Remarks

The Office Action Summary indicates that claims 1-12 are pending in the subject application; however, Applicants note that claims 13-18 were withdrawn in the Election dated January 26, 2012. The "Disposition of Claims" on the Office Action Summary page does not list claims 13-18 as pending but withdrawn from consideration. Applicants consider claims 1-18 as pending in the subject application. Applicants acknowledge that claims 13-18 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 1-3 and 9-11. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-12 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants have amended the brief description of the Figures for Figures 19-21, to recite "a monomer for the preparation of a polymer" rather than "a polymer" where inspection of the figures supports these amendments.

The Office Action of March 30, 2012 objected to the specification because of informalities in numerous examples in which the Applicants state that the pure product "was obtained in % yield". Applicants have removed the text (in % yield) from these portions of the specification, and Applicants respectfully submit that these issues are moot in view of these amendments to the specification. Accordingly, reconsideration and withdrawal of the objections is respectfully requested.

The Examiner asserts that the oath or declaration submitted in the subject application is defective on the grounds that it is not properly identified by the application number and filing date as required by 37 CFR §1.67(a). Specifically, the Examiner states that the oath or declaration is defective because it is not signed by the inventors. An executed declaration was submitted on June 2, 2010 in response to a Notice to File Missing Parts. A copy of the Transmittal Letter

accompanying the executed declaration is attached with this Amendment. Applicants respectfully assert that the inventors' declaration filed in the subject application is proper and meets the requirements of 37 CFR §1.67(a). Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

Claim 2 is objected to because of informalities. The Examiner indicates that the term "carbamate" is misspelled. Applicants gratefully acknowledge the Examiner's careful review of the claims. In accordance with the Examiner's suggestion, Applicants have replaced the word "carbomate" with "carbamate" in claim 2. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 3 and 9-11 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

The Office Action indicates that in claim 3, it is unclear whether the polymer requires both an ether moiety **and** a carbamate. Applicants have amended claims 2 to clarify that the linker comprises "at least one moiety" and claim 3 recites that "the at least one moiety is an ether moiety and a carbamate moiety" as is illustrated in figure 20. Applicant believes these amendments clarify claim 3, which indicates a linker with two moieties. Claim 9 is dependent on claim 1 and recites a "spacer". Applicant has amended claims 9 and 10, as suggested by the Examiner, to recite as being dependent on claim 5. Claim 11 has been amended to remove the exemplary verbiage within parenthesis, including the trademark name "Taxol". As amended claims 3 and 9-11 are definite. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 1-3 and 9-11 are rejected under 35 U.S.C. § 102(b) as anticipated by Maynard *et al.* (Macromolecules, 2000, 33, 6239-6248). Applicants respectfully assert that the Maynard *et al.* reference does not anticipate the amended claimed invention. Claim 1 has been amended to recite:

> "A polymer comprising a plurality of repeating diene monomers having coupled thereto at least one biologically active molecule through at least one non-amide linker, wherein carbons coupled to the linker and the at least one biologically active

molecule of each of the repeating dienes are separated by 2n+2 carbons along the polymer's backbone, where n is the number of carbons in each of two alkylene carbon backbone spacers residing between each ene and the carbon coupled to the linker of the repeating dienes."

Support for this amendment can be found throughout the specification, and specifically on pages 10, line 22 through page 11, line 4 and in Figures 1-3 with respect to the polymers, and Figures 8, 9, and 14-21 with respect to monomers to form the polymers.

It is well established that "for a prior art reference to anticipate in terms of 35 U.S.C. Sec. 102, every element of the claimed invention must be identically shown in a single reference," Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed.Cir.1988), and that "these elements must be arranged as in the claim under review," Lindemann Maschinenfabrik v. American Hoist & Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed.Cir.1984). Maynard *et al.* does not teach every element of the claimed invention arranged as in the instant claims. Maynard *et al.* teaches a polymer that does not have the linker biologically active molecule coupled to a carbon and separated by 2n+2 carbons along the polymer's backbone where n is the number of carbons in two alkylene carbon backbone spacer residing between each ene and the carbon coupled to the linker. Maynard *et al.* does not teach a repeating unit that has the linker coupled to a carbon and does not teach an alkylene carbon backbone spacer. Rather, the polymer of Maynard *et al.* can be considered to be coupled by a single nitrogen of a bicyclo unit or coupled by two carbons of a cyclo unit. As Maynard *et al.* does not teach every element of the amended claimed invention, it cannot anticipate the amended claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1-5 and 10-12 are rejected under 35 U.S.C. § 103(a) as obvious over Valenti *et al.* (Macromolecules, 1998) in view of Elvira *et al.* (Molecule, 2005). Applicants respectfully assert that the amended claimed invention is not obvious over the cited references. The Office Action correctly indicates that Valenti *et al.* teaches the synthesis of well-defined polyalcohol polymers and suggests their use as "binding substrates in the preparation of a series of drug release macromolecules" (page 2773, col. 1, paragraph 1). Valenti *et al.*, which is coauthored by instant inventor Kenneth Wagener,

does not suggest that binding is covalent bonding or that the repeating units comprise a linking group covalently bound to the bioactive agent. Rather, Valenti *et al.*, uses drug binding of the traditional definition, that being "***Interacting selectively and non-covalently with a drug***" (European Bioinformatics Institute - Databases, http://www.ebi.ac.uk/QuickGO/GTerm?id=GO:0008144) (emphasis added) Appreciation of the non-equivalence of binding and covalent bonding by the coinventors and coauthors of Valenti *et al.* is clear from the disclosure of the instant application, where ***binding is a function other than that provided by the polymers of the instant invention***. As recited on page 15 lines 22-27:

> "Advantageously, the ***polymers of the invention can be administered simultaneously or sequentially with other polymers***, drugs, or other biologically active agents. ***Examples include***, but are not limited to, antioxidants, free radical scavenging agents, peptides, growth factors, antibiotics, bacteriostatic agents, immunosuppressives, anticoagulants, buffering agents, anti-inflammatory agents, anti-pyretics, ***time-release binders***, anesthetics, steroids and corticosteroids." (emphasis added)

Although Elvira *et al.* teaches systems containing a polymeric backbone conjugated to a bioactive molecule, the polymer backbones are very different from those of the instant invention, and polymer drug conjugates taught in Elvira *et al.* are very different than those of the instant invention. Elvira teaches covalent bonding of drugs to end of a polymer (page 117 through page 119) and teaches randomly situated pendant groups on random copolymers, where either the comonomer feed or a random reaction on a regular polymer results in randomly situated bioactive agent substituents on the polymer (page 119 through page 122). Clearly, the instant amended claims are directed to a regular homopolymer where the displacement of the bioactive agents is regular, but where the displacement of the bioactive agents can be small or large and can be controlled by the value of n of the two alkylene carbon backbone spacers within the repeating units.

It is well appreciated that "All the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention" (*CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). As the term "binding" in Valenti *et al.* teaches non-covalent binding rather than covalent

bonding and Elvira *et al.* does not teach or suggest any method of achieving a polymer with regularly displaced pendant group with covalently bonded bioactive agent, the combination neither teaches nor suggests all limitations of the instant amended claimed invention. Nor do the references provide any motivation for combination of the dissimilar teachings of the prior art references. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 3 and 6-9 are rejected under 35 U.S.C. § 103(a) as obvious over the combination of Valenti *et al.* (Macromolecules, 1998) and Elvira *et al.* (Molecule, 2005), as applied to claims 1-2, 4-5, and 10-12 above, and further in view of Zhu *et al.* (Acc. Chem. Res., 2002). Applicants respectfully assert that the amended claimed invention is not obvious over the cited references. Zhu *et al.* teaches bile acids linked to a random poly(methylmethacrylate-*co*-*N*-isopropylacrylamide) backbone with oligoethylene oxide spacers in the linker (page 540, col. 2, top). However, this does not correct the deficiency of Valenti *et al.*, Elvira *et al.*, or their combination, and therefore the combination of Valenti *et al.*, Elvira *et al.*, and Zhu *et al.* also fails to teach all the claim limitations in order to establish the *prima facie* obviousness of the instant amended claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claim 4 is rejected under 35 U.S.C. § 103(a) as obvious over Maynard *et al.* (Macromolecules, 2000) as applied to claims 1-2 and 9-11 above, and further in view of) Valenti *et al.* (Macromolecules, 1998). Applicants respectfully assert that the amended claimed invention is not obvious over the cited references. Respectfully, Valenti *et al.* teaches that materials with well-defined structures are advantageous in the study of structure-property relationships and might lead to materials that are substrates in drug delivery systems (page 2765, col. 1, paragraph 1); but again the term "substrate", as indicated in Valenti *et al.* (page 2773, col. 1, paragraph 1) is with regard to a binding substrate and not a covalently bonding substrate. As indicated above, Maynard *et al.* does not teach the limitations of "wherein carbons coupled to the linker and the at least one biologically active molecule of each of the repeating dienes are separated by 2n+2 carbons along the polymer's backbone, where n is the number of carbons in each of two alkylene carbon backbone spacers residing between each ene and the carbon coupled to the linker of the repeating dienes" of the instant

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.