNA in an antibody-containing sample, which comprises the following steps:
>
> 1) applying the antibody-containing sample to affinity chromatography on Protein A or Protein G to elute the antibody with an acidic aqueous solution of low conductivity having a molarity of 0 to 100 mM;
>
> 2) adjusting the pH of the resulting eluate to pH 4 to 8 by addition of a buffer, wherein the molarity of the adjusted eluate is 0 to 100mM; and
>
> 3) removing the resulting particles.

Id. at 49-56.

50. In a subsequent communication to Chugai on October 23, 2009, the EPO cited WO '389 as a prior art reference and adopted the arguments put forth in the Third Party Observations. Specifically, the EPO stated:

> An observation by a third party concerning the present application were filed on 04.04.2008 . . . . For the reasons outlined in said observations, present claims 1-6, 8-10 and 15-17 are not novel over [WO '389] . . . . For the reasons outlined in the above mentioned observations by a third party, present claims 1-17 are not inventive over [WO '389].

Id. at 46.

51. After several further rounds of prosecution between Chugai and the EPO, another Third Party Observations document was submitted on October 2, 2015, detailing again why the pending claims were not novel or inventive over WO '389. *Id.* at 38-44. Among other things, the additional Third Party Observations demonstrated why the characteristic conditions (molarity, ionic strength, and conductivity) of the claimed acidic aqueous solution were necessarily and inherently present in the process disclosed in WO '389. *See, e.g.*, *id.* at 39 ("[WO '389] provides sufficient information to calculate the molarity of the pH adjusted eluate: . . . . In the case of Example IA: . . . . [T]he total molarity of the pH adjusted eluate is 25mM(citrate) + 23 mM(Tris) = **48 mM**") (emphasis in original); *id.* at 41("As evidenced below, [WO '389] describes an acidic aqueous solution with an ionic

strength of 0.01959 M (i.e. '0.2 or less') and a conductivity of around 150 mS/m (i.e. '300 mS/m or less').").

52. On October 12, 2015, the EPO issued a summons to attend oral proceeding. *See id.* at 32.

53. In a response dated January 21, 2016, Chugai submitted proposed narrowing amendments where "the molarity of the aqueous solution in step 1 and the acidic molarity of the adjusted eluate in step 2 [had] been amended to '30mM or less.'" *Id.* at 25. Chugai argued that WO '389 "does not disclose the feature of 'a molarity of 30 mM or less.'" *Id.* at 27. Notably, and in order to support this argument, Chugai admitted that the molarity of the neutralized eluent in Example IA of WO '389 was less than 100 mM and could be precisely calculated as follows:

> Example IA in D3 (in particular, page 19, lines 9 to 19) discloses:
>
> - the IgG was eluted by applying 15-20 l of ProSep A elution buffer (25 mM citrate, pH 3.5, see Table 1 on page 18 of D3);
> - immediately after elution, the sample was adjusted to pH 3.5 by the addition of 2.5 M HCl, held for approximately 30 minutes, and adjusted to pH 5.5 by the addition of approximately 350 ml of 1 M Tris base;
> - thereafter, the sample was filtered through a 0.1 micron Polygard CR filter in tandem with a sterile 0.2 micron Millipak 200, into a sterile container.
>
> Thus, the eluent before the filtration has:

- 375 mmol (25 mM · 15 l) of citrate
- "x" mmol (2.5 M · "Y" l(unknown)) of HCl
- 350 mmol (1 M · 0.35 l) of Tris base
- at least 15.35 l (15 l + "Y" l +0.35 l) in total volume.

Based thereon, the molarity of the eluent can be calculated to at least (375 + 350)/15.35 = 47.2 mM.

Id. at 27-28.

54. After oral proceedings were held on February 23, 2016, the EPO, on March 17, 2016, decided to refuse European Application No. 02703958.5 because no basis could be found in the original application for Chugai's proposed amendments (i.e., a molarity of "30mM or less") and the amendments also lacked clarity. *Id.* at 7-12. Chugai has filed an appeal against the EPO's decision to refuse this application, and the appeal is pending. *Id.* at 1.

VI. THE SCOPE AND CONTENT OF THE PRIOR ART

A. WO '389

55. WO '389, entitled "Antibody Purification," is the publication of an international patent application by SmithKline Beecham Corporation on behalf of Shadle et al. (Ex. 1003). U.S. Patent No. 5,429,746 ("the '746 patent") (Ex. 1008), also entitled "Antibody Purification," having the same Shadle et al. inventors, and owned by SmithKline Beecham Corporation, has the identical and critical disclosure as the disclosure from WO '389 that I discuss and rely on in forming my opinions

below.[1] As a printed publication and patent, I understand that prior art like WO '389 and the '746 patent are presumed to be enabled. Moreover, and as discussed below, the disclosures in each of the '746 patent and WO '389 would allow a POSA to practice the claimed invention, without undue experimentation.

56. The WO '389 inventors recognized that while protein A affinity column chromatography is widely used, "elution of antibody from such columns can result in leaching of residual Protein A from the support." Ex. 1003, 6. The disclosed protein purification processes of WO '389 involve purifying an IgG (Immunoglobulin) antibody by sequentially subjecting a medium containing the antibody to several purification steps, starting with Protein A affinity chromatography. *Id.* at 15. Indeed, Example IA of WO '389 teaches a process of purifying proteins and removing DNA contaminants that either expressly or inherently discloses each of the four purification steps recited in the claims of the '289 patent. *Id.* at 21-24.

57. Example IA is an example trial run of the purification of a protein (RSHZ-19, a humanized IgG antibody) at a 1 gram scale using the procedure described generically in Example 1. Ex. 1003, 16 ("The process description [of Ex-

[1] Although I rely on and cite to the disclosure of WO '389 in this declaration, the identical and critical disclosure is also found in the '746 patent.

ample 1] is normalized for any scale; linear flow rates listed are independent of column diameter, loading ratios are in mass per unit column volume. Examples are provided for the operation and the recovery at 1 gram, 40 gram, and 125 gram scales. (Examples IA-ID).”). Therefore, the process description of Example 1 is also part of Example IA. *Id.* at 15-16.

58. WO ’389 was published on August 24, 1995, more than five years before March 9, 2001, the earliest possible priority date of the ’289 Patent. The identical and critical disclosure from WO ’389 was also published in the ’746 patent on July 4, 1995, more than five years before the earliest possible priority date of the ’289 patent. Despite their prior publication date, neither WO ’389 nor the ’746 patent was before the USPTO during the prosecution of the ’289 patent. Therefore, neither prior art reference was ever considered by the Examiner before the claims of the ’289 patent were allowed.

VII. CLAIM CONSTRUCTION

A. Plain and ordinary meaning

59. I have been informed and understand that in proceedings before the Patent Office, claim terms are generally given the broadest reasonable construction in light of the specification of the patent. Under a broadest reasonable construction, I have been informed that words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history. I

have been informed that, even under the broadest reasonable interpretation, the board's construction cannot be divorced from the specification and the record evidence, and must be consistent with the one that those skilled in the art would reach. I have applied this standard in interpreting the language of all the claims.

60. I have been informed that the term "comprising" is a term of art generally used in claim drafting to indicate that the recited claim elements are essential, but other elements may be added and still form a construct within the scope of the claim.

61. With respect to the claim term "molarity," a POSA in the art would understand, consistent with the plain and ordinary meaning of this term as well as the specification of the '289 patent, that this term describes a characteristic property of a solution and has the following meaning: A measure of the concentration of a given solute within a solution in terms of the moles of that solute contained per liter of solution. A POSA would further understand that contributions from the antibody protein and contaminant DNA would not be included when determining this parameter. For example, step 2 of independent claim 1 recites, "eluting the antibody with *an acidic aqueous solution of low conductivity having a molarity of 100 mM or less*" Ex. 1001, 12:51-52 (emphasis added). A POSA would understand the broadest reasonable construction of the term "an acidic aqueous solution of low conductivity

having a molarity of 100 mM or less" is that the molarity of the acidic aqueous solution is 100 mM or less, without considering any effects of the contaminant DNA or protein from the sample. The specification of the '289 patent supports and is consistent with this construction because it specifically states, "eluting the sample from Protein A/G affinity chromatography *with an acidic aqueous solution of low conductivity*." Ex. 1001, 5:25-27 (emphasis added). The specification then proceeds to define an acidic aqueous solution of low conductivity in terms of conductivity, molarity, ionic strength, or pH ranges, and provides several acids as potential options. *Id.* at 5:28-37. The specification does not include any written description of molarity that considers the concentrations of protein or contaminant DNA. Thus, a POSA would understand that the claimed "molarity" refers to the properties of the acidic aqueous solution without the protein or contaminant DNA.

VIII. CLAIMS 1-8 AND 13 ARE ANTICIPATED

A. WO '389 Anticipates Claims 1-8 and 13 of the '289 patent

62. It is my opinion that claims 1-8 and 13 of the '289 patent are anticipated by WO '389.

1. Claim 1 is anticipated by WO '389

63. It is my opinion that WO '389 expressly or inherently discloses every limitation of claim 1. Claim 1 is reproduced below:

> 1. A method for removing contaminant DNA in an antibody-containing sample, which comprises the following[ ] steps:

> 1) applying the antibody-containing sample to affinity chromatography on Protein A or Protein G;
> 2) eluting the antibody with an acidic aqueous solution of low conductivity having a molarity of 100 mM or less;
> 3) neutralizing the eluate from step (2) to form particles by addition of a buffer to raise the pH to 4 to 8, wherein the molarity of the neutralized eluate is 100 mM or less; and
> 4) removing the particles to thereby remove contaminant DNA from the antibody-containing sample.

Ex. 1001, 12:45-58.

a. Preamble: A method for removing contaminant DNA

64. The preamble of claim 1 recites "[a] method for removing contaminant DNA in an antibody-containing sample, which comprises the followings steps . . . ." Ex. 1001, 12:45-47. To the extent that the preamble is a limitation, a POSA would understand that WO '389 explicitly discloses the preamble limitation.

65. As discussed above, I understand from counsel that the term "comprising," or in this case "comprises," is a term of art that is generally used in claim drafting to indicate that the recited claim elements are essential, but that other elements may be added and still form a construct within the scope of the claim. Thus, because the preamble of claim 1 provides that the "method for removing contaminant DNA . . . comprises the following steps," claim 1 covers purification methods with additional process steps beyond those expressly recited.

66. WO ’389 is entitled “Antibody Purification,” and discloses methods for purifying samples of antibodies. In describing its purification methods, WO ’389 states that the “procedure outlined below was developed for the *isolation and purification of a monoclonal antibody* . . . . The process is designed to prepare RSHZ-19 [*i.e.*, the antibody] of >95% purity while *removing contaminants* derived from the host cell, cell culture medium, or other raw materials.” Ex. 1003, 15 (emphases added). As to the extent of purification, WO ’389 further states that “[t]he *purified antibodies* obtained by practicing the process of this invention have the following properties: . . . *low* (< 1 pg/mg protein) *DNA* . . . .” *Id.* at 14 (emphases added).

67. The disclosures discussed above encompass “[a] method for removing contaminant DNA in an antibody-containing sample” that is recited in the preamble of claim 1. A POSA would understand that WO ’389 discloses a process for purifying antibodies, *i.e.*, “an antibody-containing sample.” Specifically, WO ’389 discloses that DNA is among the derived contaminants that are removed because the purified antibody product obtained by practicing the disclosed process has a reduced DNA concentration. Thus, a POSA would understand that WO ’389 explicitly discloses a method for removing contaminant DNA in an antibody-containing sample.

b. Step 1: Affinity chromatography on Protein A or G

68. Step 1 of claim 1 recites "applying the antibody-containing sample to affinity chromatography on Protein A or Protein G." Ex. 1001, 12:48-49. A POSA would understand that WO '389 also explicitly discloses this limitation.

69. WO '389 discloses the use of a ProSep A affinity column, which is a commonly used protein A-based affinity chromatography column. Specifically, in Example IA, WO '389 discloses the following:

> [a] 5.0 liter (20 cm diameter by 16 cm length) *ProSep A affinity column* was equilibrated with PBS (see Table 1) at 5.2 liter/min. 100 liters of conditioned *culture medium containing* 0.8 grams per liter of RSHZ-19 *monoclonal antibody was* clarified by microfiltration as described above, and *applied to the column* at a flow rate of 5.2 liter/min.

Ex. 1003, 21 (emphases added). WO '389 further discloses that this step is describing Protein A affinity chromatography on the ProSep A column. *See id.* at 15 ("The first step in the process (Protein A affinity chromatography on ProSep A) can be rapidly cycled to accommodate varying amounts of cell-free culture fluid (CCF) . . . .").

70. A POSA would understand that these prior art disclosures encompass "applying the antibody-containing sample to affinity chromatography on Protein A or Protein G." Ex. 1001, 12:48-50. As described above, the first step in the WO '389 purification process is exactly the same as what is required in step 1 of claim

1: the antibody-containing sample (*i.e.* the medium containing the monoclonal antibody) is applied to a ProSep A Protein A affinity chromatography column. The purpose of this first step of using a Protein A column is to "remove[] a large proportion of cell and media derived impurities (particularly protein and DNA in the flow-through and wash fractions), and concentrate[] RSHZ-19 [*i.e.*, the antibody] in the elution buffer for further processing." Ex. 1003, 16. Thus, a POSA would understand that WO '389 explicitly discloses step 1 of the claimed purification process of applying the antibody-containing sample to affinity chromatography on Protein A.

c. Step 2: Elution with acidic aqueous solution of low conductivity

71. Step 2 of claim 1 recites "eluting the antibody with an acidic aqueous solution of low conductivity having a molarity of 100 mM or less." Ex. 1001, 12:50-51. A POSA would understand that WO '389 also explicitly discloses this limitation.

72. After purifying the antibody sample using the ProSep A column, the next step in Example IA is to wash the column. Example IA then describes that the "IgG [antibody] was eluted by applying 15 - 20 liters of ProSep A elution buffer." Ex. 1003, 21. Table 1 of WO '389 further discloses that the conditions of the ProSep A Elution Buffer are "25 mM citrate, pH 3.5." *Id.* at 20.

73. A POSA would understand that these prior art disclosures encompass "eluting the antibody with an acidic aqueous solution of low conductivity having a

molarity of 100 mM or less." Ex. 1001, 12:50-52. As described above, the elution step in Example IA meets the limitation recited in step 2 of the '289 patent. The specification of the '289 patent defines "an acidic aqueous solution of low conductivity" as:

> [G]enerally refer[ing] to an aqueous solution of pH 1.5 to pH 3.9, preferably-of pH 2.0 to pH 3.9, more preferably of pH 2.0 to pH 3.0, which has a molarity of 0 to 100 mM, preferably 0 to 50 mM, more preferably 0 to 30 mM, or has an ionic strength of 0 to 0.2, preferably 0 to 0.12, or has a conductivity of 0 to 300 mS/m, preferably 0 to 200 mS/m, more preferably 0 to 150 mS/m.

Ex. 1001, 5:29-35. More particularly, step 2 further limits such eluting solution to "having a molarity of 100 mM or less." *Id.* at 12:50-51. By comparison, the citrate elution buffer solution used in Example IA of WO '389 has a pH of 3.5, which a POSA would understand is an acidic pH. The citrate elution buffer solution also has a molarity of 25 mM, which is significantly lower than the required 100 mM. As discussed above, molarity is a measure of the concentration of a given solute within a solution in terms of the moles of that solute contained per liter of solution. For example, a one molar solution will contain one mole of a solute per liter of solution. Ex. 1018, CRC Handbook at 3. As, discussed above, a POSA would understand that contributions from the protein and contaminant DNA would not be included when determining the molarity. In any event, because the protein and contaminant DNA

in Example IA is dilute in the eluate in terms of molarity, their contribution to molarity would be negligible and certainly not enough to raise the total molarity of the ProSep A citrate elution buffer above the claimed 100 mM limit. *See* Ex. 1003, 16 ("Protein A Chromatography removes a large proportion of cell and media derived impurities (particularly protein and DNA in the flow-through and wash fractions)."). For example, as I have shown in my calculations in the appendix entitled Formulas and Calculations, attached as Exhibit 1007, the molarity of protein in the eluate of example IA is only 0.03 mM. Ex. 1007, 1. Thus, a POSA would understand that WO '389 explicitly discloses step 2 of the claimed purification process because it uses the ProSep A Elution Buffer for eluting the antibody, which is an acidic aqueous solution of low conductivity having a molarity of 100 mM or less.

d. Step 3: Neutralizing the eluate

74. Step 3 of claim 1 recites "neutralizing the eluate from step (2) to form particles by addition of a buffer to raise the pH to 4 to 8, wherein the molarity of the neutralized eluate is 100 mM or less." Ex. 1001, 12:52-55. A POSA would understand that WO '389 explicitly or inherently discloses this limitation.

75. The next step in the purification process disclosed in Example IA of WO '389 is to neutralize and filter the eluate before further chromatography. WO '389 describes this step as follows:

> The eluate was approximately 15 liters in volume, and contained approximately 5 milligrams protein per milliliter. Immediately *after elution, the sample was* adjusted to pH 3.5 by the addition of 2.5 M hydrochloric acid, held for approximately 30 minutes, and *adjusted to pH 5.5 by the addition of approximately 350 milliliters of l M Tris base*. After *neutralizing to pH 5.5*, the sample was filtered through a 0.1 micron Polygard CR filter in tandem with a sterile 0.2 micron Millipak 200, into a sterile container."

Ex. 1003, 21 (emphases added). As described above, 350 milliliters of 1M Tris base is added to the eluate to neutralize it to pH 5.5. A POSA would know that Tris, or tris(hydroxymethyl)aminomethane, is an organic compound with the formula $(HOCH_2)_3CNH_2$ that is widely used as a component in buffer systems. WO '389 further discloses that the 1M Tris base is a buffer. *See* Ex. 1003, 16 ("[eluate is] readjusted to pH 5.5 by the addition of Tris buffer."). Thus, a POSA would understand that WO '389 explicitly discloses neutralizing the eluate from step (2) by addition of a Tris buffer to raise the pH to 5.5, which is within the pH range of 4 to 8 that is claimed in Step 3 of the '289 patent.

76. Admittedly, Example IA of WO '389 does not explicitly describe (a) the particular molarity of the neutralized eluate solution, or (b) the formation of particles in this solution. In my opinion, however, both of these claim elements are conditions that are necessarily present, and inherent, in the neutralized eluate solution disclosed in the Example IA process, even though WO '389 does not expressly

describe these properties and results. The inventors' description of such properties and results in the '289 patent and Chugai's own admissions support my conclusions.

77. First, a POSA would understand that the particular molarity of the neutralized eluate of Example IA, although not expressly disclosed, can nevertheless be calculated based on the solution conditions disclosed in WO '389. As such, the molarity is a necessarily present property of the neutralized eluate, and is inherently disclosed. I explain in detail below the molarity calculations that a POSA could have readily conducted, and also provide the calculations in the appendix entitled Formulas and Calculations, attached as Exhibit 1007.

78. Example IA discloses that the eluate of 15 L in volume is produced using 15-20 liters of the 25mM Citrate elution buffer with a pH of 3.5. Ex. 1003, 21. As such, a POSA would understand that the volume of 2.5 M HCl needed to adjust the pH of the eluate to 3.5 is minimal. Ex. 1007, 1. In fact, WO '389 explicitly states that the HCl addition step can be omitted. Ex. 1003, 17 ("The pH 3.5 treatment can be omitted if desired.").

79. Furthermore, 25 mM Citrate in 15 liters contains 375 mmol Citrate, and subsequent neutralization to pH 5.5 requires the addition of 350 ml of 1M Tris which contains 350 mmol Tris. Ex. 1003, 21; Ex. 1007, 1. Adding the 350 mmol Tris and 375 mmol Citrate in a total volume of 15.35 liters gives a total molarity of 47.2 mM (Citrate and Tris) for the neutralized eluate, which is far less than 100mM. *Id.* As,

discussed above, a POSA would understand that contributions from the protein and contaminant DNA would not be included when determining the molarity. In any event, because the protein and contaminant DNA in Example IA is dilute in the eluate in terms of molarity, their contribution to molarity would be negligible and certainly not enough to raise the total molarity of the adjusted elution buffer above the claimed 100 mM limit. *See* Ex. 1003, 16 ("Protein A Chromatography removes a large proportion of cell and media derived impurities (particularly protein and DNA in the flow-through and wash fractions)."). For example, as I have shown in my calculations in the appendix entitled Formulas and Calculations, attached as Exhibit 1007, the molarity of protein in the eluate of example IA is only 0.03 mM. Ex. 1007, 1. Thus, the molarity of the large volume of eluate neutralized by adding 350 ml of 1M Tris base to raise the pH to 5.5 in Example IA of WO '389 is necessarily—and, thus, inherently— less than 100 mM. Ex. 1007, 1-2.

80. This conclusion as to the molarity of the neutralized eluate in WO '389 is also supported by Chugai's own admissions during prosecution of the '289 patent. To secure allowance of the '289 patent, Chugai admitted that the effect of the buffer on the molarity is "extremely small":

> The purpose of the use of a buffer is to adjust the pH of the solution, and since the amount of the buffer used is very small compared with that of the solution to which the buffer is added, *the effect of the molarity of the buffer to the molarity of the whole solution is extremely small*.

> In connection with this point, we would like to point out that use of a small amount of a buffer solution to modulate a pH value of a solution of a relatively large volume is well known in this technical field.

Ex. 1005, 13 (emphasis added).

81. This conclusion as to the molarity of the neutralized eluate in WO '389 is confirmed by Chugai's admissions during prosecution of EP '589. With regards to Example IA of WO '389, Chugai admitted to the EPO that "the molarity of the eluent can be calculated to at least: (375 + 350)/15.35 = 47.2 mM." Ex. 1006, 27-28.

82. Even if the minimal effect of the HCl solution on the molarity of the neutralized eluate were included, a POSA would understand that the overall effect would be insignificant—the molarity of the neutralized eluate in Example IA would still always be well below 100 mM. Indeed as detailed in the appendix entitled Formulas and Calculations, I conservatively calculated that volume of HCl added is only 22.08 mL. Ex. 1007, 1-3. This volume of HCl is less than 0.2 % of the volume of 15 L eluate solution and would result in the total molarity of the neutralized eluate increasing to 50.8 mM. *Id.*

83. Second, and as to the formation of particles in the neutralized eluate, the conditions disclosed in Example IA fall within the same range of conditions (pH of 4-8 and molarity less than 100 mM) recited in step 3 of the claimed process, and

I rely on the '289 patent's claims (which I understand are presumed to be enabled) that such conditions are sufficient for and result in the formation of particles. I also rely on the '289 patent specification's descriptions that these claimed conditions of the neutralized eluate "produce[] particles." *See* Ex. 1001, 6:4-6 ("According to the present invention, the solution neutralized to a neutral pH level in the above stage, *in turn, produces particles* (i.e., becomes clouded)") (emphasis added); *see also* at 1:62-67 (after neutralization, the solution is "then filtered through a filter to remove *the resulting particles*") (emphasis added). The '289 patent specification further describes that the formed particles will contain contaminant DNA. *See* Ex. 1001, 6:16-19 ("Without being bound by any particular theory, the inventors of the present invention estimate that *each of these particles is a conjugate formed between physiologically active protein and DNA*. Particle removal by filtration results in a small loss of physiologically active protein because it is removed in the form of *DNA-physiologically active protein conjugates*.") (emphasis added). I also rely on Chugai's own arguments during prosecution of the '289 patent that these claimed conditions of the neutralized eluate cause particles to form. *See* Ex. 1005, 37-38 ("Thus, it is recognized that no DNA particle was precipitated in this [prior art Tsuchiya] example because of its higher conductivity, i.e. of a molarity of over 0.1M. . . . Applicants submit that no such particles are formed during the procedure of Tsuchiya because the conditions described in the disclosure and carried out in the

examples are fundamentally different from those stipulated in applicants' claims and required according to the present invention.").

84. The inherent formation of particles under the recited eluate solution conditions and containing contaminant DNA is also consistent with the teachings in the prior art. *See* Ex. 1009, Scopes at 27-30. Specifically, a POSA would understand from Scopes that proteins will aggregate by isoelectric precipitation under the conditions recited in the claims of the '289 patent:

> In the ionic strength range from zero to physiological, some proteins form precipitates because the repulsive forces are insufficient. . . . An overall charge near zero minimizes electrostatic repulsion, and may, close to the isoelectric point, result in electrostatic attraction of molecules to each other. This is called isoelectric precipitation . . . . In many cases isoelectric precipitates can be formed by lowering the pH to between 6.0 and 5.0.

Id. at 28. A POSA would further understand that "[m]ost isoelectric precipitates are aggregates of many different proteins and may include particulate fragments and *protein-nucleic acid complexes*." *Id.* at 29 (emphasis added).

85. For the reasons discussed above, it is my opinion that neutralizing the eluate solution by the addition of a Tris buffer to raise the pH to 5.5 at a molarity of 47.2 mM would inevitably and necessarily result in the formation of particles that

contain DNA contaminants. As such, this limitation of step 3 is also inherently disclosed in the Example IA process of WO '389, and all of the limitations of step 3 are expressly or inherently disclosed in the Example IA process of WO '389.

e. Step 4: Removing particles

86. Step 4 of claim 1 is the final step of the claimed purification process and recites "removing the particles to thereby remove contaminant DNA from the antibody-containing sample." Ex. 1001, 12:56-57. A POSA would understand that WO '389 either expressly or at least inherently discloses this limitation.

87. After neutralizing the eluate to pH 5.5, the next step of Example IA discloses that "the sample was filtered through a 0.1 micron Polygard CR filter in tandem with a sterile 0.2 micron Millipak 200, into a sterile container." Ex. 1003, 21.

88. A POSA would understand that Example IA expressly discloses filtering the neutralized eluate, and indeed using two separate filters—a 0.1 micron filter in tandem with a 0.2 micron filter. Although Example IA does not describe what is removed using these two filters, a POSA would understand that the purpose of such filters is to remove all particles above a certain size through filtration. *See also* Ex. 1010, Martin at 27, 30. Thus, a POSA would understand that WO '389 expressly disclosed using its two filters to remove particles, including those formed in step 3 and containing contaminant DNA.

89. To the extent WO '389 does not expressly disclose this particle removal step, this limitation is inherently met by WO '389. The particles that are necessarily formed according to the previous steps of Example IA, including those containing contaminant DNA, would inevitably and necessarily be removed by the disclosed filters. Specifically, a POSA would understand that "[a]bsolute removal of particulate solids from the process stream, including sterile filtration, serves as an essential prefiltration/protection step for downstream chromatography and ultrafiltration systems." *Id.* at 27. A POSA would also understand that "particulate impurities must be removed to prevent premature plugging. In most cases, a 0.2-µm-rate sterilizing grade membrane filter is employed as the fluid filter." *Id.* at 30.

90. I further rely on the descriptions in the specification of the '289 patent, which confirm that the 0.1 micron and 0.2 micron filters are sufficient to remove the particles. In particular, the '289 patent discloses that "*particles may be removed by filtration through a filter* to ensure efficient removal of contaminant DNA. Examples of a filter available for filtration include but are not limited to a 1.0-0.2 µm Cellulose Acetate Filter System (Corning) or TFF. Ex. 1001, 6:5-11 (emphasis added).

91. In both WO '389 and the '289 patent, the neutralized eluates are filtered by a 0.2 µm filter. Indeed, WO '389 also discloses the use of a smaller 0.1 micron filter, which will remove even more particles than the 0.2 µm filter. These filters

will either expressly or at least inherently perform the claimed process of removing particles, including those containing DNA, just as the ’289 patent claims and describes. Thus, a POSA would understand that WO ’389 expressly or at least inherently discloses the final step 4 of the claimed purification process of removing particles to thereby remove contaminant DNA. Therefore, all limitations of step 4 are either expressly or at least inherently disclosed by the Example IA process of WO ’389.

92. For these reasons, a POSA would understand that the Example IA purification process in WO ’389 discloses, either expressly or inherently, each of the process steps of claim 1, and thus anticipates claim 1.

2. Claims 2–8 and 13 are anticipated by WO ’389

93. It is my opinion that the limitations in each of dependent claims 2–8 and 13 of the ’289 patent are also anticipated by WO ’389.

a. Claim 2 is anticipated

94. WO ’389 anticipates claim 2. Claim 2 depends from claim 1 and requires that “the acidic aqueous solution of low conductivity has a molarity of 50 mM or less.” Ex. 1001, 12:59-61. The composition of the ProSep A Elution Buffer used in Example IA of WO ’389 is “25 mM citrate, pH 3.5.” Ex. 1003, 20. As described above for claim 1, a pH of 3.5 is an acidic pH and 25 mM is a molarity significantly lower than 50 mM. As such, the ProSep A Elution Buffer used in Example IA meets

the limitation of an acidic aqueous solution of low conductivity that has a molarity of 50mM or less. *Id.* WO '389 thus also anticipates claim 2.

b. Claim 3 is anticipated

95. WO '389 anticipates claim 3. Claim 3 depends from claim 1 and requires that "the acidic solution of low conductivity is selected from the group consisting of aqueous solutions of hydrochloric acid, citric acid and acetic acid." Ex. 1001, 12:62-65. As discussed above, the composition of the ProSep A Elution Buffer used in Example IA of WO '389 is "25 mM *citrate*, pH 3.5." Ex. 1003, 20 (emphasis added). A POSA would readily appreciate the 25mM Citrate buffer solution contains citric acid in solution. Ex. 1013, Apelblat I at 1-9; Ex. 1015, Fasman at 3, 6. As such, the composition of the Prosep A elution buffer used in Example IA of WO '389 is a citric acid solution of low conductivity. Ex. 1013, Apelblat I at 1-9; Ex. 1015, Fasman at 3, 6. WO '389 thus also anticipates claim 3.

c. Claim 4 is anticipated

96. WO '389 anticipates claim 4. Claim 4 depends from claim 3 and further requires that "the acidic aqueous solution has a pH of 1.5 to 3.9." Ex. 1001, 12:66-67. The composition of the ProSep A Elution Buffer used in Example IA of WO '389 is "25 mM citrate, pH 3.5." Ex. 1003, 20. A pH of 3.5 is within the claimed range of "1.5 to 3.9." Thus, WO '389 anticipates claim 4.

d. Claim 5 is anticipated

97. WO ’389 anticipates claim 5. Claim 5 depends from claim 1 and further requires that “the contaminant DNA is present at a DNA concentration of 22.5 pg/ml or less in the treated sample containing an antibody.” Ex. 1001, 13:1-3. WO ’389 discloses that “[t]he purified antibodies obtained by practicing the process of this invention have the following properties: . . . low (< 1 pg/mg protein) DNA . . . .” Ex. 1003, 14. Example IA of WO ’389 results in a purified antibody sample containing “approximately 2.4 milligrams protein per milliliter.” *Id.* A POSA would understand that multiplying <1 pg/mg protein DNA by 2.4 mg protein/ml results in the contaminant DNA in Example IA of WO ’389 being <2.4 pg/ml—within the claimed range of “22.5 pg/ml or less.” Thus, WO ’389 also anticipates claim 5.

e. Claim 6 is anticipated

98. WO ’389 anticipates claim 6. Claim 6 depends from claim 1 and further requires that “the buffer is an aqueous solution of Tris.” Ex. 1001, 13:4-5. As discussed above for claim 1, the buffer used in example IA of WO ’389 is 1M Tris base—an aqueous solution of Tris. Ex. 1003, 21 (“Immediately after elution, the sample was . . . adjusted to pH 5.5 by the addition of approximately 350 milliliters of *l M Tris base*.”) (emphasis added). Thus, WO ’389 also anticipates claim 6.

f. Claim 7 is anticipated

99. WO ’389 anticipates claim 7. Claim 7 depends from claim 1 and further requires that “the buffer is added to raise the pH to 4.3 to 7.5.” Ex. 1001, 13:6-7.

As discussed above for claim 1, in Example IA of WO '389, the buffer is added to raise the pH to 5.5—within the claimed range of "4.3 to 7.5." Ex. 1003, 21. Thus, WO '389 also anticipates claim 7.

g. Claim 8 is anticipated

100. WO '389 anticipates claim 8. Claim 8 depends from claim 1 and further requires that "the antibody is a humanized monoclonal antibody." Ex. 1001, 13:8-9. In Example IA of WO '389, "[t]he procedure . . . was developed for the isolation and purification of a monoclonal antibody against Respiratory Syncytial Virus (RSV)." Ex. 1003,15. WO '389 specifies that "[t]his antibody is a 'humanized' IgG . . . ." *Id.*. IgG is Immunoglobulin G, a type of antibody. Thus, WO '389 discloses that the antibody is a humanized monoclonal antibody and anticipates claim 8.

h. Claim 13 is anticipated

101. WO '389 anticipates claim 13. Claim 13 depends from claim 1 and further requires that "the particles are removed by filtration through a filter." Ex. 1001, 14:9-10. Example IA of WO '389 discloses that "[a]fter neutralizing to pH 5.5, the sample was filtered through a 0.1 micron Polygard CR filter in tandem with a sterile 0.2 micron Millipak 200, into a sterile container." Ex. 1003, 21. As discussed above for claim 1, the particles that are necessarily present and inherently formed in Example IA of WO '389 are also necessarily removed by filtration through

a filter. Thus, WO '389 either expressly or at least inherently discloses that the particles are removed by filtration through a filter, and anticipates claim 13.

102. In sum, WO '389 discloses, either expressly or inherently, every limitation of each of claims 2–8 and 13, and, therefore, anticipates each of these claims.

IX. CLAIMS 1-8 AND 13 ARE OBVIOUS

103. If not anticipated, it is my opinion that claims 1-8 and 13 of the '289 patent would have been obvious to a POSA in light of the disclosures in WO '389 and the knowledge and skills of a POSA. It is my understanding that there is nothing inconsistent in concurrent rejections for obviousness and for anticipation.

104. As described above in the previous section for anticipation, WO '389 discloses an antibody purification process that falls within the scope of claims 1-8 and 13 in the '289 patent. There is no patentable difference between the prior art antibody purification process of Example IA in WO '389 and the claimed invention. In particular, a POSA would understand from the teachings of WO '389 that DNA contaminants would be removed from an antibody sample by applying the sample to Protein A affinity chromatography column, eluting the antibody sample with an acidic citrate solution of 25 mM and pH of 3.5, and then neutralizing the solution by raising the pH to 5.5 using a Tris buffer while the molarity of the solution remains below 100 mM. The neutralized buffer solution is then filtered using a 0.1 micron and a 0.2 micron filter.

105. In view of the disclosures of WO '389 as discussed above, the conditions of the neutralized eluate of Example IA in WO '389 would inherently have formed particles, and a POSA would have been motivated to remove such particles or aggregates containing DNA formed in the neutralized eluate solution of Example IA as part of the purification process. Indeed, a POSA would understand that the purpose of the 0.1 micron and 0.2 micron filters in the Example IA process is to filter and remove particulates at this particular stage of the process to protect the subsequent chromatography columns. *See* Ex. 1010, Martin at 341 ("Absolute removal of particulate solids from the process stream, including sterile filtration, serves as an essential prefiltration/protection step for downstream chromatography . . . ."). As such, a POSA would have had a reasonable expectation of success that the 0.1 micron and 0.2 micron filters would work as intended to remove any particles that are formed.

106. For at least these reasons, it is my opinion that each of claims 1-8 and 13 would have also been obvious to a POSA in light of the teachings of WO '389.

X. CONCLUSION

107. In sum, for the reasons I have discussed above, it is my opinion that claims 1-8 and 13 of the '289 patent would have been anticipated and/or obvious to a POSA as of March 2001 in view of WO '389.

108. I understand that this declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also understand that I may be subject to cross-examination concerning this declaration, and I will appear for cross-examination, if required of me, during the time allotted for cross-examination.

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

Date: 18 May 2017

Todd M. Przybycien, Ph.D.

ATTACHMENT A

Todd M. Przybycien
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I. BACKGROUND

Education

California Institute of Technology, Pasadena, CA

6/86 - 3/89 Ph.D. in Chemical Engineering with Minor in Biology
Advisor: Prof. James E. Bailey
Thesis: "Structure, Function and Aggregation Kinetics in Salt-Induced Protein Precipitation" (1989) *Diss. Abst. Int. B* **50**, 2057.

9/84 - 6/86 M.S. in Chemical Engineering
Advisor: Prof. James E. Bailey
Thesis: "Structure-Function Relationships in Inorganic Salt-induced Precipitation of α-Chymotrypsin"

Washington University, St. Louis, MO

9/80 - 5/84 B.S. in Chemical Engineering, cum laude

9/80 - 5/84 A.B. in Chemistry, magna cum laude

Employment

Carnegie Mellon University, Pittsburgh, PA

7/02 – current Professor, Departments of Biomedical Engineering, Chemical Engineering

7/02 – 7/08 Founding Head, Department of Biomedical Engineering

7/00 – 6/02 Head, Biomedical & Health Engineering Program

6/98 – 6/02 Associate Professor, Chemical Engineering

Rensselaer Polytechnic Institute, Troy, NY

6/96 - 5/98 Howard P. Isermann Associate Professor of Chemical Engineering

1/91 - 5/96 Howard P. Isermann Assistant Professor of Chemical Engineering

Monsanto Agricultural Company, St. Louis, MO

3/89 - 12/90 Senior Research Engineer, Purification Process Development Group, Animal Sciences Division

Consulting

AbbVie, North Chicago, IL; Alza Corporation, Palo Alto, CA, Biopharmaceutical Implant R&D Group; Amgen, Inc., Thousand Oaks, CA, Recovery Process Engineering Group; Asahi Kasei Bioprocess, Chicago, IL; Biogen Idec, Inc., Cambridge, MA; Genetics Institute, Andover, MA, Drug Product Development Group; Genzyme Transgenics, Framingham, MA; Hospira, New York, NY; Inhale Therapeutic Systems, San Carlos, CA, Research and Development Group; Merck Research Laboratories, West Point, PA, BioProcess R&D Group; Protein Design Labs, Inc., Mountain View, CA, Product Development; Protiva Division of Monsanto (Pharmacia/Pfizer), St. Louis, MO, Purification Process Development

Professional Honors and Awards

2014 – current	Editorial Board member, *Chemical Engineering Progress*
2010	Fellow, American Institute of Chemical Engineers
2009	Erskine Fellow, University of Canterbury, Department of Chemical and Process Engineering, Christchurch, NZ
2008 – current	Adjunct Professor, Departamento Biotecnología e Ingenieria de Alimentos, Instituto Tecnologico y de Estudios Superiores de Monterrey (Tec de Monterrey), Monterrey, MX
2007, 2009	BME Professor of the Year, CMU Graduate Biomedical Engineering Society
2003	Whitaker Foundation Academic Leadership Program
2000 – 2002	Associate Editor, *Biotechnology and Bioengineering*
1998	Fellow, American Institute for Medical and Biological Engineering
1997 – current	Editorial Board member, *Separation Science and Technology*
1997	Early Career Award, Faculty of Rensselaer Polytechnic Institute
1997	Camille Dreyfus Teacher-Scholar Award, Dreyfus Foundation
1995	Faculty Early Career Development Award, National Science Foundation
1985	Honorable Mention, National Science Foundation Graduate Research Fellowship
1984 – 1985	Amoco Foundation Graduate Research Fellowship
1984 and prior	Phi Beta Kappa (liberal arts and sciences honorary), Tau Beta Pi (engineering honorary), Omicron Delta Kappa (leadership and service honorary), Ethan A.H. Shepley Award (leadership, scholarship and service to campus community, Washington University), George E. Kassabaum Award (outstanding senior man, Washington University Interfraternity Council), Outstanding Senior Chemical Engineer (American Institute of Chemists), Outstanding Junior Chemistry Major (Chemical Council of Greater St. Louis), Alexander S. Langsdorf Engineering Fellow (Washington University), National Merit Scholar, National Society of Professional Engineers Scholarship

II. SCHOLARSHIP

Research Interests

Area: applied biophysics - addressing the practical problems and underlying fundamental phenomena associated with the production, formulation, and delivery of pharmaceutical proteins generated by the biotechnology industry. The focus is on protein denaturation, aggregation and adsorption phenomena probed on the molecular level with spectroscopic, optical and biophysical tools and then connected to studies of macroscopic, process-level behavior. Molecular-level/process level connections are made with mechanistic models, molecular simulations and informatics tools. The overall goal is the development of structure-processing relationships that improve our ability to design and operate processes, formulations and delivery devices.

Area: biosensors. Microelectromechanical systems- (MEMS-) based sensors for chemical species detection and macroscopic optical sensors. Applications range from biosecurity, to analytics and diagnostics.

Current Research Topics

Bioprocessing

- Next-generation affinity chromatography media (e.g. protein A media) via PEGylated ligands with enhanced selectivity and robustness performance in protein separations
- Protein precipitation as a continuous platform capture process for the downstream processing of high concentration secreted recombinant proteins

Protein/drug delivery

- Enhancing spreading, mucolysis and antimicrobial activity in pulmonary drug delivery with surfactants (in collaboration with S. Garoff and R. Tilton)

Water purification

- Development of elaborated natural materials for water purification (in collaboration with R. Tilton)

Applied biophysics

- Characterization of the morphology of PEGylated proteins (in collaboration with R. Tilton)

Biosensors

- Development of a hand-held tissue reflectance spectrometer for detection of incipient pressure ulcers regardless of skin pigmentation and associated modeling of light transport in skin (in collaboration with J. Kainerstorfer)

Research Support: External Grants Awarded

2016 Co-I: NIST NNMI, "NIIMBL: The National Institute for Innovation in Manufacturing BiopharmaceuticaLs," PI: K. Lee (University of Delaware), amount (to USA Bio, LLC): $70,000,000, 01/01/17-12/31/21.

2016 Co-PI: Proctor & Gamble Corporation, Amendment to "Adsorption and Interfacial Transport of ZPT Microparticles," PI: R. Tilton, Co-PI: S. Garoff, amount: $382,223, 06/01/16-05/30/19.

2015 Co-PI: NSF (CBET 1510293) "Surfactant Induced Post-Deposition Dispersal of Solid Particles at Liquid/Air Interfaces with Application to Pulmonary Drug Delivery," PI: S. Garoff, Co-PI: R. Tilton, amount: $352,700, 09/01/15-08/31/18.

2013 Co-PI: Proctor & Gamble Corporation, "Adsorption and Interfacial Transport of ZPT Microparticles," PI: R. Tilton, Co-PI: S. Garoff, amount: $328,652, 05/01/13-04/30/16.

2012 Co-PI: NSF (CBET 1159369) "Surfactant Induced Post-Deposition Transport of Aerosols with Application to Pulmonary Drug Delivery," PI: S. Garoff, Co-PI: R. Tilton, amount: $300,000, 09/01/12-08/31/15.

2012 PI: NSF (CBET 1159886) "Next-Generation Affinity Chromatography with PEGylated Ligands", $300,000, 08/01/12-07/31/2016.

2011 Co-I: NIH NHLBI (1R01HL105470-01A1) "Improving Inhaled Drug Delivery with Self-Dispersing Liquids," Co-PIs: T. Corcoran, S. Garoff, $2,931,228, 12/15/2011-11/30/16.

2010 PI: Carnegie Mellon Technology Transfer Office/Heinz Foundation/Innovation Works GAP Funding, "The development of a diagnostic instrument for pressure ulcer (bedsore) detection," Co-PI: S. Gaspard, $25,000, 05/01/10-12/31/10.

2009 Co-PI: NSF (CBET 0931057) "Marangoni Driven Spreading on Entangled Polymer Subphases with Application to Pulmonary Drug Delivery," PI: S. Garoff, Co-PI: R. Tilton, amount: $339,199, 10/1/09-9/30/12.

2009 PI: Center for the Integration of Medical Innovative Technology (CIMIT, Boston, MA), "Development of a Diagnostic Instrument (the "Rubitect") for Early Stage Pressure Ulcers (Bed sores)," amount $10,000 (finalist award), period 03/01/09-06/30/09.

2008 PI: University of Pittsburgh Medical Center, "Development of a prototype pressure ulcer sensor," Co-PI: M. Siegel, amount: $101,310 awarded, but not distributed.

2008 PI: Samuel & Emma Winters Foundation (Award #1030470), "Development of a prototype device for incipient pressure ulcer detection in darkly pigmented skin," amount: $10,000, period: 7/1/08-6/30/10.

2008 Co-PI: NSF (CBET 0755284), "Interfacial Activity of PEG-modified Proteins with Application to Sustained Release," PI: R. Tilton, amount: $293,619, period: 8/1/08-7/31/11.

2007 PI: Genentech, Inc., "Investigation of Protein Structure by Raman Spectroscopy", amount: $30,000, period: 10/1/07-9/30/08.

2007 PI: Merck Research Laboratories, BioProcess R&D Undergraduate Research Grant, amount $5,350, period: 10/1/07-8/31/08.

2006 PI: Merck Research Laboratories, BioProcess R&D Undergraduate Research Grant, amount $6,000, period: 6/1/06-5/31/07.

2005 Co-I: Bombardier, Inc. Grant, "Advanced Transit Security Technologies", PI: Y. Cai, Co-Is: S. Hauan (CMU), G. Fedder (CMU), amount: $50,000, period: 1/1/05 to 12/31/05

2005 Co-PI: Pennsylvania Infrastructure Technology Alliance (PITA), "Inhibition of Pathogenic Biofilm Formation on Re-Usable Medical Devices Using Ethylenediaminetetraacetate (EDTA)", PI: J. VanBriesen, amount $55,307, period: 1/1/05-12/31/05.

2004 PI: NSF Research Experience for Undergraduates supplement to "Group Proposal: Rational Protein Bioprocessing with Hydrophobic Separations Media", amount $30,000, period: 6/1/04 to 8/31/04

2002 PI: NIH NIBIB (RFA-EB-02-002) Sensor Development and Validation (1 R21 EB000735-01): "A MEMS Membrane-based Gravimetric Biosensor", Co-Is: K. Gabriel (CMU), S. Hauan (CMU), amount: $377,608, period: 9/30/02 to 8/30/04

2002 PI: NSF Biochemical Engineering and Biotechnology Large Grant Program (BES 0214183): "Group Proposal: Rational Protein Bioprocessing with Hydrophobic Separations Media", Co-PIs: S. Cramer (RPI), C. Breneman (RPI), E. Fernandez (UVa), J. O'Connell (UVa), amount: $1,454,239, period: 9/1/02 to 8/31/07

2000 Co-PI: NSF Biochemical Engineering and Biotechnology Program (BES 9907504): "Elucidating Structure Versus Function Relationships for Adsorbed Enzyme Layers", PI: R. Tilton (CMU), amount: $500,000, period: 9/1/00 to 8/31/03

1997 PI: NSF Research Experience for Undergraduates supplement to "CAREER Program: Research and Education in Chemical Engineering and Biotechnology", amount $10,000, period: 12/1/97 to 11/30/98

1997 PI: Camille and Henry Dreyfus Foundation, Camille Dreyfus Teacher-Scholar Award (TC-97-013): "Rational Manipulation of Protein Aggregation Behavior," amount $60,000, period: 6/1/97 to 5/31/02

1997 Co-PI: NASA Microgravity Biotechnology: Research and Flight Experiment Opportunities Program (NAG8-1379): "Protein Crystal-Based Nanomaterials," PI: J. Bell (RPI), amount: $547,000, period: 9/1/97 to 8/31/01

1995 PI: NSF Engineering Research Equipment Grant: "Acquisition of an Infrared Spectrometer for the Analysis of Protein-Surface Interactions," co-PIs: G. Belfort (RPI) and S. Cramer (RPI), amount: $32,000 (total project costs $65,872)

1995 PI: NSF Faculty Early Career Award: "Research and Education in Chemical Engineering and Biotechnology," amount: $310,000, period: 6/15/95 to 11/30/99

1994 PI: NSF Academic Research Infrastructure Grant: "Acquisition of a Raman Spectrometer for Protein Structural Analysis," amount: $166,038 (total project costs $238,323)

1993 PI: NSF Small Grant for Exploratory Research: "Conducting Polymer Chromatography for Protein Separations," co-PI: G. Wnek (RPI), amount: $20,000, period: 9/1/93 to 2/31/95

1992 PI: NSF Initiation Grant: "Characterization of Mixing Phenomena Impacting the Formation of Protein Precipitates for Bioprocessing Applications," amount: $100,000, period: 8/1/92 to 7/31/95

1992 PI: Engineering Foundation Research Initiation Grant: "Characterization of Protein Solubility and Aggregation Behavior for Bioprocess Design and Scaleup" declined after receipt of NSF Initiation Grant

Research Support: Carnegie Mellon Grants Awarded

2002 Co-PI: Seed Fund Initiative: "Detection and Control of Pharmaceutical Polymorphism," PI: R. Suter, Co-PIs: J. Schneider, D. Sholl, R. Tilton, amount: $74,240.

1999 PI: Seed Fund Initiative "Building Recombinant DNA Technology Expertise in Chemical Engineering," amount: $55,158.

Publications: Refereed Papers - corresponding author underlined

58. Sharma R, Corcoran TE, Garoff S, Przybycien TM, Tilton RD, "Transport of a partially wetted particle at the liquid/vapor interface under the influence of an externally imposed surfactant generated Marangoni stress," *Colloids and Surfaces A: Physicochemical and Engineering Aspects* in press; doi: 10.1016/j.colsurfa.2016.08.002

57. Stetten AZ, Moraca G, Corcoran TE, Tristram-Nagle S, Garoff S, Przybycien TM, Tilton RD, "Enabling Marangoni flow at air-water interfaces through deposition of aerosolized lipid dispersions," *Journal of Colloid & Interface Science* 484, 270-278 (2016); doi: 10.1016/j.jcis.2016.08.076

56. Nordmark B, Tilton RD, Przybycien TM, "Comparative coagulation performance study of *Moringa oleifera* cationic protein fractions with varying water hardness," *Journal of Environmental Chemical Engineering* 4, 4690-4698 (2016); doi: 10.1016/j.jece.2016.10.029

55. Dunér G, Kim M, Garoff S, Przybycien TM, Tilton RD, "Effect of Polyelectrolyte-Surfactant Complexation on Marangoni Transport at a Liquid-Liquid Interface," *Journal of Colloid and Interface Science* **467**, 105-114 (2016); doi: 10.1016/j.jcis.2016.01.011

54. Dunér G, Garoff S, Przybycien TM, Tilton RD, "Transient Marangoni Transport of Colloidal Pareticles at the Liquid/Liquid Interface Caused by Surfactant Convective-Diffusion under Radial Flow," *Journal of Colloid and Interface Science* **462**, 75-87 (2016); doi:10.1016/j.jcis.2015.09.042

53. Sharma R, Khanal A, Corcoran T, Garoff S, Przybycien TM, Tilton R, "Surfactant Driven Post-Deposition Spreading of Aerosols on Complex Aqueous Subphases. 2: Low Deposition Flux Representative of Aerosol Delivery to Small Airways," *Journal of Aerosol Medicine and Pulmonary Drug Delivery* **28**, 394-405 (2015); doi:10.1089/jamp.2014.1167

52. Khanal A, Sharma R, Corcoran T, Garoff S, Przybycien TM, Tilton R, "Surfactant Driven Post-Deposition Spreading of Aerosols on Complex Aqueous Subphases. 1: High Deposition Flux Representative of Aerosol Delivery to Large Airways," *Journal of Aerosol Medicine and Pulmonary Drug Delivery* **28**, 382-393 (2015); doi:10.1089/jamp.2014.1168

51. González-Valdez J, Yoshikawa A, Weinberg J, Benavides J, Rito-Palomares M and Przybycien TM, "Toward improving selectivity in affinity chromatography with PEGylated affinity ligands: The performance of PEGylated protein A," *Biotechnology Progress* **30**, 1364-1379 (2014); 10.1002/btpr.1994
50. Cisneros-Ruiz M, Mayolo-Deloisa K, Rito-Palomares M, Przybycien TM, "Separation of PEGylated variants of Ribonuclease A and apo-alpha-Lactalbumin via Reversed Phase Chromatography," *Journal of Chromatography A* **1360**, 209-216 (2014); 10.1016/j.chroma.2014.07.085
49. Sharma R, Corcoran T, Garoff S, Przybycien T, Swanson E, Tilton R, "Quasi-Immiscible Spreading of Aqueous Surfactant Solutions on Entangled Aqueous Polymer Solution Subphases," *ACS Applied Materials and Interfaces* **5**, 5542-5549 (2013); 10.1021/am400762q
48. Ahmad MM, Przybycien TM, "Towards Optimal Aqueous Two-Phase Extraction System Flowsheets for Protein Purification", *Journal of Chemical Technology and Biotechnology* **88**, 62-71 (2013); doi: 10.1002/jctb.3858
47. Sharma R, Kalita R, Swanson E, Corcoran T, Garoff S, Przybycien T, Tilton R, "Autophobing on Liquid Subphases Driven by Interfacial Transport of Amphiphilic Molecules", *Langmuir* **28**, 15212-15221 (2012); doi 10.1021/la303639w
46. Corcoran TE, Thomas KM, Garoff S, Tilton RD, Przybycien TM, Pilewski JM, "Imaging the post-deposition dispersion of an inhaled surfactant aerosol," *Journal of Aerosol Medicine and Pulmonary Drug Delivery* **25**, 290-296 (2012); doi: 10.1089/jamp.2011.0920
45. Pai SS, Heinrich F, Canady A, Przybycien TM, Tilton RD, "Coverage-dependent morphology of PEGylated lysozyme layers adsorbed on silica," *Journal of Colloid and Interface Science* **370**, 170-175 (2012). doi:10.1016/j.jcis.2011.12.065
44. Pai SS, Hammouda B, Hong K, Pozzo DC, Przybycien TM, Tilton RD (2011) "The Conformation of the Poly(ethylene glycol) Chain in Mono-PEGylated Lyosyme and Mono-PEGylated Human Growth Hormone," *Bioconjugate Chemistry* **22**, 2317-2323; 10.1021/bc2003583
43. Koch K, Dew B, Corcoran T, Przybycien T, Tilton R, Garoff S (2011) "Surface Tension Gradient Driven Spreading on Aqueous Mucin Solutions: A Possible Route to Enhanced Pulmonary Drug Delivery," *Molecular Pharmaceutics* **8**, 387-394; 10.1021/mp1002448
42. Pai SS, Przybycien TM, Tilton RD (2010) "Protein PEGylation Attenuates Adsorption and Aggregation on a Negatively Charged and Moderately Hydrophobic Polymer Surface," *Langmuir* **26**, 18231-18238; 10.1021/la102709y
41. Ahmad MM, Hauan S, Przybycien TM (2010) "Flowsheet Simulation of Aqueous Two-Phase System for Protein Extraction", *Journal of Chemical Technology and Biotechnology* **85**, 1575-1587; 10.1002/jctb.2469
40. Cisneros-Ruiz M, Mayolo-Deloisa K, Przybycien TM, Rito-Palomares M (2009) "Separation of PEGylated from Unmodified Ribonuclease A using Sepharose HIC Media," *Separation and Purification Technology* **65**, 105-109; 10.1016/j.seppur.2008.10.038
39. Daly S, Przybycien TM, Tilton RD (2007) "Aggregation of lysozyme and of poly(ethylene glycol)-modified lysozyme after adsorption to silica," *Colloids and Surfaces B: Biointerfaces* **57**, 81-88; 10.1016/j.colsurfb.2007.01.007
38. Valentine J, Przybycien TM, Hauan S (2007) "Design of Acoustic Wave Biochemical Sensors using MEMS," *Journal of Applied Physics* 101, 064508-1—064508-9; 10.1063/1.2711392. Selected by the editor for inclusion in the 1 April 2007 issue of the *Virtual Journal of Biological Physics Research*, www.vjbio.org
37. Xiao Y, Jones TT, Laurent AH, O'Connell JP, Przybycien TM, Fernandez E (2007) "Protein Instability During HIC: Hydrogen Exchange Labeling Analysis and a Framework for Describing Mobile and Stationary Phase Effects," *Biotechnology and Bioengineering* **96**, 80-93; 10.1002/bit.21186

36. Daly S, Przybycien TM, Tilton RD (2005) "Adsorption of poly(ethylene glycol)-modified ribonuclease A to a poly(lactide-co-glycolide) surface," *Biotechnology & Bioengineering* **90**, 856-868; 10.1002/bit.20481
35. Daly S, Przybycien TM, Tilton RD (2005) "Adsorption of Polyethylene Glycol Modified Lysozyme to Silica," *Langmuir* **21**, 1328-1337; 10.1021/la048316y
34. Sethuraman A, Vedantham G, Imoto T, Przybycien TM, Belfort G (2004) "Protein Unfolding at Interfaces: Slow Dynamics of α-Helix to β-Sheet Transition," *Proteins: Structure, Function and Bioinformatics* **56**, 669-678; 10.1002/prot.20183
33. Berglund KD, Truong MT, Tilton RD, Przybycien TM, Garoff SG, Walker LM (2004) "Rheology of Transient Networks Containing Hydrophobically Modified Cellulose, Anionic Surfactant and Colloidal Silica: Role of Selective Adsorption," *Rheologica Acta* **43**, 50-61; 10.1007/s00397-003-0319-6
32. Sullivan MM, Green JJ, Przybycien TM (2003) "Development of a Novel Gene Delivery Scaffold Utilizing Colloidal Gold-Polyethylenimine Conjugates for DNA Condensation," *Gene Therapy* **10**, 1882-1890; 10.1038/sj.gt.3302083
31. Choi EJ, Foster MD, Daly S, Tilton RD, Przybycien TM, Majkrzak CF, Witte P, Menzel H (2003) "Effect of Flow on Human Serum Albumin Adsorption to Self-Assembled Monolayers of Varying Packing Density," *Langmuir* **19**, 5464-5474; 10.1021/1a026811t
30. Daly S, Przybycien TM, Tilton RD (2003) "Coverage Dependent Orientation of Lysozyme Adsorbed on Silica," *Langmuir* **19**, 3848-3857; 10.1021/la026690x
29. Berglund KD, Przybycien TM, Tilton RD (2003) "Coadsorption of Sodium Dodecylsulfate with Hydrophobically Modified Nonionic Cellulose Polymers II: Role of Surface Selectivity in Adsorption Hysteresis," *Langmuir* **19**, 2714-2721; 10.1021/la026430f
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Presentations: Invited Seminars, Talks and Panel Presentations Given as Presenter – since 2007

128. Przybycien TM, Weinberg J, "Use of Stealth Technology to Enhance Selectivity in the Capture Step for Monoclonal Antibody Production," talk presented at the 8th Eastern Mediterranean Conference on Chemical Engineering, Haifa, Israel, 28 February 2017.
127. Przybycien T, "Capture via Continuous Precipitation," Bioprocess R&D talk given at Eli Lilly and Company, Indianapolis, IN, 23 August 2016.
126. Przybycien T, "Continuous Precipitation-Based Processes for Protein Purification," keynote talk given at The 8th Annual Bioprocessing Summit, Boston, MA, 15 August 2016.
125. Przybycien T, Weinberg J, "Making Protein A Media Stealthy," talk given at the 29th International Symposium on Preparative and Process Chromatography (PREP 2016), Philadelphia, PA, 19 July 2016.
124. Weinberg J, Zhang S, Carta G, Przybycien T, "Mitigating Impurity Interactions with Protein A and Monoclonal Antibodies During Chromatography with PEGylated Ligands," invited poster given at Recovery of Biological Products XVII (Recovery XVII), Bermuda, 19-23 June 2016.
123. Gu Q, Li Z, Przybycien T, Zydney A, "Alternative Downstream Processing based on Continuous Coupled Precipitation-Filtration Capture Operations," talk given at Recovery of Biological Products XVII (Recovery XVII), Bermuda, 23 June 2016.
122. Przybycien TM, "Alternative Downstream Processing based on Continuous Coupled Precipitation-Filtration Capture Operations," talk given at Boehringer Ingelheim, Inc., Fremont, CA, 16 June 2016.
121. Przybycien TM, "Design Considerations for Continuous Precipitation Processes," talk given at 2016 BioProcess International Europe conference, Vienna, Austria, 13 April 2016.
120. Przybycien TM, "Never Mind Chromatography, Here's Precipitation," talk given at session in honor of Steven Cramer at 251st American Chemical Society National Meeting, San Diego, CA, 13 March 2016.
119. Przybycien T, Jaquez O, Gronke R, "Design of a Continuous Precipitation Operation for Protein Capture," poster and podium summary presented at Integrated Continuous Manufacturng II (ICB II), Berkeley, CA, 1-5 November 2015.
118. Przybycien TM, "Antibody Purification with PEGylated Protein A Affinity Chromatography Media," keynote talk given at 3rd European Congress of Applied Biotechnology (ECAB3), Nice, France, 1 October 2015.
117. Przybycien TM, "A Continuous Precipitation Process for High Titer Recombinant Protein Capture and Purification," talk given at The Bioprocessing Summit, Boston, MA, 6 August 2015.
116. Przybycien TM, "Affinity Chromatography with PEGylated Protein Ligands," keynote talk given at 34th International Symposium on the Separation of Proteins, Peptides and Polynucleotides, (ISPPP 2015) Würzburg, Germany, 7 November 2014.
115. Przybycien TM, "Unconventional Applications of Poly(ethylene glycol)-modified Proteins in BioProcessing and Drug Delivery," seminar given in the Department of Surface and Corrosion Science at KTH Royal Institute of Technology, Stockholm, Sweden, 4 November 2014.
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109. Przybycien TM, "PEGylating Protein A Media: Increasing Selectivity for MAbs by Decreasing Non-Specific Binding," talk given at IBC's 10th BioProcess International Conference & Exhibition, Boston, MA, 19 September 2013.
108. Przybycien TM, "Enhancing Protein A Selectivity via PEGylation," talk given at the 9th Aannual PEGS – The Essential Protein Engineering Summit, Boston, MA, 2 May 2013.
107. Przybycien TM, "Unconventional Applications of Poly(ethylene glycol)-modified Proteins in BioProcessing and Drug Delivery," Grain Processing Corporation-sponsored seminar presented at the Department of Chemical Engineering, Michigan Technical University, 22 February 2013.
106. González-Valdez J, Yoshikawa A, Benavides J, Rito-Palomares M, Przybycien TM, "Enhancing Selectivity in Affinity Chromatography via PEGylated Macromolecular Affinity Ligands, or How to Make Protein A Media More Expensive," poster given at the Recovery of Biological Products XV conference, Stowe, VT, 29 July 2012.
105. Przybycien TM, "Poly(ethylene glycol)-modified Proteins: Solution and Interfacial Behavior, and Unconventional Applications in BioProcessing and Drug Delivery," seminar given at the National Technical University of Athens, Department of Chemical Engineering, 4 May 2012.
104. Przybycien TM, "Poly(ethylene glycol)-modified Proteins: Solution and Interfacial Behavior, and Unconventional Applications in BioProcessing and Drug Delivery," seminar given at the University of Patras, Department of Chemical Engineering, 3 May 2012.
103. Corcoran TE, Garoff S, Peterson E, Przybycien TM, Tilton RD, "Surfactant-Enhanced Spreading with Application to Pulmonary Drug Delivery," talk presented at the 7th Eastern Mediterranean Conference on Chemical Engineering, Corfu, Greece, 28 April 2012.
102. Przybycien TM, "Poly(ethylene glycol)-modified Proteins: Solution and Interfacial Behavior, and Unconventional Applications in BioProcessing and Drug Delivery," seminar given at Aristotle Univerity Thessaloniki, Department of Chemical Engineering, 26 April 2012.
101. Przybycien TM, "Relieving the Taxing Effects of Interfacial Adsorption on Pharmaceutical Proteins in PLG-based Microsphere Delivery Systems," seminar given at Tulane University, Department of Chemical and Biomolecular Engineering, 15 April 2011.
100. Przybycien TM, "PEGylation as Panacea: PLG-based Microsphere Delivery of PEG-modified Proteins," seminar given at Arizona State University, School for Engineering of Matter, Transport and Energy, 3 December 2010.
99. Jaquez OA, Gronke R, Przybycien TM, "Design and Optimization of a Scalable, Continuous Precipitation Process for the Capture and Purification of High Titer Monoclonal Antibodies," poster presented at the Recovery of Biological Products XIV Conference, Lake Tahoe, CA, 1-6 August 2010.
98. Przybycien TM, "Biomedical Measurements and Biomedical Sensors: Problems and Solutions," at IEEE 3rd Annual International Measurement University, Trento, Italy, 19 July 2010.
97 Przybycien TM, "Predicting Formulated Protein Physical Stability in Terms of Tendency to Self Associate and Tendency to Unfold," seminar given at Bogazici University, Department of Chemical Engineering, Istanbul, Turkey, 16 March 2010.
96. Przybycien TM, "A MEMS Membrane-based Acoustic Biosensor," seminar given at Middle Eastern Technical University, Department of Chem Engineering, Ankara, Turkey, 15 Mar 2010.
95. Pai S, Canady A, Tilton R, Przybycien TM, "Combating Interfacial Losses of Protein Drugs in Poly(lactide-co-glycolide) Microsphere Delivery Systems with Protein PEGylation," talk

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94. Przybycien TM, "PEGylation as Panacea? PLG-based Microsphere Delivery of PEG-modified Proteins," seminar presented at Departamento Biotecnología e Ingenieria de Alimentos, Monterrey, MX, 18 February 2010.
93. Przybycien TM, "PEGylation as Panacea: PLG-based Microsphere Delivery of PEG-modified Proteins," seminar presented at University of Canterbury, Department of Chemical and Process Engineering, Christchurch, NZ, 20 August 2009
92. Przybycien TM, "Kinetic and Structural Phenomena in Protein Precipitation Operations," talk presented at Biogen Idec, Inc., Cambridge, MA, 4 November 2008
91. Bartkovsky M, Liao A, Fedder GK, Hauan S, Przybycien TM, "Towards a MEMS Membrane-based Gravimetric Biosensor," talk presented at the 16th International Conference on Mechanics in Medicine and Biology, Pittsburgh, PA, 25 July 2008.
90. Przybycien TM, Laurent A, "Connecting Protein Structure Perturbations on Hydrophobic Separations Media to Protein Physical Properties," talk presented at the Recovery of Biological Products XIII Conference, Quebec, PQ, Canada, 23 June 2008.
89. Przybycien TM, "PEG Modified Proteins," talk presented at the Drug and Nucleic Acid Delivery Symposium, Univ. Pittsburgh School of Pharmacy, 2 June 2008.
88. Przybycien TM, "Understanding Protein Structural Change in Hydrophobic Chromatography", seminar presented at Departamento Biotecnología e Ingenieria de Alimentos, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, MX, 11 April 2008.
87. Przybycien, TM, "Reckoning protein physical stability in terms of tendency to self-associate", talk presented at the Symposium in Honor of Ruben Carbonnell at the ACS Spring 2008 national meeting, New Orleans, LA, 7 April 2008.
86. Cisneros-Ruiz M, Rito-Palomares M, Przybycien TM, "The Separation of PEGylated Protein Conjugates via Reversed Phase Chromatography: PEG as a Group-Specific RPC Tag," talk presented at 14th International Conference on BioPartitioning and Purification, Lisbon, Portugal, 18 June 2007.

Presentations: Contributed Talks and Posters – since 2007 (presenter underlined)

186. Przybycien TM, "Modeling Protein Solubility in Synergistic "Multi-mode" Precipitation Operations," talk given at the 10th HIC RPC Hydrophobic Bioprocessing conference, Scottsdale, AZ, 14 February 2017
185. Przybycien TM, Tilton RD, Garoff S, Sharma R, Iasella S, Corcoran TE, "The Roles of Competing Dissolution, Diffusion and Transient Marangoni Convection Fluxes in Surfactant-Enhanced Spreading of Aerosols for Pulmonary Delivery," talk given at the 2016 American Institute of Chemical Engineers Annual Meeting, San Francisco, CA, November 17, 2016; selected as best of session
184. Weinberg J, Zhang S, Carta G, Przybycien T, "Single and Multi-component IgG Adsorption on Protein A Chromatography Resins," talk given at 29th International Symposium on Preparative and Process Chromatography (PREP 2016), Philadelphia, PA, 18 July 2016.
183. Sharma R, Corcoran T, Garoff S, Przybycien TM, Tilton RD, "Transport of a partially wetted single particle at the liquid/vapor interface under the influence of an externally imposed surfactant generated Marangoni stress," talk given at 90th ACS Colloid & Surface Science Symposium, Harvard University, 7 June 2016
182. Duner G, Tilton RD, Przybycien TM, Garoff S, "Marangoni transport of particles at the fluid-fluid interface, talk given at 90th ACS Colloid & Surface Science Symposium, Harvard University, 7 June 2016
181. Nordmark B, Tilton R, Przybycien T, "Validation of a coagulation assay used to determine the effect of ionic strength on the turbidity reduction capabilities of *Moringa oleifera* cationic protein

fractions," poster given at the 90th ACS Colloid & Surface Science Symposium, Harvard Univ., 6 June 2016

180. Iasella SV, Tilton RD, Przybycien TM, Garoff S, "Hydrophobic modification of drugs to enhance post-deposition dispersal of inhaled aerosol medications," poster given at the 90th ACS Colloid & Surface Science Symposium, Harvard University, 6 June 2016
179. Stetten AZ, Moraca G, Tristram-Nagle SA, Corcoran T, Garoff S, Przybycien TM, Tilton RP, "Enabling Marangoni transport at air-fluid interfaces through deposition of aerosolized lipid dispersions," talk given at 90th ACS Colloid & Surface Science Symposium, Harvard University, 6 June 2016
178. Weinberg J, Przybycien T, "Mechanistic Modeling of Antibody Transport, Adsorption Equilibrium, and Uptake Kinetics in Protein A Chromatography Resins with PEGylated Ligands" talk presented at 251st American Chemical Society National Meeting, San Diego, CA, 16 March 2016
177. Stetten A, Corcoran T, Tristam-Nagle S, Garoff S, Przybycien T, Tilton R, "Enabling Marangoni Flow through Aerosolization of Lipid Dispersions," talk presented at the 2015 American Institute of Chemical Engineers Annual Meeting, Salt Lake Atlanta, GA, November 11, 2015.
176. Sharma R, Corcoran T, Garoff S, Przybycien T, Reed D, Tilton R, "Enhanced Post-Deposition Dispersal of Aerosolized Medicine by Marangoni Flows," talk presented at the 2015 American Institute of Chemical Engineers Annual Meeting, Salt Lake Atlanta, GA, November 9, 2015.
175. Dunér G, Tilton R, Przybycien T, Garoff S, "Marangoni Transport of Interfacial Particles Around Partially Wetted Obstacles," talk presented at the 2015 American Institute of Chemical Engineers Annual Meeting, Salt Lake Atlanta, GA, November 9, 2015.
174. Weinberg JB, Przybycien TM, "The Stability, Selectivity, and Performance of PEGylated Protein A Chromatography Resin," poster presented at the 3rd European Congress of Applied Biotechnology (ECAB3), Nice, France, 30 September 2015.
173. Weinberg JB, Przybycien TM, "A Detailed Mechnaistic Model for Predicting Protein A Chromatography Column Performance," poster presented at the 28th International Symposium on Preparative and Process Chromatography (PREP 2015), Philadelphia, PA, July 27, 2015.
172. Dunér G, Tilton R, Przybycien T, Garoff S, "Marangoni transport of colloidal particles at the liquid-liquid interface: Forming interfacial tension gradients by surfactant convection-diffusion in radial," talk presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 17, 2015.
171. Sharma R, Corcoran T, Garoff S, Przybycien T, Tilton R, "Transport of particles at the liquid/vapor interface under the influence of Marangoni flows," talk presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 17, 2015.
170. Stetten AZ, Corcoran T, Garoff S, Przybycien TM, Tilton RD, Tristam-Nagel SA, "Creating lipid monolayers by aerosolization for the purpose of inducing Marangoni flow," talk presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 16, 2015.
169. Dunér G, Tilton R, Przybycien T, Garoff S, "Marangoni transport of interfacial colloids: the effect of cationic polyelectrolyte-anionic surfactant complexes on application and rinsing," talk presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 15, 2015.
168. Nordmark BA, Przybycien TM, Tilton RD, "Interfacial activity and coagulant performance of proteins extracted from Moringa oleifera seeds," poster presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 15, 2015.

167. Stetten A, Tilton R, Przybycien T, Garoff S, "Long-time persistence of fluid drops atop miscible fluid subphases," poster presented at 89th American Chemical Society Colloid and Surface Science Symposium, Carnegie Mellon University, Pittsburgh, PA, June 15, 2015.
166. Weinberg JB, Przybycien TM, "Improving the Selectivity of Protein A Chromatography with PEGylated Affinity Ligands: Performance Characterization and Modeling of PEGylated Protein A," talk presented 18th International Conference on Biopartitioning and Purification (BPP 2015), Vienna, Austria, June 9, 2015.
165. Weinberg JB, Przybycien TM, "Towards Improving the Selectivity of Protein A Chromatography with PEGylated Ligands: Performance Characterizations of PEGylation Strategies," talk presented at the 249th American Chemical Society National Meeting, Denver, CO, March 26, 2015.
164. Dunér G, Garoff S, Przybycien T, Tilton RD, "Adsorption and Transient Marangoni Convection of Colloidal Particles at the Liquid-Liquid Interface," talk presented at the 2014 American Institute of Chemical Engineers Annual Meeting, Atlanta, GA, 20 November 2014.
163. Khanal A, Corcoran TE, Garoff S, Przybycien T, Tilton RD, "Spreading of surfactant-laden aerosols at fluxes comparable to the conducting zone in pulmonary airways," talk presented at 88th American Chemical Society Colloid and Surface Science Symposium, University of Pennsylvania, Philadelphia, PA, June 23 – 25, 2014.
162. Sharma R, Corcoran TE, Garoff S, Przybycien T, Tilton RD, "Self-dispersing aerosol drug carriers for pulmonary drug delivery at low deposition fluxes," talk presented at 88th American Chemical Society Colloid and Surface Science Symposium, University of Pennsylvania, Philadelphia, PA, June 23 – 25, 2014.
161. Stetten AZ, Corcoran TE, Garoff S, Przybycien T, Tilton RD, "Long time persistence of drops atop miscible simple or complex fluid subphases," talk presented at 88th American Chemical Society Colloid and Surface Science Symposium, University of Pennsylvania, Philadelphia, PA, June 23 – 25, 2014.
160. Stetten AZ, Corcoran TE, Garoff S, Przybycien T, Tilton RD, "Enhancement of the spreading of phospholipids on liquid subphases via aerosolization," poster presented at the 88th American Chemical Society Colloid and Surface Science Symposium, University of Pennsylvania, Philadelphia, PA, June 23 – 25, 2014.
159. Przybycien TM, Duan Q, "Impact of Mobile Phase Uncertainty on Yield, Purity and Throughput in Protein Separation by Ion Exchange Chromatography," talk presented at 247th American Chemical Society National Meeting, Dallas, TX, 18 March 2014.
158. Gronke RS, Jaquez O, Przybycien TM, "Using Continuous Precipitation for the Purification of High Titer Monoclonal Antibodies," talk presented at IBC's Biopharmaceutical Development & Production, San Diego, CA, 26 March 2014 (invited).
157. Khanal A, Sharma R, Corcoran T, Przybycien TM, Garoff S, Tilton RD, "Post-deposition spreading and dispersal of surfactant-laden aerosols on miscible subphases consisting of entangled polymer solutions," poster presented at Gordon Research Conference on Colloidal, Macromolecular and Polyelectrolyte Solutions, February 16 – 20, 2014, Ventura, CA
156. Cheng A-C, Przybycien TM, "Economic and Environmental Sustainability in Single-Use Versus Multi-Use Equipment Decision-Making for Bioprocesses," talk presented at the 2013 American Institute of Chemical Engineers Annual Meeting, San Francisco, CA, 6 November 2013.
155. Khanal A, Sharma R, Corcoran T, Swanson E, Przybycien T, Garoff S, Tilton R, "Surfactant-enhanced post-deposition spreading of aerosols with application to pulmonary drug delivery," talk presented at the 2013 American Institute of Chemical Engineers Annual Meeting, San Francisco, CA, 4 November 2013.
154. Duan Q, Przybycien TM, "Propagation of Variance in Ion Exchange Chromatography for Protein Separations: Impact of Mobile Phase Variance," poster given at the 17th International Conference on Biopartitioning and Purification, Newport, RI, 6 October 2013.

153. Przybycien TM, Tilton RD, Wang Y, Zapanta CZ, "A Unique Dual Major Approach for Undergraduate Biomedical Engineering Education," talk given at the 2013 Biomedical Engineering Society Annual Conference, Seattle, WA, 26 September 2013.
152. Khanal A, Sharma R, Corcoran T, Swanson E, Przybycien T, Garoff S, Tilton R, "Self-dispersing drug carriers for pulmonary delivery," talk presented at the 87th ACS Colloid and Surface Science Symposium, Riverside, CA, 26 June 2013.
150. Khanal A, Sharma R, Kalita R, Gao F, Corcoran T, Peterson E, Przybycien T, Garoff S, Tilton R, "Self-dispersing drug carriers for pulmonary delivery: spreading of aqueous surfactant solutions on model airway surface liquid subphases," talk presented at the Swedish Academy of Pharmaceutical Sciences (Läkemedelsakadamin) and Controlled Delivery and Release Centre Conference on Challenges and Opportunities in Controlled Delivery and Release, Södertälje, Sweden, 13 November 2012.
149. Sharma R, Kalita R, Corcoran T, Peterson E, Przybycien T, Garoff S, Tilton R, "Autophobing on liquid subphases via interfacial transport of amphiphilic molecules," talk presented at the Annual Meeting of the American Institue of Chemical Engineers, Pittsburgh, PA, 28 October 2012.
148. Canady A, Przybycien TM, Tilton RD, "Does poly(ethylene glycol) conjugation protect proteins from conformational change during emulsion-based microsphere encapsulation?," talk presented at the Annual Meeting of the American Institue of Chemical Engineers, Pittsburgh, PA, 28 October 2012.
147. Khanal A, Sharma R, Kalita R, Gao F, Corcoran T, Peterson E, Przybycien T, Garoff S, Tilton R, "Self-dispersing drug carriers for pulmonary delivery: spreading of aqueous surfactant solutions on model airway surface liquid subphases," talk presented at the Annual Meeting of the American Institue of Chemical Engineers, Pittsburgh, PA, 28 October 2012.
146. Sharma R, Kalita R, Peterson E, Corcoran T, Garoff S, Przybycien T, Tilton R, "Autophobing on liquid subphases by surface transport," talk presented at the 19th International Symposium on Surfactants in Solution, Edmonton, Alberta, Canada, 27 June 2012.
145. Khanal A, Sharma R, Kalita R, Gao F, Peterson E, Corcoran T, Garoff S, Przybycien T, Tilton R, "Marangoni Driven Spreading on Model Airway Surface Liquid Subphases," talk presented at the 19th International Symposium on Surfactants in Solution, Edmonton, Alberta, Canada, 27 June 2012.
144. Khanal A, Sharma R, Kalita R, Gao F, Corcoran T, Peterson E, Garoff S, Przybycien T, Tilton R, "Spreading of aqueous surfactant solutions on model airway surface liquid subphases," 86th ACS Colloid and Surface Science Symposium, The Johns Hopkins University, Baltimore, MD, June 12, 2012.
143. Sharma R, Kalita R, Corcoran T, Peterson E, Garoff S, Przybycien T, Tilton R, "Autophobing on liquid subphases," 86th ACS Colloid and Surface Science Symposium, The Johns Hopkins University, Baltimore, MD, June 13, 2012.
142. Canady A, Przybycien TM, Tilton RD, The Behavior of PEGylated Proteins at Oil/Water Interfaces Relevant to Formulation in and Delivery from Poly(lactide-co-glycolide) Microspheres," talk presented at ACS Spring National Meeting, San Diego, CA, 25 March 2012.
141. Gonzalez-Valdez J, Benevides J, Rito-Palomares M, Przybycien TM, "Towards Improving Selectivity in Affinity Chromatography with PEGylated Affinity Ligands: The Performance of PEGylated Protein A," poster presented at 16th International Conference on BioPartitioning and Purification (BPP 2011), Puerto Vallarta, MX, 19 September 2011.
140. Koch K, A. Khanal, F. Gao, T. Corcoran, S. Garoff, T. Przybycien, R. Tilton, "Quasi-Immiscible Spreading of Aqueous Surfactant Solutions on Aqueous Entangled Polymer Solutions," ACS Colloid and Surface Science Symposium, June 2011.
139. Kim AL, Przybycien TM, "Connecting the Aggregation Behavior of Human Growth Hormone to its Colloidal and Conformational Stability," ACS Spring National Meeting, Anaheim, CA, 28 March 2011.

138. Pai SS, Przybycien TM, Tilton RD, "Determination of the Conformation of Protein-Conjugated Poly(ethylene glycol) Chains by Small-Angle Neutron Scattering," talk presented at AIChE National Meeting, Salt Lake City, UT, 11 November 2010.
137. Jaquez OA, Gronke RS, Przybycien TM, "Design of a Scalable Continuous Precipitation Process for the Capture and Purification of High Titer mAbs," talk presented at AIChE National Meeting, Salt Lake City, UT, 9 November 2010.
136. Koch K, B. Dew, S. Garoff, T. Przybycien, R. Tilton, T. Corcoran Optimizing Surfactants for Use in Self-Dispersing Aerosol Drug Formulations, Annual Meeting Cystic Fibrosis Foundation, Baltimore, MD, October, 2010
135. Dew B, Koch K, Garoff S, Przybycien T, Tilton R, "Surface Tension Gradient Driven Spreading on Mucin Solutions," talk presented at the 84th Colloid and Surface Science Symposium of the American Chemical Society, Akron, OH, 20-23 June 2010
134. Khanal A, Garoff S, Przybycien TM, Tilton RD, "Effects of Surfactants on Mucus Rheology," poster presented at the 84th Colloid and Surface Science Symposium of the American Chemical Society, Akron, OH, 20-23 June 2010
133. Canady A, Pai SS, Przybycien TM, Tilton RD, "The Effects of Poly(ethylene glycol) Conjugation on Protein Structure and Activity," poster presented at the 84th Colloid and Surface Science Symposium of the American Chemical Society, Akron, OH, 20-23 June 2010.
132. Kim AL, Przybycien TM, "Second virial coefficients, unfolding free energies and predictions of self-association rate constants for protein formulations,"poster presented at the 239th ACS National Meeting, San Francisco, CA, 23 March 2010.
131. Pai SS, Canady A, Tilton RD, Przybycien TM, "PEGylation can attenuate protein adsorption and aggregation related to poly(lactide-co-glycolide) depot delivery systems," talk presented at the 239th ACS National Meeting, San Francisco, CA, 23 March 2010.
130. Dew B, Weygand MJ, Lin C-Y, Chung C-H, Peddireddy K, Przybycien TM, Pilewski JM, Corcoran TE, Garoff S, Tilton RD, "Surfactant Formulation Principles for Self-Dispersing Aerosol Drug Carriers based on Marangoni Flow in the Pulmonary Airways," presented at the 2009 National American Institute of Chemical Engineers Meeting, Nashville, TN, 12 Nov 2009
129. Pai SS, Przybycien TM, Tilton RD, "Impact of protein PEGylation on adsorption mechanisms related to poly(lactide-co-glycolide) drug delivery depot systems," presented at the 2009 Annual Biomedical Engineering Society meeting, Pittsburgh, PA, 10 October 2009
128. Gaspard S, Przybycien TM, Siegel M, "Development of a Point-of-Care Device for Quantitative Stage-I Pressure Ulcer Diagnosis Independent of Skin Color," poster presented at the 2009 Annual Biomedical Engineering Society meeting, Pittsburgh, PA, 9 October 2009
127. Przybycien T, Laurent A, "Helix-sheet inter-conversion on protein adsorption to reverse phase chromatography media," poster presented at the 2009 BioPartitioning and Purification conference, Uxbridge, UK, 14-18 June 2009
126. Pai SS, Przybycien TM, Tilton RD, "Protein adsorption in PLG microsphere delivery systems: impact of protein PEGylation, poster presented at the 83rd ACS Colloid and Surface Science Symposium, New York, NY, 14-18 June 2009
125. Weygand M, Dew B, Garoff S, Lösche M, Przybycien T, Tilton R, "The surface properties of a lung mucus model system," presented at the 2009 American Physical Society meeting, Pittsburgh, PA, 16-20 March April 2009
124. Pai SS, Przybycien TM, Tilton RD, "Poly(ethylene glycol)-Modified Proteins: Implications for Poly(lactide-co-glycolide)-Based Microsphere Delivery, " presented at the 2008 Annual Meeting of the American Institute of Chemical Engineers, Philadelphia, PA, 14 November 2008
123. Laurent A, Przybycien TM, "Universal secondary structure perturbation mode for proteins in reversed-phase chromatography," presented at the 236th ACS National Meeting, Philadelphia, PA, 18 August 2008.

122. Dew B, Chung C-H, Corcoran TE, Garoff S, Przybycien TM, Tilton RD, "Spreading of Aqueous Surfactant Solutions on Entangled Mucin Solutions" presented at the 82nd ACS Colloids and Surface Symposium, NC State University, 18 June 2008.
121. Gaspard S, Przybycien TM, Seigel M, "Skin Color Compensated Colorimeter for Detection and Classification of Pressure Ulcers," presented at the IEEE International Instrumentation and Measurement Technology Conference (I^2MTC 2008), Vancouver, BC, 13 May 2008.

III. TEACHING

Education Support: External Grant Awarded

1993 PI: Camille and Henry Dreyfus Foundation Special Grant in the Chemical Sciences: "Development of a Fermentation Experiment for the Chemical Engineering Undergraduate Laboratory at Rensselaer," co-PIs: J.L. Plawsky and B.W. Bequette, amount: $20,000

Education Support: Rensselaer Polytechnic Institute Grants Awarded

1993 Co-PI: Capital Program, Institute-wide: "Ricketts Classroom Computing: Mobile Computer Station," PI: H. Bungay, co-PIs: W. Bequette, J. Plawsky, amount ~$18,000.

1992 PI: Committee on Computing in Engineering Education, School of Engineering: IBM RS/6000 Unix workstation, amount ~$15,000

Students Supervised: Postdoctoral Research Associates

Carnegie Mellon University, Fall 1998 – current

1. Dr. Gunnar Dunér; June 2013 – September 2016 (co-advised with Profs. R. Tilton, S. Garoff)
   Research Area: Surfactant-enhanced particle spreading at the oil/water interface

Students Supervised: Ph.D. Students

Carnegie Mellon University, Fall 1998 - current

33. Ms. Madeline Sauleda; PhD Physics expected 2020 (co-advised with Profs. R. Tilton, S. Garoff)
    Currently in Physics research lab rotation program
32. Mr. Steven Iasella; PhD ChE expected 2018 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis Area: Surfactant-enhanced spreading of aerosol powders on airway surface liquid mimics
31. Ms. Qin Gu; PhD ChE expected 2018
    Thesis Area: Protein capture via continuous, coupled precipitation-microfiltration
30. Ms. Brittany Nordmark; PhD ChE expected 2018 (co-advised with Prof. R. Tilton)
    Thesis Area: Floculating agents based on *Moringa oleifera* proteins for water purification
29. Mr. Justin Weinberg; PhD ChE expected 2017
    Thesis Area: Next-generation affinity chromatography media with PEGylated ligands
28. Ms. Amy Stetten; PhD Physics expected 2017 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis Area: Lipid-enhanced spreading
27. Dr. Ramankur Sharma; PhD ChE 2016 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis: "Surfactant-induced Marangoni transport on liquid surfaces"
    Currently employed at Intel, Inc., Portland, OR
26. Dr. Amsul Khanal: PhD BME 2014 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis: “Spreading of Surfactant-Laden Aerosols on Entangled Polymer Solution Subphases”
    Currently employed at Blue Cross Blue Shield Association, Chicago, IL
25. Dr. Adam Canady: PhD ChE 2013 (co-advised with Prof. R. Tilton)
    Thesis: “Adsorption of Poly(ethylene glycol) Conjugated Proteins to Oil/Water Interfaces Relevant to Drug Delivery”
    Currently employed by Mylan, Inc., Morgantown, WV
24. Dr. Jane Valentine: PhD BME 2013 (co-advised with Prof. S. Hauan)
    Thesis: “Modeling and Optimization of a MEMS Membrane-based Acoustic-wave Biosensor”
    Recipient of a U.S. Department of Homeland Security Graduate Fellowship
    Currently employed by Center for Simulation of Advanced Rockets at the University of Illinois.
23. Dr. Jose Guillermo Gonzalez Valdez (of Tec de Monterrey, Monterrey, Mexico): DSc Biotech 2012 (co-advised with Profs. J. Benevides Lozano and M. Rito-Palomares of Tec de Monterrey)
    Thesis: “Analysis,Recovery and Potential New Uses of PEGylated Proteins”
    Thesis designated as “Outstanding Thesis” by examining committee and Tec de Monterrey.

Currently employed as an assistant professor at Tec de Monterrey, Monterrey, MX.

22. Dr. Sanna Gaspard: PhD BME 2011
Thesis: "The Development and Evaluation of a Point-of-Care Tissue Reflectance Spectroscopy-based Device for Early Stage Pressure Ulcer Detection"
Recipient of a 2009 BMES Research Award
Currently employed as CEO of Rubitect, Inc., a Pittsburgh, PA-based startup company.

21. Dr. William Hum: PhD ChE 2011
Thesis: "Curvature Effects an the Adsoprtion of Plasma Proteins to Polystyrene"
Currently employed as Global Technology Lead, Industrial Lubricants, BASF, New York, NY.

20. Dr. Sheetal Pai: PhD ChE 2011 (co-advised with Prof. R. Tilton)
Thesis: "Adsorption of Poly(Ethylene Glycol) Conjugated Proteins to Biomaterials used in Delivery"
Currently employed as Senior Research Scientist at AbbVie, Inc, Mannheim, Germany.

19. Dr. Andrew Kim: PhD ChE 2009
Thesis: "Rational, High-Throughput Screening for Formulations that Physically Stabilize Recombinant Proteins"
Currently employed as Scientist II, Process Developemnt at Zymogenetics, Inc., Seattle, WA.

18. Dr. Abigail Laurent: PhD ChE 2008
Thesis: "Understanding Protein Structural Change in Hydrophobic Chromatography"
Currently employed as Staff Scientist, Tinoro, Inc., Carlsbad, CA

17. Dr. Mayra Cisneros-Ruiz (of Tec de Monterrey, Monterrey, Mexico): DSc Biotech 2006 (co-advised with Prof. M. Rito-Palomares of Tec de Monterrey)
Thesis: "Chromatographic Separation of Polymer-Protein Conjugates"
Thesis designated as "Outstanding Thesis" by examining committee and Tec de Monterrey.

16. Dr. Murni Ahmad: PhD ChE 2006 (co-advised with Prof. S. Hauan)
Thesis: "Design of Aqueous Two-Phase Protein Extraction Processes"
Currently employed as an assistant professor at the Universiti Teknologi Petronas, Malaysia.

15. Dr. Jessica Tucker: PhD ChE 2006 (co-advised with Prof. R. Tilton)
Thesis: "Novel Extracellular Matrix Mimics: Applications in Drug Delivery and Protein Receptor-Binding"
Currently employed as Director, Division of Biosafety, Biosecurity and Emerging Biotechnology Policy, OSP, at the National Institutes of Health, Bethesda, MD

14. Dr. Michael Bartkovsky: PhD ChE 2006 (co-advised with Prof. S. Hauan)
Thesis: "Development of an Acoustic-Wave MEMS Biosensing Device"
Currently employed as Associate Director, R&D Process Development & Operation Support at CSL Behring, Kankakee, IL

13. Dr. Susan Daly: PhD ChE August 2004 (co-advised with Prof. R. Tilton)
Thesis: "The Effect of Polyethylene Glycol Modification on the Structure of Adsorbed Enzyme Monolayers"
Recipient of the CMU Chemical Engineering John E. Swearingen Fellowship
Recipient of the CMU Chemical Engineering PPG Fellowship
Currently employed as Principal Scientist, Johnson & Johnson, Skillman, NJ.

12. Dr. Millicent Ow Sullivan: PhD ChE May 2003
Thesis: "Colloidal Gold/Polyethylenimine Formulations for Gene Delivery"
Recipient of a Clare Booth Luce Graduate Fellowship in Science and Engineering
Currently employed as Associate Professor of Chemical and Biomolecular Engineering at the University of Delaware.

11. Dr. Derek Berglund: PhD ChE December 2002 (co-advised with Prof. R. Tilton)
Thesis: "Tuning Adsorption via Polymer-Surfactant Complexation" Recipient of 2003 Student Award of the Polymer group of the Pittsburgh Section of the ACS.

Currently employed as Director, Small Molecule Design and Development at Eli Lilly & Co., Indianapolis, IN

10. Dr. Angela (Wilcox) Blake-Haskins: PhD ChE May 2002
Thesis: "High Throughput Screening Techniques for Conditions that Inhibit Protein Self-Association"
Recipient of the Mark Dennis Karl Outstanding Graduate Teaching Award from CMU
Currently employed as Senior Scientist, Drug Delivery & Device Development at MedImmune, Washington, DC

9. Dr. Arthur Hewig: PhD ChE December 2001
Thesis: "Simulation of Protein Crystallizability"
Currently employed as Director, Purification Process Development at Amgen, Thousand Oaks, CA.

8. Dr. Ganesh Vedantham: PhD ChE April 2000
Thesis: "The Structural Response of Proteins to Bioseparations and Drug Delivery Environments"
Recipient of ACS BIOT Division W.H. Peterson award for best student poster presentation at the 2000 National Meeting in San Francisco.
Currently employed as Executive Director, Lead Drug Substance Process Development at Amgen, Puerto Rico

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998

7. Dr. Kartik Kumar, PhD ChE June 1999
Thesis: Electrochemically Modulated Ion Exchange Chromatography for Protein Separations
Currently employed as Head, Pest Control Formulation, Reckitt Benckiser, Gurgaon, India.

6. Dr. H. Gerald Sparks: MS ChE December 1996, PhD ChE April 1999
Thesis: "Investigation of Non-Specific Protein Adsorption to Clinically Relevant Polymeric Surfaces Through Predictive Modeling, Kinetic Measurements, and Fourier Transform Infrared Spectroscopy"
Recipient of Rensselaer Institute Service Award
Currently employed as Senior Research Scientist II at Gilead Sciences, Inc., Orange County, CA

5. Dr. Samir Sane (co-advised with Prof. S. Cramer): PhD ChE February 1999
Thesis: "Secondary Structure Characterization of Proteins Using Amide I Band Raman Spectroscopy: Methods Development and Applications to Bioprocesing"
Currently Director of US Early Stage Pharmaceutical Development, Genentech, Inc., South San Francisco, CA.

4. Dr. Philippe Lam: MS ChE August 1994, PhD ChE August 1997
Thesis: "Electrochemically Modulated Liquid Chromatography for Protein Separation"
Currently employed as a Senior Research Engineer, Late Stage Pharmaceutical and Device Development, Genentech, Inc., South San Francisco, CA

3. Dr. Sugunakar Patro: MS ChE August 1992, PhD ChE December 1995
Thesis: "Theoretical and Experimental Investigations of Specificity in Protein Self-Association"
Currently employed as Executive Director and Therapeutic Area Head, Cardiovascular, Metabolic & Neurosciences, Amgen, Inc., Thousand Oaks, CA

2. Dr. Stelios Tzannis: MS ChE December 1994, PhD ChE August 1995
Thesis: "Protein-Surface Interactions in Drug Delivery Systems"
Currently President & CEO at Delos Pharmaceuticals, Inc., San Fancisco, CA.

1. Dr. Harish V. Iyer: MS ChE August 1994, PhD ChE May 1995
Thesis: "Theoretical and Experimental Investigations on the Impact of Mixing in Protein Precipitation Processes"
Currently Senior Advisor, Scientific Programs, Bill and Melinda Gates Foundation, Hyderabad, India.

Students Supervised: M.S. Students

Carnegie Mellon University, Fall 1998 – current

27. Mr. Aditya Patel: MS expected December 2017 (co-advised with Profs. R. Tilton, S. Garoff)
26. Ms. Mengjie Zhao: MS expected December 2017 (co-advised with Profs. R. Tilton, S. Garoff)
25. Ms. Yuqi Zhang: MS expected December 2017 (co-advised with Profs. R. Tilton, S. Garoff)
24. Mr. Anubhav Khanna: MSCPS expected December 2017 (co-advised with Profs. R. Tilton, S. Garoff)
23. Mr. David Yao: MS expected May 2017
    Research Area: Demonstration systems for aqueous two-phase separations
22. Ms. Sachi Nagada: MS December 2016 (co-advised with Prof. R. Tilton)
    Research Area: Production of solid aerosols for pulmonary delivery via spray-drying
    Currently a software engineer at Fidelity Investments
21. Mr. Zheng Zhang: MSCPS December 2016 (co-advised with Prof. R. Tilton)
    Research Area: Simulation of PEG chain morphology in protein-PEG conjugates
20. Mr. Haichao Wu: MS ChE December 2015 (co-advised with Prof. R. Tilton)
    Research Area: Marangoni-assisted spreading on subphase geometries mimicking lung airways
    Currently a PhD student in chemical engineering at the University of Colorado.
19. Mr. Zechen Zhang: MS ChE December 2014 (co-advised with Prof. R. Tilton)
    Research Area: Detecting drug spreading on pulmonary airway surface mimics
    Currently a PhD student in chemical engineering at Virginia Tech.
18. Ms. Niyatee Ravipati: MS ChE December 2014
    Research Area: Towards a platform precipitation-based process for high concentration secreted proteins
    Currently an Engineer at Nagarjuna Shubotech, Hyderabad, India.
17. Mr. Raj Maniar: MS ChE December 2014
    Research Area: Single-use equipment decision-making in bioprocessing
16. Mr. Qiyang Duan: MS ChE December 2013
    Research Area: Propagation of variance in ion exchange chromatography of proteins
    Curently Project Supervisor at CITIC Construction Company, Beijin, China.
15. Mr. An-Chi Cheng: MS ChE December 2013
    Research Area: Single-use versus multi-use equipment decision-making in bioprocess design
    Currently Process Integration Engineer at Taiwan Semiconductor Manufacturing Company, Hsinchu Science Park, Taiwan
14. Ms. Shih-hsin Chang: MS ChE December 2013 (co-advised with Prof. R. Tilton)
    Research Area: Interfacial tension of PEGylated protein solutions
    Currently LDPE Process Specialist at Formosa Plastics
13. Ms. Yao Yu: MS BME May 2013 (co-advised with Prof. R. Tilton)
    Thesis Area: Release of PEGylated Proteins from Biodegradable Microspheres
    Currently a Research Scientist at Merck, Inc., Palo Alto, CA
12. Ms. Sneha Solanki: MS ChE December 2012 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis Area: Surfactant Carriers for Enhanced Pulmonary Drug Delivery – Surfactant Transport
    Currently a staff engineer at Covestro (formerly Bayer) Corp., Baytown, TX
11. Dr. Ramankur Sharma: MS ChE May 2012 (co-advised with Profs. R. Tilton, S. Garoff)
    Thesis Area: Surfactant Carriers for Enhanced Pulmonary Drug Delivery – Existence of Transient Lens
    Went on to PhD study at Carnegie Mellon University with Profs. Tilton, Garoff and myself as co-advisors
10. Ms. Roomi Kalita: MS ChE May 2012 (co-advised with Profs. R. Tilton, S. Garoff)

Thesis Area: Surfactant Carriers for Enhanced Pulmonary Drug Delivery –Spreading Coefficient Studies
Currently a staff engineer at Fluor-Daniels, Houston, TX

9. Mr. Kevin Koch: MS Physics May 2011 (co-advised with Profs. R. Tilton, S. Garoff)
Thesis Area: Surfactant-Enhanced Spreading on Entangled Polymer Solutions
Currently a staff scientist at Intel, Inc., San Francisco, CA
8. Ms. Marianne Mota: MS ChE August 2008 (co-advised with Prof. R. Tilton)
Thesis Area: Sustained Release of PEG-Protein Conjugates
Currently a staff scientist at L'Oreal, Inc., New York, NY
7. Dr. Murni Ahmad: MSChE January 2002 (co-advised with Prof. S. Hauan)
Thesis Area: Design of Aqueous Two-Phase Extraction Systems for Bioseparations
Went on to PhD study at Carnegie Mellon University with Prof. Hauan and myself as co-advisors

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998

6. Dr. Arthur Hewig: MS ChE October 1999
Thesis: Mixing and Scale Effects on Salt-Induced Protein Precipitation
Recipient of the Rensselaer Institute Service Award
5. Dr. Angela Wilcox: MS ChE May 1999
Thesis: "Formulation and Physical Stability of Recombinant Human Growth Hormone using Self-Interaction Chromatography"
Named a GE Faculty For the Future Fellow
4. Dr. Ganesh Vedantham: MS ChE December 1997 (co-advised with Prof. G. Belfort)
Thesis: "Towards the Development of New Low Fouling Modified Polysulfone Membranes"
Recipient of the 1998 North American Membrane Society Award and a Howard P. Isermann Special Fellowship in Biochemical Engineering
3. Dr. Stelios Tzannis: Optional MS ChE December 1994
2. Dr. Harish V. Iyer: Optional MS ChE August 1994
1. Dr. Sugunakar Patro: MS ChE August 1992
Thesis: A two-Dimensional Lattice Model for Protein Aggregate Structure

Students Supervised: Undergraduate Students

Carnegie Mellon University, Fall 1998 - current

41. Ms. Allison Kirkby, BS ChE, BME Class of 2017, Spring 2016-Spring 2017
40. Mr. Eddie Healy, BS ChE, BME Class of 2018, Fall 2015-Spring 2016, Fall 2016-Spring 2017
39. Ms. Yein Lee (w J. Schneider), BSChE Class of 2017, Summer 2015
38. Ms. Gillian Crews, BS ChE, BME Class of 2017, Summer 2015-Spring 2016, Fall 2016-Spring 2017
37. Mr. Enosh Schachar, BSChE Class of 2018, Summer 2015-Fall 2015
36. Mr. Muyuan Li (w B. Tilton), BS ChE, BME Class of 2016, Fall 2014-Spring 2016
35. Ms. Erica Green, BS ChE, BME Class of 2015, Fall 2014-Spring 2015, CIT Honors Thesis
34. Ms. Annette Ko, BS ChE, BME Class of 2015, Fall 2013-Spring 2014
33. Mr. Eamon Cullinane (w M. Domach, J Schneider), BSChE Class of 2015, summer 2013
32. Mr. Krithiknath Tirupapuliyur (w M. Domach, J. Schneider), BSChE Class of 2015, Summer 2013
31. Mr. Yi Shi (with B. Tilton, S. Garoff), BSChE Class of 2014, Fall 2012-Spring 2013
30. Ms. Rocio Garay (with B. Tilton), BSChE Class of 2013, Spring 2012-Spring 2013
29. Mr. Anand Sastry (with B. Tilton, S. Garoff), BSChE/BME Class of 2013, Spring 2012-Fall 2012
28. Mr. Alex Yoshikawa, BSChE/BME Class of 2012, Fall 2011-Spring 2012, CIT Honors Thesis
27. Ms. Nikunja Kolluri (with B. Tilton), BSChE/BME Class of 2011, Fall 2009, Spring 2010, Fall 2010, Spring 2011

26. Mr. Robert Weigmann, BSChE/BME Class of 2010, Spring 2010
25. Mr. Austin Good (with B. Tilton, S. Garoff), ChE Class of 2010, Spring 2010
24. Ms. Aislin McCloskey (with J. Schneider), BSChE Class of 2012, Summer 2009
23. Ms. Amanda DiIenno, BSChE/BME Class of 2009, Fall 2007 – Spring 2009, CIT Honors Thesis
22. Ms. Martha Ryan, BSChE Class of 2008, Summer 2006
21. Mr. Kenneth Hu, BSChE/BME Class of 2006, Fall 2005, Spring 2006, CIT Honors Thesis
    Recipient of AIChE local section professional promise award.
20. Mr. Dan McNerny, BSChE/BME Class of 2005, Summer 2004
19. Ms. Muriel (Molly) Hosier, BSChE/BME Class of 2004, Fall 2003, Spring 2004, CIT Honors Thesis
18. Ms. Kathryn Masterson, BSMechE/BME Class of 2005, Summer 2003
17. Ms. Jen Airone, BSChE Class of 2003, Spring 2003
16. Mr. Jordan Green, BSChE/BME Class of 2003, Summer 2002 – Spring 2003
    Recipient of ICI, Inc. Summer Research Fellowship
    Recipient of Whitaker Foundation Graduate Research Fellowship, NSF Graduate Research Fellowship and Phi Kappa Phi Graduate Fellowship
    CIT Honors Thesis: Colloidal Gold Scaffold for Gene Delivery; 3rd Place in CIT Meeting of Minds competition
15. Ms. Joy Appel, BSChE Class of 2002, Summer 1999 - Spring 2002
    Intel-Summer Undergraduate Research Grant (SURG) Awardee, 2 years
    Recipient of Parfitt Memorial Research Award, CMU ChE Dept
14. Ms. Stacey Carothers, BSChE Class of 2003, Summer 1999
    Carnegie Mellon AIChE Scholarship Awardee
13. Mr. Paul Butts, BSChE Class of 2000, Spring 1999 - Spring 2000
    Summer Undergraduate Research Grant (SURG) Awardee

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998

12. Ms. Jennifer (Baier) Leach: undergraduate research project, Spring and Fall 1997
    Recipient of GE Faculty For the Future Undergraduate Research Award
11. Ms. Elyse Shapiro: undergraduate research project, Summer 1997 to Fall 1998
10. Ms. Angela (Wilcox) Blake-Haskins: undergrad research project, Summer 1996 through Spring 1997
    Recipient of GE Faculty For the Future Undergraduate Research Award
    Continued on to M.S. study at Rensselaer and Ph.D. study at Carnegie Mellon
9. Mr. Paul Taylor: undergraduate research project, Fall 1995 through Spring 1996
    Recipient of the W. Lincoln Hawkins Undergraduate Research Fellowship from the National Action Council for Minorities in Engineering
8. Mr. Art Hewig: undergraduate research project, Summer 1995 through Summer 1996
7. Mr. Derek Young: Senior Project (Chemical Engineering) Fall 1994, Spring 1995
6. Mr. Richard Molloy: undergraduate research project, Spring 1994
5. Ms. Ana Quinteros: undergraduate research project, Fall 1993
4. Mr. Gilbert Cooper: undergraduate research project, Summer 1993
3. Mr. Anthony Eaton: undergraduate research project, Fall 1992
2. Mr. Joseph Dunn: undergraduate research project, Fall 1991, Spring 1992
1. Ms. Karin Pihel: undergraduate research project, Spring 1991

Students Supervised: Visiting Students and Exchange Students

Carnegie Mellon University, Fall 1998 – current

6. Mr. Jonathan Mah: visiting B.S. student January 2013-May 2013 (co-advised R. Tilton), project: Aerosolization of fluorocarbons and fluorosurfactants for pulmony delivery; University of Melbourne, Department of Chemical and Biomolecular Engineering

5. Mr. José Pepé Gonzalez: visiting Ph.D. student August 2010-June 2011, project: PEGylated affinity chromatography media feasibility studies; Departamento Biotecnología e Ingenieria de Alimentos, Instituto Tecnologico y de Estudios Superiores de Monterrey, Monterrey, MX
4. Ms. Letizia Luperini: practical internship student June-July 2006, project: equilibrium unfolding of PEGylated apo-α-lactalbumin; Department of Chemical Engineering, Universidad Iberoamericana, Mexico City, Mexico.
3. Ms. Mayra Cisneros-Ruiz: visiting Ph.D. student September 2004 through December 2005; Centro de Biotecnologia of the Tecnologico de Monterrey, Monterrey, Mexico.
2. Ms. Jessica Schoebel: undergraduate practical internship (*Studienarbeiten*), Oct 2001 through Feb 2002, project report: "The Effects of Mixing and Scale on the Precipitation of Bovine Somatotropin with Sodium Chloride"; final thesis (*Diplomarbeit*) April 2003 through October 2003, thesis title: "The behavior of PEGylated lysozyme on reversed phase chromatography media"; ChE student at Technical University of Münster, Münster, Germany.

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998

1. Mr. Carlo Shiu: undergraduate research project, Fall 1995 through Spring 1996
   AE^3 Exchange Program Student from University College London

MD/PhD Students Advised: MSTP Steering Committee (Career Advisor)

Univ. of Pittsburgh-Carnegie Mellon Medical Scientist Training Program

5. Mr. John Kang, Spring 2008 – Summer 2013
4. Mr. Vineet Agrawal, Fall 2006 – Spring 2011
3. Ms. Patrice Thorpe, Fall 2006 – Spring 2008
2. Mr. Scott VanEpps, Fall 2002 – Spring 2007
1. Mr. Ken Urish, Fall 2002 – Spring 2008

Courses Taught and Student-based Evaluations

Carnegie Mellon University, Fall 1998 – current

Course Number	Course Title	Units	Class	Num of Students (responders)	Semester Offered		Overall FCE Ratings*: Course	Instr
06-100	Intro to ChE	12	frosh	61 (48)	F1999		3.48	3.50
				69 (59)	F1998		3.69	3.64
06-607	PChem Coll&Surfaces	9	ugrad/ grad	28 (16)	S2011		3.94	4.06
06-722/42-722	BioProcess Design	12	grad	8 (4)	S2015		3.5	3.75
06-622/42-622	BioProcess Design	12	ugrad/	8 (6)	S2012		4.33	4.5
			grad	6 (4)	S2010		4.0	4.0
06-722/42-607	BioProcess Design	12	grad	3 (3)	S2001		4.33	5.00
				10 (9)	S2000		4.12	4.11
42-101	Intro to BHE/BME+	12	frosh	50 (26)	F2005		3.44	3.92
				77 (29)	S2005		2.46	2.85
				15 (12)	F2003		3.92	4.17
				36 (30)	F2002		3.90	3.97
				39 (33)	F2001		4.06	4.15
				48 (36)	S2001		4.06	4.11
				47 (37)	F2000		3.97	4.19
42-302/689H	BME SysModAnalysis+ 5.0		9	ugrad/grad	4(2)	F2017		5.0
				6 (4)	F2016		3.00	3.50
42-321	Cell & Molec Biotech	9	ugrad/	9 (7)	F2013		4.29	4.29
			grad	14 (11)	F2012		4.45	4.27
				10 (5)	F2011		3.60	4.25
				10 (4)	F2010		4.0	4.25
				9 (2)	F2009		4.0	4.0
				6 (4)	F2008		3.5	3.0
				6 (2)	F2007		4.0	4.0
				12 (4)	F2006		3.2	3.5
42-424	Biological Transport	9	senior/ grad	3(2)	S2007		5.0	5.0
42-604/42-704	Biological Transport	9	ugrad/	7 (5)	S2004		4.20	4.40
			grad	10 (8)	S2003		4.63	4.63
				11	S1999		3.75	4.13

* The Faculty-Course Evaluation student rating program conducted by Carnegie Mellon uses a 1.0 (low) to 5.0 (high) rating scale.

\+ Newly developed course

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998

Course Number	Course Title	Credit Hours	Class	Num of Students	Semester Offered	Overall τβπ Ratings*: Course	Instr
20.201	Eng. Thermo.	3	soph	125	S1998	2.9	3.3
				24	F1997	3.3	3.7
				139	S1997	2.7	3.4
				53	F1996	3.1	3.5
20.203	Matl & Ener. Bal.	3	soph	72	F1993	2.5	3.0
32.234	ChE Thermo.	3	junior	23	S1996	3.3	3.3
				67	F1995	3.4	3.7
				65	F1994	3.2	3.5
				43	S1994	3.5	3.9
				28	S1993	3.5	3.7
				84	F1992	2.8	3.1
				51	F1991	3.0	3.5
				21	S1991	2.6	3.1
32.415	ChE Lab I (Fermentation Expt.)	2	senior	67	F1997	N/A	N/A
				75	F1996	3.1	2.8
				92	F1995	3.3	2.8
				16	F1994	N/A	N/A
32.416	ChE Lab II (Distillation Expt.)	2	senior	63	S1994	N/A	2.7
				57	S1993	N/A	N/A
				33	S1992	N/A	N/A
32.696/4	BioProcess Desgn+	3	grad	9	S1998	N/A	N/A
				9	S1996	3.8	4.0
				5	S1992	3.0	3.5

* The τβπ formal student rating program conducted by the Rensselaer School of Engineering used a 0.0 (low) to 4.0 (high) rating scale.
\+ Newly developed course

Washington University, University College, Fall 1990

Course Number	Course Title	Credit Hours	Class	Num of Students	Semester Offered	Overall Ratings: Course	Instr
Biotech 411*	Intro. Ind. Microbiol.	3	masters	25	F1990	N/A	N/A

* I served as guest instructor for 12 contact hours; Prof. Ales Prokop was course director.

IV. SERVICE

Administrative Service and Leadership

Faculty Senate, Carnegie Mellon University
- Chair: May 2016 – May 2017 (2nd term)
  - CMU Board of Trustees, *ex officio*, voting member
    - Presidential Review Committee, co-chair
    - Educational Affairs and Enrollment Committee, member
    - Research, Innovation and Entrepreneurship Committee, member
  - Budget and Financial Affairs Committee, member
  - Elected Leadership Council, member
  - Middle States Commission on Higher Education CMU Coordinating Committee
    - Standard VII: Governance, Leadership and Administration Committee: co-chair
  - Task Force on the CMU Experience
    - Steering Committee, member
    - Faculty and Staff Professional Development Working Group, co-chair
  - University Education Council, member
  - University Research Council, member
  - University Risk Initiatives Steering Committee, member
- Chair: May 2015 – May 2016
  - CMU Board of Trustees, *ex officio*, voting member
    - Educational Affairs and Enrollment Committee, member
    - Research, Innovation and Entrepreneurship Committee, member
  - Budget and Financial Affairs Committee, member
  - Middle States Commission on Higher Education CMU Coordinating Committee
    - Standard VII: Governance, Leadership and Administration Committee: co-chair
  - Task Force on the CMU Experience
    - Steering Committee, member
    - Faculty and Staff Professional Development Working Group, co-chair
  - University Education Council, member
  - University Risk Initiatives Steering Committee, member
- Vice-chair: May 2014 – May 2015
  - University Education Council, member
  - University Risk Initiative Steering Committee, member
  - University Strategic Plan Development
    - Steering Committee for Pillar #3, "The Transformative Carnegie Mellon University Experience", member
    - Faculty Working Group of Pillar #3, co-chair
- Senator, Biomedical Engineering: May 2013 – May 2014

Summary:
- Faculty Senate Policy and Procedure Business and Action on Faculty Working Group Strategic Plan
- Developed "Faculty Voices" document summarizing faculty recommendations to the University strategic plan via series of town hall meetings and focus groups; this served as guidance to both the University strategic planning process and as a road map for the subsequent actions of the Faculty Senate
- Established Elected Leadership Council comprising elected chair and vice-chair (or equivalent) of Faculty Senate, Staff Council, Student Government, Student Senate and the Graduate Student Assembly; working to also incorporate Alumni Association and Andrew Carnegie Society (a CMU leadership and donor group)

Re-established Faculty Affairs Council of Faculty Senate
Re-established, with the Dean of the Libraries, the Senate-University Library Advisory Committee
Re-established, with Vice-Provost for Research, the University Research Council
Obtained faculty representation on the University Total Compensation Committee
Policy deliberation highlights: campus smoking policy, minors on campus policy, add/drop/withdrawal policy, syllabi policy, two-factor authentication policy, policy against retaliation, tenured faculty retirement options policy

Department of Biomedical Engineering, Carnegie Mellon University
Founding Head: July 2002 – July 2008
Programmatic Research/Infrastructure Support: External Grants Awarded to BME Department
2008 PI: Pennsylvania Department of Community Economic Development, Keystone Innovation Starter Kit, "PA Go KIZ Biomaterials Faculty Starter Kit", amount: $250,000, period: 3/1/08 – 2/28/10
2004 PI: Pennsylvania Department of Health, Tobacco Settlement Fund (RFA 03-07-06): "Health Research Formula Fund 04-05", amount $822,602, period: 1/1/05 to 12/31/07
2001 PI: Scaife Charitable Foundation, gift, amount $1,000,000, period: 9/1/01 to 6/30/05

Summary: Department Founding and Expansion
Developed second 5-year strategic plan for BME Department
Grew faculty from 1.5 FTE to 10 FTE
Hired 9 faculty members at Assistant, Associate and Full Professor levels
Grew staff from 1.0 FTE to 4.0 FTE
Hired 5 staff members
Grew departmental budget from $300,000/yr to $3,000,000/yr
Grew PhD student body from 3 to 40
Grew undergraduate student body from 60 to 200 (sophomores/juniors/seniors)
Oversaw development and implementation of second generation (track system) undergraduate curricula.
Oversaw development of course-option BME Masters program
Oversaw expansion of departmental infrastructure
$450,000 establishment of new departmental offices
$550,000 renovation of 15,000 sqft of research space
Achieved improvement of USN&WR graduate ranking from unranked in 2002 to 23rd in 2008

Biomedical and Health Engineering Program, Carnegie Mellon University
Program Head: July 2000 – June 2002
Summary: Expansion of Degree Programs to include Undergraduates and Transition to Departmental Status
Co-led, with Dean of College of Engineering, college-level, university-level and board-level approval process for new BME Department, the first new department in the college in 27 years
Oversaw implementation of unique, first generation, undergraduate dual-degree program in biomedical engineering
Developed first 5-year strategic plan for nascent BME Department

Professional Service

Professional Societies, Meetings and Conferences

American Chemical Society - member

BIOT Division

Awards Chair and Executive Committee member, 2014 – 2016, 2017 – current

89th Colloid and Surface Science Symposium, Carnegie Mellon University, June 2015

Session Chair (with N. Alvarez) "General Papers" (9 sessions)

78th Colloid and Surface Science Symposium, Yale University, June 2004

Session Co-Chair, "Biocolloids and Biointerfaces"

251st National Meeting, Spring 2016

Area Coordinator (with J. Neville, A. Noyes) BIOT "Downstream Processing" (10 sessions)

241st National Meeting, Spring 2011

Session Chair, BIOT "Downstream Process Modeling"

239th National Meeting, Spring 2010

Area Coordinator (with N. Rathore) BIOT "Biophysical & Biomolecular Processes" (6 sessions)

236th National Meeting, Fall 2008

Session Co-Chair (with J. McCue) BIOT "Downstream Process Modeling"

234th National Meeting, Fall 2007

Session Chair, BIOT "Protein Aggregation" at Fall 2007 National Meeting

224th National Meeting, Fall 2002

Session Co-Chair (with L. Steele) BIOT "High Throughput Screening Techniques for Process Development"

218th National Meeting, Fall 1999

Session Co-Chair (with R.D. Tilton) COLL "Surface Chemistry: Medical and Biological Applications"

211th National Meeting, Spring 1996

Poster Session Chair, BIOT "Advances in Biochemical Technology"

Poster Session Chair, BIOT "Sci-Mix"

207th National Meeting, Sping 1994

Session Co-chair (with C.E. Glatz) BIOT "Protein Aggregation in Bioprocessing Environments"

American Institute of Chemical Engineers – fellow

Society for Biological Engineers

Managing Board Member, 2010-current

Division 15 Food, Pharmaceutical and Biochemical Engineering

Past-Chair, 2005

Chair, 2004

First Vice-Chair, 2003

Second Vice-Chair, 2002

Area 15c Biochemical Engineering

Programming Chair, Annual Meeting, 1998

Programming Co-Chair, 1997

National Programming Committee

Member, 2000-2005

2012 Fall Annual Meeting

Topical Conferences co-organizer (with S. Little), "Topical Conference A: Biomedical Applications of Chemical Engineering" (25 sessions)

2009 Fall Annual Meeting
Session Co-chair (with B. Marques), Area 15b,c "Downstream Processing: Purification /Polishing"
2008 Fall Annual Meeting
Session Co-chair (with J. Morgan), Area 15c "Protein Aggregation"
2004 Fall Annual Meeting
Sesison Co-Chair, Area 8: "Characterization of Pharmaceutical Powders and Interfacial Phenomena"
Session Chair, Area 15: FPBE Division Plenary, FPBE Division Posters, FBBE Open Business Mtg, Fall 2004 Annual Meeting (4 sessions)
2000 Fall Annual Meeting
Session Co-chair, Area 15c "Focus on Viral Vaccines and Gene Therapy"
1995 Fall Annual Meeting
Session Co-Chair, Area 15c "Bioseparations" (3 sessions)
1992 Fall Annual Meeting
Session Co-Chair, Area 1 "Transport Phenomena in Bioseparations" (2 sessions)
1991 Fall Annual Meeting
Session Co-Chair, Area 1 "Fundamental Research in Heat and Mass Transfer: Biochemical Applications,"
Session Co-Chair, Area 1, and poster session "Fundamental Research in Heat and Mass Transfer"

American Institute of Medical and Biological Engineering – fellow
College of Fellows, 2011 biomedical engineering nomination subcommittee - member

China/USA/Japan Joint Chemical Engineering Conference
Member US Delegation and Co-Chair of session "Sustainable Technologies and Green Processing," at Fall 2005 meeting

ECI Integrated Continuous Biomanufacturing (ICB) Conference series
ICB III, Cascais, Portugal, September 2017
Workshop Co-Chair "Increasing Speed to Clinic with Continuous Biomanufacture
ICB II, Berkeley, CA, November 2015
Scientific Committee member

HIC RPC Hydrophobic Bioprocessing (HIC RPC) Conference
10th HIC RPC, Scottsdale, AZ, February 2017
Scientific Committee chair

International Conference on BioPartitioning and Purification (BPP) conference series
BPP 2013, Newport, RI, October 2013
Scientific Advisory Board member
Session Chair: Oral Session 3: "Non-Chromatographic Separations"
BPP 2011, Puerto Vallarta, Mexico, June 2011
Conference Co-Chair (with M. Rito-Palomares and J. Asenjo)
BPP 2009, Uxbridge, UK, June 2009
International Scientific Committee member
Session Co-chair (with D. Fisher) "Protein Purification"
BPP 2007, Lisbon, Portugal, June 2007
International Scientific Committee member
Session Co-chair (with A. Middelberg) "Bioparticle and Complex Biostructures Purification"
BPP 2005, Delft, The Netherlands, June 2005
International Scientific Committee member

Session Co-chair (with P. Lester) “Industrial Challenges”

Recovery of Biological Products (Recovery) conference series

Board Member and Website chair, August 2012 - current

Recovery XVII, Southampton, Bermuda, June 2016

Debate Moderator “Disruptive Technologies”

Recovery XV, Stowe, VT, July – Aug 2012

Conference Co-Chair (with J. Myers and A. Staby)

Recovery XIII, Quebec, Canada, June 2008

Workshop Co-Chair (with M. Croughan) “New Initiatives in BioProcess Technology Education”

Recovery XII, Phoenix, AZ, April 2006

Session Co-Chair (with C. Fee) “Downstream of Downstream”

Recovery X, Cancun, Mexico, June 2001

Session Co-Chair (with C. Lowe) "Molecular Science of Bioseparations"

Separation Technology Conference series

Separation Technology VII: Separations for Clean Technology, Davos, Switzerland, October 1997

Session Co-chair (with G. Belfort) “Using Genetic Engineering for Bioseparations”

Proposal Reviewing:

Ben Franklin Technology Center of Western Pennsylvania

Challenge Grant Program

Government of New Zealand

Ministry of Business, Innovation & Employment ad hoc reviewer, May 2013

University Institutes Programme ad hoc reviewer, Nov 2009

Government of Portugal

Foundation for Science and Technology

Chemistry and Biochemistry review panel member, Aug 2008

National Aeronautics and Space Administration

Microgravity Biotechnology program

Review panel for NRA-96-OLMSA-03, Dec 1996

Review panel for NRA-00-HEDS-03, Jan 2001

Review panel for NRA-01-OBPR-INTRM, May 2001

National Institutes of Health

Synthetic and Biological Chemistry Study Section

Review panel ZRG1 IMST-D(13)B, Biomaterial Delivery Systems and Nanotechnology, 21,22 Feb 2011

Review panel ZRG1 BCMB-R 50, Nanotechnology and Nanoscience, 1, Nov 2005

National Research Council

Board on Science and Technology for International Development

National Science Foundation

Chemical, Bioengineering, Environmental, and Transport Systems (CBET) programs

Review panel for CAREER award program, Sep 2012

Review panel for Bioseparations program, Nov 2009, Mar 2014

Review panel for Interfacial Phenomena, Nov 2008, May 2011

Biotechnology and Biochemical Engineering (BES) programs

Review panel for Large Group Proposals program, May 1995, Mar/Apr 2005

Review panel for CAREER award program, Nov 1999, Nov 2002.

Chemical and Thermal Systems (CTS) program

Review panel for research equipment grant proposals, April 1992.
Engineering Research Center (ERC) prgm - MIT Biological Process Engineering Center
Annual Site Review Team, June 1996 & July 1995
Renewal Site Review Team, April 1994.
Physiology and Behavior (Biophysics) program
North Carolina Biotechnology Center
Academic Research Initiation Grants Program
Pittsburgh Tissue Engineering Initiative
Seed Grant Review Committee, May 1999
State of Indiana, 21st Century Research and Technology Fund
Ad Hoc reviewer, Jul 2004, Oct 2004, Feb 2006, Apr 2007, Jan 2009, Jun 2009, May 2011
Review Panel, May 2000, Jan 2001, Nov 2001, Jan 2004
State of New York, Watson Young Investigator Program
Review Panel, Sep 2002, Feb 2005

Manuscript Reviewing
Associate Editor, *Biotechnology and Bioengineering*, 2000 - 2002
Editorial Board Member, *Separation Science and Technology*, 1997 - present
Reviewer for: *Acta Crystallographia Section D, American Institute of Chemical Engineers Journal, Analytical Chemistry, Archives of Biochemistry and Biophysics, Biochemical Engineering Journal, Bioseparations, Biomaterials, Biotechnology and Bioengineering, Biotechnology Progress, Chemical Engineering Science, Chemistry of Materials, Fluid Phase Equilibria, Gene Therapy, Food and Bioproducts Processing, Industrial and Engineering Chemistry Research, International Journal of Pharmaceutics, Journal of Chromatography A, Journal of Chromatography B, Journal of Colloid and Interface Science, Journal of Membrane Science, Journal of Pharmaceutical Science, Langmuir, Materials Research Society Proceedings, Proceedings of the National Academy of Sciences, Protein Engineering Design and Selection, Separation and Purification Technology, Separation Science and Technology, Talanta, Trends in Polymer Science,* American Chemical Society Books, Blackwell Science, Kluwer Academic Publishers, Van Nostrand Reinhold Publishers, Prentice Hall Publishers

External Academic Service
Program Reviewing
New York University/NYU Poly Bioengineering Initiative, External Advisory Panel chair, Sep-Nov 2011
University of British Columbia, Michael L. Smith Laboratories (formerly the Biotechnology Laboratory), External Review Committee member, Apr 2005
External PhD Examiner
Dr. Chih-Pei Lin, Monash University, Melbourne, Australia, School of Chemistry – external Ph.D. thesis examiner, June 2014
Dr. Ralf Sommer, Universität für Bodenkultur Wien, Vienna, Austria, Department of Biotechnology – external Ph.D. thesis examiner, January - 2014
Dr. Nitin Kumar Pandey, IIT Kharagpur, India, Department of Chemistry – external Ph.D. thesis examiner, Dec 2013
Dr. Vinod Damodaran, University of Canterbury, Christchurch, NZ, Department of Chemical and Process Engineering – external Ph.D. thesis examiner, March 2010
Dr. Norzita Ngadi, University of Canterbury, Christchurch, NZ, Department of Chemical and Process Engineering – external Ph.D. thesis examiner, August 2009

Dr. Yunzhi Xiao, University of Virginia, Department of Chemical Engineering – thesis committee member 2006 - 2007
Dr. Jace Fogle, Univesity of Virginia, Department of Chemical Engineering – thesis committee member 2005 - 2006
Dr. Alison Clark, University of British Columbia, Department of Physics & Astronomy – external Ph.D. thesis examiner, September 2004

Internal Academic Service
Carnegie Mellon University, Fall 1998 - current
University, School and Departmental Committees
University
Biotechnology Implementation Committee
member: Fall 2000 – Spring 2003
Committee on Space Master Plan for Experimental Sciences
member: Fall 2001 – Spring 2002
Search Committee: Associate Vice-President for Enterprise Risk Management
co-chair: January 2017 - current
Search Committee: Dean of the College of Engineering
member: Spring 2004
College of Engineering (Carnegie Institute of Technology)
Ad Hoc Promotion and Tenure Committee
member: Fall 2010 – current
College Council
member: Summer 2000 – Summer 2008
Promotion and Tenure Review Committee
member: Summer 2002 – Summer 2008
Search Committee: Department Head of Biomedical Engineering
member: Fall 2016 – Spring 2017
Search Committee: Department Head of Materials Science and Engineering
member: Spring 2005
Staff Awards Committee
member: Spring 2010

Candidacy Exam/Ph.D. Committees (other than directly advised students)
Mr. Nicholas Lamson, Chemical Engineering, member 2016-
Ms. Yun-ru Huang, Chemical Engineering, member 2016-
Ms. Lisa Kasiewicz, Chemical Engineering, member 2015-
Mr. Alan Campbell, Biomedical Engineering, member 2015-
Mr. Steven Klara, Chemical Engineering, member 2014-
Dr. Emily Friedrich, Chemistry, member 2014-2014
Dr. Allison Elder, Chemistry, member 2009- 2013
Dr. Hoyong Chung, Chemistry, member 2009-2011
Dr. Elizabeth Booth-Gauthier, Biomedical Engineering, member 2009-2012
Dr. Christopher Highley, member 2009-2012
Dr. Usha Kuppuswamy, Biomedical Engineering, member 2009-2012
Dr. Teresa Kirschling, Chemical Engineering, member 2008-2011
Dr. Samuel Hund, Biomedical Engineering, member 2009-2010
Dr. Steven Sun, Biomedical Engineering, member 2009-2010
Dr. Jonathan Didier, Biomedical Engineering, member 2008-2009
Dr. JitKang Lim, Chemical Engineering, member 2006-2009

Dr. Sasha Bahkru, Biomedical Engineering, member 2008-2009
Dr. Oxana Selivanova, Chemical Engineering, member 2006-2009
Dr. Andy Kusumo, Chemical Engineering, member 2005-2008
Dr. Jeffrey Savard, Chemical Engineering, member 2005-2008
Dr. Ken Urish, Bioengineering (Univ. Pittsburgh), member 2005-2006
Dr. Bruno Marques, Chemical Engineering, member 2003-2005
Dr. Nathan Domagalski, Chemical Engineering, member 2002-2005
Dr. Justin Legleitner, Chemistry, member 2002-2005
Dr. James Vernille, Chemical Engineering, member 2001-2004
Dr. Timothy Powers, Chemical Engineering, member 1999-2001
Dr. Chan Phalakornkule, Chemical Engineering, member 1999-2000
Dr. Brian Priore, Chemical Engineering, member 1998-2001

Center for Complex Fluids Engineering/Colloids, Polymers and Surfaces Program
center member: Fall 2000 to present
co-organizer: 2000 CPS Workshop on Pharmaceutical Processing (L. Walker, organizer, B. Tilton, co-organizer)

Department of Biomedical Engineering
Graduate Admissions
director: Summer 2000 – Summer 2008
Graduate Affairs Committee
chair: Fall 2009 – 2010
Search Committee: Joint BME-MSE Faculty Search
co-chair Fall 2008-Spring 2009

Department of Chemical Engineering
Faculty Awards Committee
member: Fall 2008 – current
Graduate Admissions Committee
director: Summer 1999-Summer 2000, Summer 2012-Summer 2015
member: Fall 1998-Spring 1999, Fall 2010-Spring 2012
Infrastructure Committee
member: Summer 2001 to Summer 2002
Ph.D. Committee
chair: Fall 2015 – Spring 2016
Ph.D. Qualifier Exam Committee
chair: Fall 2010
member: Fall 2016
"Sleeping Bag Weekend" Committee
member: Fall 1998 – Spring 1999
Seminar Program
chair: Fall 1999, Spring 2011
Undergraduate Committee
member: Fall 2010-Spring 2015

Department of Chemistry
Search Committee: Materials/Biomaterials Faculty Search
member: Fall 2002--Spring 2003, Fall 2003 – Spring 2004

Rensselaer Polytechnic Institute, Spring 1991 – Summer 1998
Institute, School and Departmental Committees
Institute
21st Century Classroom Task Force

member: Spring 1993

School of Engineering

Engineering Faculty Council

at-large representative: Fall 1991 – Fall 1992

Candidacy and Ph.D. Exam Committees (other than directly advised students)

Dr. Brian P. Frank, Chemical Engineering, member 1997-1998
Dr. David Wood, Chemical Engineering, member 1996-1998
Dr. Hans M. Muhlemann, Chemical Engineering, member 1996-1998
Dr. Venkata S. Vunnum, Chemical Engineering, member 1996-1997
Dr. Timothy J. Cavanaugh, Chemical Engineering, member 1995-1998
Dr. Hanuman Mallubhotla, Chemical Engineering, member 1995-1998
Dr. Amitava Kundu, Chemical Engineering, member 1995-1996
Dr. Stuart R. Gallant, Chemical Engineering, member 1994-1995
Dr. Jeffrey A. Koehler, Chemical Engineering, member 1994-1996
Dr. Christopher C. Roberts, Chemistry, member 1994-1997
Dr. Louis P. Russo, Chemical Engineering, member 1994-1996
Dr. Gonzalo C. Serafica, Chemical Engineering, member 1994-1997
Dr. Zenya Zhu, Chemistry, member 1994-1995
Dr. Yen-Han Lin, Chemical Engineering, member 1993-1994
Dr. Ravi Gopinath, Chemical Engineering, member 1993-1994
Dr. Shishir Gadam, Chemical Engineering, member 1993-1994
Dr. Ramesh L. Narayan, Chemistry, member 1993-1995
Dr. Swagata Dasgupta, Chemistry, member 1993-1994
Dr. Joseph Gerstner, Chemical Engineering, member 1993-1994
Dr. Peter Gostomski, Chemical Engineering, member 1993-1995
Dr. Hiroshi Yokoi, Chemical Engineering, member 1993-1994
Dr. Peter R. Elliker, Chemistry, member 1992-1994
Dr. Peter M. Futerko, Chemical Engineering, member 1992-1993
Dr. Guhan Jayaraman, Chemical Engineering, member 1992-1993
Dr. Young J. Kim, Chemical Engineering, member 1992-1993
Dr. Katherine L. McKinney, Chemical Engineering, member 1992-1993
Dr. Dauh-Rurng Wu, Chemical Engineering, member 1992-1993

Chemical Engineering Department

Graduate Affairs Committee

chair: Fall 1994 – Fall 1997
member: Fall 1991 – Spring 1994, Spring 1998

Search Committee: Faculty Search

member: Fall 1996 – Spring 1998

Search Committee: Department Head/Isermann Chair Search Committee

member: Summer 1997 – Spring 1998

Seminar Program

chair: Fall 1991 – Spring 1992

Ph.D. Qualifying Exam Committee

member: Spring 1992 – Spring 1998

Community Service

First Congregational Church of Etna, PA
- Church Council
  - Member, March 2000 – March 2003
  - Vice-President, April 2003 – March 2008
  - Trustee, March 2005 – February 2013
  - President, March 2008 – February 2013

Hugh O'Brien Youth Leadership Program, Western Massachusetts region
- Counselor, May 1993 – June 1997

Town of West Stockbridge, MA
- West Stockbridge Water Advisory Board,
  - Engineering Subcommittee Member, January 1994 – June 1994

West Stockbridge Congregational Church, West Stockbridge, MA
- Church Council
  - Trustee, January 1998 – June 1998