

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DeGRADO *et al.*

Appl. No.: 10/801,951

Filed: March 17, 2004

For: **Facially Amphiphilic Polymers and  
Oligomers and Uses Thereof**

Confirmation No.: 2895

Art Unit: 1617

Examiner: CHONG, Yong Soo

Atty. Docket: 1694.0630003/JMC/M-R/KHR

**Brief on Appeal Under 37 C.F.R. § 41.37**

*Mail Stop Appeal Brief - Patents*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

A Notice of Appeal from the final rejection of claims 16-48 and 67-73 was filed on May 4, 2009. A Decision on the Pre-Appeal Brief Review Request was mailed on June 23, 2009. Appellants hereby file one copy of this Appeal Brief, together with the required fee set forth in 37 C.F.R. § 41.20(b)(2). An Evidence Appendix containing Exhibits 1-4 follows page 46 of this paper.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

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***I. Real Party in Interest (37 C.F.R. § 41.37(c)(1)(i))***

The real party in interest in this Appeal is The Trustees of the University of Pennsylvania, Center for Technology Transfer, 3160 Chestnut Street, Suite 200, Philadelphia, Pennsylvania 19104, the assignee of record.

***II. Related Appeals and Interferences (37 C.F.R. § 41.37(c)(1)(ii))***

All other prior and pending appeals, interferences or judicial proceedings known to Appellants, Appellants' legal representative, or assignee which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal are listed below:

- A request for pre-appeal conference was filed in the captioned application. A Decision on the Pre-Appeal Brief Review Request was mailed on June 23, 2009. The Panel decided that the above-captioned application remains under appeal because there is at least one issue for appeal. The Panel Decision is included in the Related Proceedings Appendix, as required under 37 C.F.R. § 41.37(c)(1)(x).

The listing of the foregoing proceeding is not meant to be an admission that the above-mentioned proceeding directly affects, is directly affected by, or has a bearing on the Board's decision in the pending appeal.

**III. Status of Claims (37 C.F.R. § 41.37(c)(1)(iii))**

Claims 16-48 and 67-73 are pending and rejected. Claims 1, 15, 49, 54-56, 62, 63, 65, and 66 are pending and withdrawn, as being directed to nonelected claims. Claims 2-14, 50-53, 60, 61, 64, and 57-59 were cancelled. Claims 16-48 and 67-73 are being appealed.

**IV. Status of Amendments (37 C.F.R. § 41.37(c)(1)(iv))**

No claims were cancelled or amended since the Final Office Action was mailed on February 2, 2009.

**V. Summary of Claimed Subject Matter (37 C.F.R. § 41.37(c)(1)(v))**

Appellants' invention, as recited by independent claims 16, 17, and 67, is generally directed to a method of treating a microbial infection in an animal in need thereof comprising administering to the animal an effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an amphiphilic oligomer of general Formula II:  $R^1-[-x-A_1-x-y-A_2-y-]_m-R^2$  or an acceptable salt or solvate thereof. The m group of Formula II is defined as 1 to about 20 (claim 16); 1 to 10 (claim 17); or 1, 2 or 3 (claim 67).

Claims 16-48 and 67-73 are supported throughout the specification, *e.g.*, as shown in Table 1 below:

Table 1: Illustrative Support in the Specification for the Pending Claims

Claim No.	Illustrative Support from the Specification
16	p. 52, l. 4 to p. 61, l. 24
17	p. 52, l. 4 to p. 61, l. 24
18	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 1-6
19	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 6-8
20	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 9-10
21	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 9-12

Claim No.	Illustrative Support from the Specification
22	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 12-14
23	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 12-15
24	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 12-14; p. 55, ll. 16-20
25	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 28-31
26	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 1-6
27	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 1-6; p. 56, ll. 19-21
28	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29
29	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 1-2
30	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 1-2; p. 57, ll. 2-3
31	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 4-7
32	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 4-7; p. 57, ll. 1-11
33	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 12-16
34	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 12-16; p. 57, l. 19
35	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 12-16; p. 57, ll. 20-21
36	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 3-5
37	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 24-25
38	p. 52, l. 4 to p. 61, l. 24; p. 56, ll. 27-29; p. 57, ll. 29-31
39	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8
40	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 58, ll. 9-10
41	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 58, ll. 16-19
42	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 58, ll. 16-19; p. 58, l. 19
43	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 59, ll. 10-14
44	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 59, ll. 16-20
45	p. 52, l. 4 to p. 61, l. 24; p. 58, ll. 6-8; p. 59, ll. 21-23
46	p. 52, l. 4 to p. 61, l. 24; p. 59, l. 29
47	p. 52, l. 4 to p. 61, l. 24; p. 59, l. 30
48	p. 52, l. 4 to p. 61, l. 24; p. 52, l. 4 to p. 54, l. 31
67	p. 52, l. 4 to p. 61, l. 24; p. 52, l. 4 to p. 54, l. 31
68	p. 52, l. 4 to p. 61, l. 24; p. 100, ll. 1-3
69	p. 52, l. 4 to p. 61, l. 24; p. 16, ll. 6-17; p. 89, l. 26 to p. 90, l. 2
70	p. 52, l. 4 to p. 61, l. 24; p. 55, ll. 14-15
71	p. 52, l. 4 to p. 61, l. 24
72	p. 52, l. 4 to p. 61, l. 24; p. 52, l. 4 to p. 54, l. 31
73	p. 52, l. 4 to p. 61, l. 24; p. 52, l. 4 to p. 54, l. 31

**VI. Ground of Rejection to be Reviewed (37 C.F.R. § 41.37(c)(1)(vi))**

The sole remaining ground of rejection applicable to the pending claims is obviousness-type double patenting.

Claims 16-48 and 67-73 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent"), a copy of which is provided as Exhibit 1.

**VII. Argument (37 C.F.R. § 41.37(c)(1)(vii))**

**A. Methods of Treating a Microbial Infection in an Animal, as Recited in Claims 16-48 and 67-73, are Patentably Distinct from the Compounds and Method of Coating a Substrate as Claimed in the '102 Patent**

**1. Legal Principles Related to Obviousness Type Double Patenting**

**a) Overview of Obviousness Type Double Patenting**

The Federal Circuit has articulated two inquiries that must be made in determining whether a rejected claim is unpatentable for nonstatutory double patenting. *General Foods v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278, 23 U.S.P.Q.2d 1839, 1843 (Fed. Cir. 1992)(citing *In re Vogel*, 422 F.2d 438, 439, 164 U.S.P.Q. 619, 622-21 (C.C.P.A. 1970)); *see also*, *Manual of Patent Examining Procedure*, 8th edition, revision 7 ("MPEP"), § 804, pp. 800-21-22 (July 2008). The court defines these inquiries as follows:

Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting.

*General Foods*, 972 F.2d at 1278, 23 U.S.P.Q.2d at 1843. The court emphasized that where a "rejected claim defines *more* than an obvious variation, it is *patentably distinct*." *Id.* (emphasis in original).

Obviousness-type double patenting is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. § 103 except that the patent underlying the double patenting rejection is

not considered prior art. *In re Braithwaite*, 379 F.2d 594, 600 n.4, 154 U.S.P.Q. 29, 34, n. 4 (C.C.P.A. 1967). Thus, as with the nonobviousness requirement of section 103, an obviousness-type double patenting analysis starts with construing the claims. Specifically, the pending claims and the claims of the prior art patent must be construed. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968, 58 U.S.P.Q.2d 1869, 1878 (Fed. Cir. 2001); MPEP, § 804, p. 800-22.

During examination, an Examiner is required to give the words of a *claim being examined* their broadest *reasonable* interpretation consistent with the specification, and consistent with the interpretation that would have been reached by a person of ordinary skill in the art. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 U.S.P.Q.2d 1827, 1830 (Fed. Cir. 2004) (emphasis added). A word must be given its plain meaning unless the plain meaning is inconsistent with the specification, *i.e.*, the "ordinary and customary meaning" given to the term by those of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 2005)(*en banc*).

Additionally, according to the MPEP, "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." MPEP, § 804, p. 800-22 (*citing In re Vogel*, 422 F.2d 438, 441-42, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970)). Therefore, before rejecting pending claims under the judicially created doctrine of obviousness-type double patenting, the Examiner *should consider the manner in which a term is used in the specification of the prior art patent* when determining the scope of the claims of the prior art patent.

The analysis of obviousness-type double patenting will often consider whether a claim at issue is obvious over an earlier patented claim. *See, e.g., In re Longi*, 759 F.2d 887, 895-96, 225 U.S.P.Q. 645, 648 (Fed. Cir. 1985). However, "[t]he fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." MPEP § 2144.08, pp. 2100-154-53 (*citing In re Baird*, 16 F.3d 380, 382, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994)).

For example, in *Ex parte Whalen*, 89 U.S.P.Q.2d 1078 (Bd. Pat. App. & Int. 2008) the Examiner rejected the pending claims at issue for obviousness type double patenting because the "patented claim[s] anticipates the scope of the pending claim[s]." *Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1080 (Bd. Pat. App. & Int. 2008). On appeal, the Board found that the Examiner did not provide evidence sufficient to show that the pending claims were anticipated by the patent claims and that the claims on appeal were obvious variants. *Id.* at 1081 Accordingly, the Board reversed the Examiner's rejection.

Furthermore, the Federal Circuit has held that double patenting invalidity must be determined on a claim-by-claim basis. *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 22 U.S.P.Q.2d 119, 1124-25 (Fed. Cir. 1992).

#### ***b) Overview of Obviousness Law***

Also, an obviousness-type double patenting analysis generally parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. *See In re Braat*, 937 F.2d 589, 19 U.S.P.Q.2d 1289, 1292 (Fed. Cir. 1991); MPEP § 804, p. 800-21. Thus, the factual inquiries that are applied in determining obviousness under § 103 under *Graham v. John Deere Co. of Kansas City*,

383 U.S. 1, 148 U.S.P.Q. (BNA) 459 (1966) are generally employed when making an obviousness-type double patenting analysis. In *Graham*, the Supreme Court instructed that

[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

*Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966).

The U.S. Supreme Court reviewed and restated its obviousness jurisprudence originally established over forty years ago in *Graham*. See *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). In *KSR*, the Court determined that the Federal Circuit had been too rigid in *requiring* use of the teaching-suggestion-motivation ("TSM") test to determine obviousness. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Nonetheless, the Court recognized that TSM analysis could provide a helpful insight, emphasizing that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art." *Id.* at 1741, 82 U.S.P.Q.2d at 1396. Rather, there must be a reason or rationale behind an obviousness determination and "this analysis should be made explicit." *Id.* (citing *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")).

In response to *KSR*, the Office issued "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR Int'l Co. v. Teleflex Inc.*" 72

Fed. Reg. 195, pp. 57526-35 (October 10, 2007)("Guidelines"). The Guidelines reiterate and emphasize the Examiner's role as a factfinder, using the factual inquiries set forth in *Graham*. Based on the fact record, the Examiner must use "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Guidelines at 57529 col. 1 (internal citation omitted).

The Guidelines present several rationales which may be used by an Examiner to reject a claimed invention as obvious, one of which is the familiar TSM test. Common to all the rationales is the requirement for the Examiner to demonstrate, based on the *Graham* factual inquiries, that a person of ordinary skill in the art *would*, as of the filing date, have recognized that the claimed invention, as a whole, was predictable, or would have had a reasonable expectation of success. *Guidelines* at 57529, col. 1.

**2. *A Method of Treating a Microbial Infection in an Animal with Compounds as Presently Claimed is Non-Obvious Over Compounds and the Use of the Compounds to Coat the Surface of a Substrate as Claimed in the '102 Patent***

Pending independent claim 16 is directed to *a method of treating a microbial infection in an animal in need thereof* comprising administering to the animal an effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an amphiphilic oligomer of general Formula II:  $R^1-[-x-A_1-x-y-A_2-y-]_m-R^2$  or an acceptable salt or solvate thereof. The m group is defined as 1 to about 20 in claim 16. Claims 18-48 and 69-73 depend directly or indirectly from claim 16 and further define  $R^1$ , x,  $A_1$ , y,  $A_2$ ,  $R_2$ , or the type of microbial infection.

Pending independent claim 17 is directed to *a method of treating a microbial infection in an animal in need thereof* comprising administering to the animal an effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an

amphiphilic oligomer of general Formula II:  $R^1-[-x-A_1-x-y-A_2-y-]_m-R^2$  or an acceptable salt or solvate thereof. The m group is defined as 1 to about 10 in claim 17.

Pending independent claim 67 of the above-captioned application is directed to *a method of treating a microbial infection in an animal in need thereof* comprising administering to the animal an effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and an amphiphilic oligomer of general Formula II:  $R^1-[-x-A_1-x-y-A_2-y-]_m-R^2$  or an acceptable salt or solvate thereof. The m group is defined as 1, 2, or 3 in claim 67. Additionally, claim 68 depends from claim 67 and specifies three species of oligomers.

The Examiner rejected claims 16-48 and 67-73 as allegedly being unpatentable over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent") under the judicially created doctrine of obviousness-type double patenting. *See, e.g.*, Office Action mailed February 2, 2009, p. 3, l. 4 to p. 4, l. 18.

The '102 patent discloses and claims synthetic

polymeric compounds with anti-microbial properties which can be applied to or dispersed throughout devices, articles and surfaces and which are capable of killing microorganisms on contact, but leach into the environment more slowly than traditional small molecule anti-microbials. The polymeric materials may be deposited as a film on the surface of a substrate or may be dispersed.

The '102 patent, col. 4, ll. 60-67.

In contrast, the claimed methods of pending claims 16-48 and 67-73 are generally directed to treating an infection by administering an oligomer with antimicrobial properties to an animal.

As described in detail below, the pending claims differ from the claims of the '102 patent in two substantial ways: (i) the claimed method of uses and (ii) the genres of compounds to be administered. For the reasons set forth below, the Examiner has not shown why either the currently claimed method of use is an obvious variant of the method of use of the '102 patent, or that the subgenus of compounds to be used in the method of the currently pending claims is *prima facie* obvious over the compounds of claimed in the '102 patent. Thus, the Examiner has not shown that the invention of the currently pending claims as a whole is an obvious variant of the claims of the '102 patent.

Accordingly, the Examiner's rejection should be reversed.

***a) Pending Claims 16-48 and 67-73 are Directed to a Method of Treating a Microbial Infection in an Animal, which is Not an Obvious Variant of Claim 26 of the '102 Patent which Requires Coating a Substrate***

The first step of an obviousness-type double patenting rejection is construing the claims of being examined and the claims of the prior art patent. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968, 58 U.S.P.Q.2d 1869, 1878 (Fed. Cir. 2001); MPEP § 804, p. 800-22.

Usually, the preamble does not limit a claim. *DeGeorge v. Bernier*, 768 F.2d 1318, 1322, n.3, 226 U.S.P.Q. 758, 761, n. 3 (Fed. Cir. 1985). However, where a preamble is needed to give meaning to the claim and define the invention, it will be considered a limitation. *Bell Communications Research v. Vitalink Communications Corp.*, 55 F.3d 615, 621, 34 U.S.P.Q.2d 1816, 1820 (Fed. Cir. 1995). Additionally, if language in the preamble "breathes life into the claim" it is a necessary limitation, even though it appears in the preamble. *Loctite Corp. v. Ultraseal Ltd.*,

781 F.2d 861, 866, 228 U.S.P.Q. 90, 92 (Fed. Cir. 1985), overruled on other grounds by *Nobelpharma AB v. Implant Innovations*, 141 F.3d 1059, 46 U.S.P.Q.2d 1097 (Fed. Cir. 1998).

The preambles of independent claims 16, 17 and 67 are limiting because the preambles breathe life into the claims. The bodies of the claims recite "administering to the animal," while the preambles of the claims recite "animal in need thereof." To understand which "animal" the body refers, reference to the preamble is required. Therefore, the preambles of the pending claims must be a limitation. Thus, claims 16-48 and 67-73 are directed to "[a] method of treating a microbial infection in an animal in need thereof."

The plain and ordinary meaning of a microbial infection is an invasion and multiplication of microorganisms in body tissues of an animal. *See* Dorland's Medical Dictionary for Healthcare Consumers (Exhibit 2). Therefore, pending claims 16-48 and 67-73 are directed to the use of the oligomers of Formula II or a salt thereof to treat the invasion and multiplication of microorganisms in *body tissues* of an animal.

In comparison, claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to a polymer or oligomer of a specific formula. The '102 patent, col. 33, l. 2 to col. 43, l. 22. Claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent do not claim a use of the polymer or oligomer of the specific formula. *Id.* Therefore, a person having ordinary skill in the art (PHOSITA), reviewing *only* claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent, would not know for what purposes the claimed polymers or oligomers are to be used. A PHOSITA, reviewing *only* claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent, *would not have* expected that the compounds of claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent could be administered to an animal to treat the invasion and

multiplication of microorganisms in body tissues of an animal. Accordingly, pending claims 16-48 and 67-73 of the current application do *not* define an obvious variation of the invention of claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent.

The Examiner also rejected pending claims 16-48 and 67-73 as allegedly being unpatentable over claim 26 of the '102 patent. *See e.g.*, Office Action mailed February 2, 2009, p. 3, l. 4 to p. 4, l. 18. Claim 26 of the '102 patent is generally directed to a method of killing microorganisms comprising providing a substrate having disposed thereon a contact killing, facially amphiphilic polymer or oligomer of claim 1, claim 14, or claim 20; and placing the facially amphiphilic polymer or oligomer on the substrate in contact with a microorganism to allow formation of pores in the cell wall of the microorganism. The '102 patent, col. 45, ll. 14.

In the Office Action, the Examiner stated that

[a] person of ordinary skill in the art would have been motivated to administer to an animal infected with a microorganism a pharmaceutical composition comprising an oligomer [of claim 1, claim 14, or claim 20 of the '102 patent] because: (1) of general teaching that the disclosed oligomers inhibit the growth of microorganisms on a surface; (2) interpreting the term "substrate" broadly includes any surface in need of killing microorganism [sic], such as the skin or internal organs; and (3) animals with a microbial infection is a species within the broad genus of substrates. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a microbial infection in an animal by administering a composition comprising an oligomer of [claim 1, claim 14, or claim 20 of the '102 patent].

Office Action mailed February 2, 2009, p. 4, ll. 7-15.

Therefore, the Examiner construed the term "substrate" in claim 26 of the '102 patent as encompassing any surface in need of killing a microorganism, including skin or internal organs of an animal. *Id.* When construing the claims of the '102 patent, the Examiner should not construe the

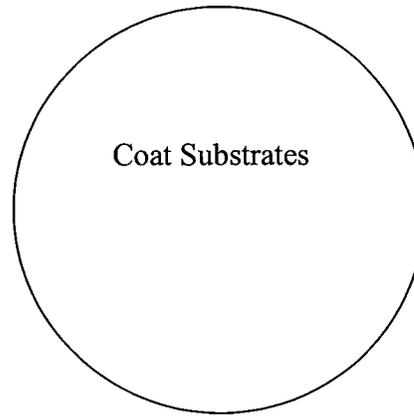
claims broadly. Instead, the Examiner must consider the manner in which the term is used in the '102 patent specification when determining the claim scope. *See* MPEP, § 804, p. 800-22. A review of the '102 patent specification demonstrates that the Examiner has taken the term "substrate" as used in claim 26 completely out of context.

The '102 patent disclosure, taken as a whole, indicates that the term "substrate" was intended to encompass inanimate surfaces, *not* living tissues. *See e.g.*, the '102 patent, at col. 26, lines 47-62. For instance, the '102 patent describes the use of polymers as "a surface-mediated microbicide that only kills organisms in contact with the surface." *Id.* at col. 26, lines 63-65. Additionally, the '102 patent states that "any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers." *Id.* at col. 27, lines 5-6. Moreover, claims 27 and 28 of the '102 patent, which depend from claim 26, further define "substrate" as wood, synthetic polymers, plastics, natural and synthetic fibers, cloth, paper, rubber and glass, all substrates that are *not* infected living surfaces. *Id.* at col. 45, lines 23-31. In fact, the '102 patent provides no guidance regarding routes of administration to an animal, useful pharmaceutically acceptable carriers or diluents, how the polymers are metabolized, or any potential toxicity associated with administration to the animals. Thus, a PHOSITA would not reasonably interpret the term "substrate", in view of the plain language of claim 26 and the '102 patent specification, to broadly encompass an infected living surface, such as the skin or internal organs. As such, the Examiner's construction of the term "substrate" of claim 26 of the '102 patent is wrong.

Because the Examiner erred in construing the term "substrate" of claim 26 of the '102 patent, the Examiner has misunderstood the scope of claim 26. As shown below, the method of use of pending claims 16-48 and 67-73 *does not* overlap with the scope of claim 26 of the '102 patent.



Pending Claims



Claim 26 of the '102 Patent

Therefore, a claim directed to treating the invasion and multiplication of microorganisms in *body tissues* of an animal with an oligomer is not an obvious variant of a claim directed to applying an oligomer or polymer to a *non-living* surface. Accordingly, for at least this reason, claims 16, 18-45, 48, and 70-73 are *not* an obvious variant of claim 26 of the '102 patent.

Furthermore, a PHOSITA would not have expected a polymer or oligomer that functions as a surface antimicrobial agent, when attached to or applied to a substrate, such as wood or cloth, to be effective in treating a microbial infection in an animal when administered to the animal, as recited by pending claims 16-48 and 67-73. Specifically, Dr. David P. Nicolau, Pharm.D., FCCP, an expert in the infectious disease field, stated *inter alia*, that

a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal.

Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP, pp. 3-4, ¶ 8, a copy of which is provided as Exhibit 3.

Similarly, Dr. Harry Bermudez, who has expertise in the biopolymers field, opined that

a person of ordinary skill in the art would not conclude from [the] disclosure in the '102 patent the polymers would not be toxic and would be safe to be administered as a pharmaceutical composition to treat a mammal with a microbial infection.

Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D., p. 5, ¶ 9, a copy of which is provided as Exhibit 4.

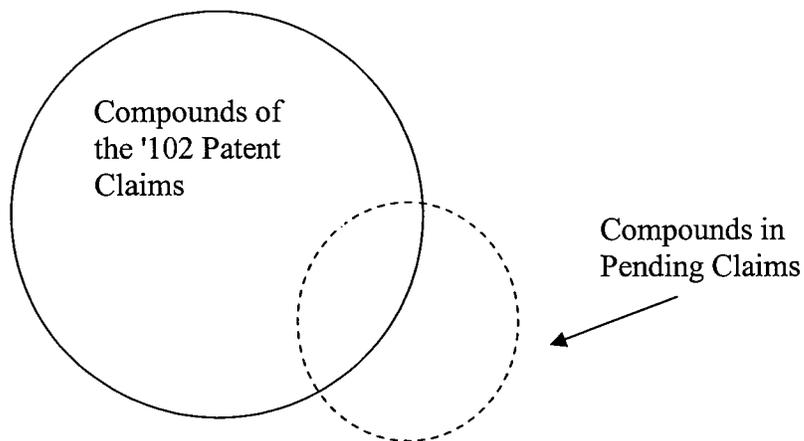
The Examiner has not established why a PHOSITA would expect that a polymer or oligomer that functions as a surface antimicrobial agent, as recited in claim 26 of the '102 patent, would be effective in treating the invasion and multiplication of microorganisms in body tissues of an animal when administered to the animal, as recited in pending claims 16-48 and 67-73. As such, pending claims 16-48 and 67-73 do *not* define an obvious variation of the invention of claim 26 of the '102 patent.

For these reasons, pending claims 16-48 and 67-73 are patentably distinct from the invention of claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent. Accordingly, the rejection of claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting has been overcome, and Appellants respectfully request that the rejection be reversed.

**b) *The Examiner has not Satisfied his Burden of Establishing that Administering Shorter Oligomers to Treat a Microbial Infection in an Animal is Prima Facie Obvious***

Claims 16-48 and 67-73 are directed to administering an oligomer with only 1 to about 20 (claims 16, 18-48, and 69-73), only 1 to 10 (claim 17), or 1, 2, or 3 (claims 67 and 68) monomeric units to an animal with a microbial infection in need of treatment. As described above, the Examiner has not satisfied his burden of showing that the currently claimed method is an obvious variant of the method of claim 26 of the '102 patent. Additionally, for the reasons set forth below, the Examiner has not established a showing that the compounds to be administered in the currently pending methods are *prima facie* obvious over the compounds to be administered in the method claimed in the '102 patent.

Claim 26 of the '102 patent requires application of a polymer or oligomer of claim 1, claim 14, or claim 20 to the surface of a substrate. The polymer or oligomer of claim 1, claim 14, or claim 20 has 2 to about 500 monomer units. Because *m* is defined for the polymers or oligomers to be applied to the surface as 2 to about 500 in claim 26 of the '102 patent, as shown below, the oligomers to be used in the method of pending claims 16-48 and 67-73 constitutes a sub-genus of the polymers or oligomers to be applied in the method of claim 26 of the '102 patent.



Even though there is some overlap in the structural formulae of pending claims 16-48 and 67-73 and claim 26 of the '102 patent, that overlap is insufficient for the Examiner to establish a *prima facie* case of obviousness to satisfy the requirements of the judicially created doctrine of obviousness-type double patenting. See MPEP § 2144.08, pp. 2100-154-53 (citing *In re Baird*, 16 F.3d 380, 382, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994)("The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness."). The Examiner has not pointed to any evidence as to why a PHOSITA, reviewing only claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent, would select the subgenus of oligomers containing only 1 to about 20 (claims 16, 18-48, and 69-73), only 1 to 10 (claim 17), or 1, 2, or 3 (claims 67 and 68) monomeric units, to treat a microbial infection in an animal, as recited in pending claims 16-48 and 67-73. Therefore, similar to the Examiner's rejection in *Ex parte Whalen*, the Examiner has not provided a rationale that the method of treating a microbial infection of

pending claims 16-48 and 67-73 is an obvious variant of claim 26 of the '102 patent. *See Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1081 (Bd. Pat. App. & Int. 2008). Accordingly, the Examiner's rejection of obviousness-type double patenting should be reversed.

Additionally, when considering whether a pending claim is an obvious variant of a prior patent claim, the relevant time frame for determining whether the claims are patentably distinct is on the filing date of the later application. *Takeda Pharm. Co., Ltd. v. Doll*, 561 F.3d 1372, 1377, 90 U.S.P.Q.2d 1496, 1500 (Fed. Cir. 2009). Therefore, when determining whether the currently pending claims are an obvious variant of the claims of the '102 patent, the PHOSITA must look at the state of the art at the time the currently pending application was filed.

The PCT application to which the '102 patent claims priority was filed March 7, 2002, and published December 19, 2002. Therefore, a PHOSITA would have been aware of the '102 patent's teachings at the time the currently pending application was filed. As such, the PHOSITA would have considered the '102 patent disclosure when determining whether the currently pending claims are an obvious variant of the '102 patent claims. Based upon the '102 patent specification, a PHOSITA would have been taught away from using short anti-microbial oligomers.

For example, the '102 specification indicates that "[f]acially amphiphilic molecules with molecular weights of about 0.8 kD to about 20 kD will be more prone to leach from the surface of the substrate." The '102 patent, col. 5, ll. 57-58. According to Dr. Bermudez, based upon this disclosure,

a person of ordinary skill in the art, when applying the polymers disclosed in the '102 patent to the surface of an object, would be motivated to use a polymer having a number of monomer units at the higher end of the disclosed range.

Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D., p. 3, ¶ 8. Therefore, the '102 patent teaches a PHOSITA away from using a short antimicrobial oligomer.

Additionally, Dr. Bermudez stated that

it is my opinion that a person of ordinary skill in the art would not expect that an oligomer containing only 1 to about 20 monomer units to be applied to the surface of an object would necessarily be effective when administered to an animal to treat a microbial infection.

*Id.* Therefore, Appellants have submitted evidence that a person having expertise in the art would not have expected that compounds having only 1 to about 20 monomer units for surface application would necessarily be effective to treat an animal with a microbial infection.

Because Appellants have submitted evidence that a PHOSITA would not have been motivated, and in fact would have been taught away from using the genus of oligomers of the currently pending claims, the Examiner's rejection of obviousness-type double patenting should be reversed.

Accordingly, for at least these reasons, the rejection of pending claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting is improper.

### 3. *Summary*

Appellants have shown the following:

1. The Examiner rejected currently pending claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1,

4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent"). Office Action mailed February 2, 2009.

2. The '102 patent discloses and claims synthetic "polymeric compounds with anti-microbial properties that can be applied to or dispersed throughout devices, articles and surfaces and which are capable of killing microorganisms on contact, but leach into the environment more slowly than traditional small molecule anti-microbials." The '102 patent, col. 4, ll. 60-65.

3. The currently pending claims are generally directed to a method of treating a microbial infection by administering an oligomer with antimicrobial properties to an animal.

4. The plain and ordinary meaning of a microbial infection is an invasion and multiplication of microorganisms in body tissues of an animal. *See* Dorland's Medical Dictionary for Healthcare Consumers (Exhibit 2).

5. Claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to a polymer or oligomer of a specific formula, not a use of the polymer or oligomer of the specific formula. The '102 patent, col. 33, l. 1 to col. 43, l. 39.

6. A person having ordinary skill in the art, reviewing *only* claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent, would not know for what purposes the claimed polymers or oligomers are to be used and would not have expected that the compounds could be administered to an animal to treat the invasion and multiplication of microorganisms in body tissues of an animal.

7. Claim 26 of the '102 patent is generally directed to a method of killing microorganisms comprising providing a substrate coated with a contact killing, facially amphiphilic

polymer or oligomer of claim 1, claim 14, or claim 20 and placing the facially amphiphilic polymer or oligomer on the substrate in contact with a microorganism. The '102 patent, col. 45, ll. 14-22.

8. The Examiner construed the term "substrate" in claim 26 of the '102 patent as encompassing any surface in need of killing a microorganism, including skin or internal organs of an animal. Office Action mailed February 2, 2009, p. 4, ll. 7-15.

9. A review of the '102 patent specification demonstrates that the Examiner has taken the term "substrate" as used in claim 26 completely out of context because the '102 patent disclosure, taken as a whole, indicates that the term "substrate" was intended to encompass inanimate surfaces, *not* living tissues. *See e.g.*, the '102 patent, col. 26, lines 47-62; col. 27, lines 5-6; col. 45, lines 23-31.

10. A person having ordinary skill in the art would not have expected a polymer or oligomer that functions as a surface antimicrobial agent, when attached to or applied to a substrate, such as wood or cloth, to be effective in treating a microbial infection in an animal when administered to the animal, as recited by pending claims 16-48 and 67-73. *See* Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP, pp. 3-4, ¶ 8 (Exhibit 3); Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D., p. 5, ¶ 9 (Exhibit 4).

11. The Examiner has not pointed to any evidence as to why a person having ordinary skill in the art, reviewing only claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent, would select the subgenus of oligomers within currently claims 16-48 and 67-73.

12. Appellants have submitted evidence that a person having ordinary skill in the art would not have been motivated, and in fact would have been taught away from using the genus of oligomers of the currently pending claims.

Therefore, based on the factual findings set forth in detail herein, and further in view of USPTO guidance and well-settled case law, Appellants respectfully conclude that pending claims 16-48 and 67-73 are patentably distinct from claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent.

**B. Conclusion**

For the reasons disclosed above, Appellants respectfully submit that the rejection of pending claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting is in error and should be reversed, and that these claims be allowed to issue.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



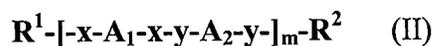
Marsha A. Rose  
Attorney for Appellants  
Registration No. 58,403

Date: 9/23/2009

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

**VIII. Claims Appendix (37 C.F.R. § 41.37(c)(1)(viii))**

16. A method of treating a microbial infection in an animal in need thereof, said method comprising administering to the animal an effective amount of a pharmaceutical composition comprising an amphiphilic oligomer of Formula II:



or an acceptable salt or solvate thereof,

wherein:

x is  $\text{NR}^8$ ,  $-\text{N}(\text{R}^8)\text{N}(\text{R}^8)-$ , or  $-\text{C}(\text{R}^7\text{R}^{7'})\text{NR}^8-$ , and y is  $\text{C}=\text{O}$ ;

wherein  $\text{R}^8$  is hydrogen or alkyl;  $\text{R}^7$  and  $\text{R}^{7'}$  are independently hydrogen or alkyl, or  $\text{R}^7$  and  $\text{R}^{7'}$  together are  $-(\text{CH}_2)_p-$ , wherein p is 4 to 8;

$\text{A}_1$  and  $\text{A}_2$  are independently optionally substituted *o*-, *m*-, or *p*-phenylene or one of  $\text{A}_1$  and  $\text{A}_2$  is optionally substituted *o*-, *m*-, or *p*-phenylene and the other of  $\text{A}_1$  and  $\text{A}_2$  is optionally substituted heteroarylene, wherein  $\text{A}_1$  and  $\text{A}_2$  are independently optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;

$\text{R}^1$  is

- (i) hydrogen, a polar group (PL), or a non-polar group (NPL), and  $\text{R}^2$  is  $-\text{x-A}_1\text{-x-R}^1$ , wherein  $\text{A}_1$  is as defined above and is optionally substituted with

one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups; or

- (ii) hydrogen, a polar group (PL), or a non-polar group (NPL), and  $R^2$  is  $-x-A'-x-R^1$ , wherein  $A'$  is arylene or heteroarylene and is optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;
- (iii)  $-y-A_2-y-R^2$ , and  $R^2$  is hydrogen, a polar group (PL), or a non-polar group (NPL); or
- (iv)  $-y-A'$  and  $R^2$  is  $-x-A'$ , wherein  $A'$  is aryl or heteroaryl and is optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups; or
- (v)  $R^1$  and  $R^2$  are independently a polar group (PL) or a non-polar group (NPL);  
 or
- (vi)  $R^1$  and  $R^2$  together form a single bond;

NPL is a nonpolar group independently selected from the group consisting of

$-B(OR^4)_2$  and  $-(NR^{3'})_{q1NPL}-U^{NPL}-(CH_2)_{pNPL}-(NR^{3''})_{q2NPL}-R^4$ , wherein:

$R^3$ ,  $R^{3'}$ , and  $R^{3''}$  are independently selected from the group consisting of hydrogen, alkyl, and alkoxy;

$R^4$  and  $R^{4'}$  are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, and heteroaryl, any of which is optionally substituted with one or more alkyl or halo groups;

$U^{NPL}$  is absent or selected from the group consisting of O, S, S(=O), S(=O)<sub>2</sub>,  $NR^3$ , -C(=O)-, -C(=O)-N=N- $NR^3$ -, -C(=O)- $NR^3$ -N=N-, -N=N- $NR^3$ -, -C(=N-N( $R^3$ )<sub>2</sub>)-, -C(=NR<sup>3</sup>)-, -C(=O)O-, -C(=O)S-, -C(=S)-, -O-P(=O)<sub>2</sub>O-, - $R^3$ O-, - $R^3$ S-, -S-C=N- and -C(=O)- $NR^3$ -O-, wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

the -(CH<sub>2</sub>)<sub>pNPL</sub>- alkylene chain is optionally substituted with one or more amino or hydroxy groups, or is unsaturated;

pNPL is 0 to 8;

q1NPL and q2NPL are independently 0, 1 or 2;

PL is a polar group selected from the group consisting of halo, hydroxyethoxymethyl, methoxyethoxymethyl, polyoxyethylene, and -(NR<sup>5</sup>)<sub>q1PL</sub>-U<sup>PL</sup>-(CH<sub>2</sub>)<sub>pPL</sub>-(NR<sup>5</sup>)<sub>q2PL</sub>-V, wherein:

$R^5$ ,  $R^5'$ , and  $R^{5''}$  are independently selected from the group consisting of hydrogen, alkyl, and alkoxy;

$U^{PL}$  is absent or selected from the group consisting of O, S, S(=O), S(=O)<sub>2</sub>,  $NR^5$ , -C(=O)-, -C(=O)-N=N-NR<sup>5</sup>-, -C(=O)-NR<sup>5</sup>-N=N-, -N=N-NR<sup>5</sup>-, -C(=N-N(R<sup>5</sup>)<sub>2</sub>)-, -C(=NR<sup>5</sup>)-, -C(=O)O-, -C(=O)S-, -C(=S)-, -O-P(=O)<sub>2</sub>O-, -R<sup>5</sup>O-, -R<sup>5</sup>S-, -S-C=N- and -C(=O)-NR<sup>5</sup>-O-, wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

V is selected from the group consisting of nitro, cyano, amino, hydroxy, alkoxy, alkylthio, alkylamino, dialkylamino, -NH(CH<sub>2</sub>)<sub>p</sub>NH<sub>2</sub> wherein p is 1 to 4, -N(CH<sub>2</sub>CH<sub>2</sub>NH<sub>2</sub>)<sub>2</sub>, diazamino, amidino, guanidino, guanyl, semicarbazone, aryl, heterocycle and heteroaryl, any of which is optionally substituted with one or more of amino, halo, cyano, nitro, hydroxy, -NH(CH<sub>2</sub>)<sub>p</sub>NH<sub>2</sub> wherein p is 1 to 4, -N(CH<sub>2</sub>CH<sub>2</sub>NH<sub>2</sub>)<sub>2</sub>, amidino, guanidino, guanyl, aminosulfonyl, aminoalkoxy, aminoalkylthio, lower acylamino, or benzyloxycarbonyl;

the -(CH<sub>2</sub>)<sub>pPL</sub>- alkylene chain is optionally substituted with one or more amino or hydroxy groups, or is unsaturated;

pPL is 0 to 8;

q1PL and q2PL are independently 0, 1 or 2; and

m is 1 to about 20;

and a pharmaceutically acceptable carrier or diluent.

17. A method of treating a microbial infection in an animal in need thereof, said method comprising administering to the animal an effective amount of a pharmaceutical composition comprising an amphiphilic oligomer of Formula II:



or an acceptable salt or solvate thereof,

wherein:

x is NR<sup>8</sup>, y is C=O, and R<sup>8</sup> is hydrogen or alkyl;

A<sub>1</sub> and A<sub>2</sub> are independently optionally substituted *o*-, *m*-, or *p*-phenylene or pyrimidinylene, wherein A<sub>1</sub> and A<sub>2</sub> are independently optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;

R<sup>1</sup> is hydrogen, a polar group (PL), or a non-polar group (NPL), and R<sup>2</sup> is -x-A<sub>1</sub>-x-R<sup>1</sup>, wherein A<sub>1</sub> is as defined above and is optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;

NPL is -(NR<sup>3'</sup>)<sub>q1NPL</sub>-U<sup>NPL</sup>-(CH<sub>2</sub>)<sub>pNPL</sub>-(NR<sup>3''</sup>)<sub>q2NPL</sub>-R<sup>4'</sup>, wherein:

$R^3$ ,  $R^{3'}$ , and  $R^{3''}$  are independently selected from the group consisting of hydrogen,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

$R^{4'}$  is selected from the group consisting of hydrogen,  $C_1$ - $C_{10}$  alkyl,  $C_3$ - $C_{18}$  branched alkyl,  $C_2$ - $C_{10}$  alkenyl,  $C_2$ - $C_{10}$  alkynyl,  $C_3$ - $C_8$  cycloalkyl,  $C_6$ - $C_{10}$  aryl, and heteroaryl, any of which is optionally substituted with one or more  $C_1$ - $C_6$  alkyl or halo groups;

$U^{NPL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-C(=O)-N=N-NH-$ ,  $-C(=O)-NH-N=N-$ ,  $-N=N-NH-$ ,  $-C(=N-N(R^3)_2)-$ ,  $-C(=NR^3)-$ ,  $-C(=O)O-$ ,  $-R^3S-$  and  $-R^3O-$ , wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

the  $-(CH_2)_{pNPL}-$  alkylene chain is optionally substituted with one or more amino or hydroxy groups;

$pNPL$  is 0 to 6;

$q1NPL$  and  $q2NPL$  are 0;

PL is  $-(NR^{5'})_{q1PL}-U^{PL}-(CH_2)_{pPL}-(NR^{5'})_{q2PL}-V$ , wherein:

$R^5$ ,  $R^{5'}$ , and  $R^{5''}$  are independently selected from the group consisting of hydrogen,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

$U^{PL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-C(=O)-N=N-NH-$ ,  $-C(=O)-NH-N=N-$ ,  $-N=N-NH-$ ,

-C(=N-N(R<sup>5</sup>)<sub>2</sub>)-, -C(=NR<sup>5</sup>)-, -C(=O)O-, -R<sup>5</sup>O-, and -R<sup>5</sup>S-, wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

V is selected from the group consisting of nitro, cyano, amino, hydroxy, C<sub>1</sub>-C<sub>6</sub> alkoxy, C<sub>1</sub>-C<sub>6</sub> alkylthio, C<sub>1</sub>-C<sub>6</sub> alkylamino, C<sub>1</sub>-C<sub>6</sub> dialkylamino, -NH(CH<sub>2</sub>)<sub>p</sub>NH<sub>2</sub> wherein p is 1 to 4, -N(CH<sub>2</sub>CH<sub>2</sub>NH<sub>2</sub>)<sub>2</sub>, diazamino, amidino, guanidino, guanyl, semicarbazone, C<sub>6</sub>-C<sub>10</sub> aryl, heterocycle, and heteroaryl;

the -(CH<sub>2</sub>)<sub>pPL</sub>- alkylene chain is optionally substituted with one or more amino or hydroxy groups;

pPL is 0 to 6;

q1PL and q2PL are 0;

m is 1 to 10,

and a pharmaceutically acceptable carrier or diluent.

18. The method of claim 16, wherein x is NR<sup>8</sup>, y is C=O, and R<sup>8</sup> is hydrogen or alkyl.

19. The method of claim 16, wherein x is -N(R<sup>8</sup>)N(R<sup>8</sup>)-, y is C=O, and R<sup>8</sup> is hydrogen.

20. The method of claim 16, wherein A<sub>1</sub> and A<sub>2</sub> are independently optionally substituted *o*-, *m*-, or *p*-phenylene.

21. The method of 20, wherein  $A_1$  and  $A_2$  are independently optionally substituted *m*-phenylene.

22. The method of claim 16, wherein one of  $A_1$  and  $A_2$  is *o*-, *m*-, or *p*-phenylene, and the other of  $A_1$  and  $A_2$  is heteroarylene.

23. The method of claim 22, wherein one of  $A_1$  and  $A_2$  is *m*-phenylene, and the other of  $A_1$  and  $A_2$  is pyrimidinylene.

24. The method of claim 22, wherein one of  $A_1$  and  $A_2$  is substituted with one or more polar (PL) groups and one or more nonpolar (NPL) groups and the other of  $A_1$  and  $A_2$  is unsubstituted.

25. The method of claim 16, wherein  $A_1$  and  $A_2$  are optionally substituted *m*-phenylene, and one of  $A_1$  and  $A_2$  is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of  $A_1$  and  $A_2$  is unsubstituted.

26. The method of claim 16, wherein  $R^1$  is hydrogen, a polar group (PL), or a non-polar group (NPL), and  $R^2$  is  $-x-A_1-x-R^1$ , wherein  $A_1$  is as defined in claim 16 and is substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups.

27. The method of claim 26, wherein  $R^1$  is a polar (PL) group and  $R^2$  is  $-x-A_1-x-R^1$ , where  $A_1$  is substituted with one or two polar (PL) groups and one non-polar (NPL) group.

28. The method of claim 16, wherein:

NPL is  $-(NR^{3'})_{q1NPL}-U^{NPL}-(CH_2)_{pNPL}-(NR^{3''})_{q2NPL}-R^{4'}$ , and  $R^3$ ,  $R^{3'}$ ,  $R^{3''}$ ,  $R^{4'}$ ,  $U^{NPL}$ ,  $pNPL$ ,  $q1NPL$  and  $q2NPL$  are as defined in claim 16.

29. The method of claim 28, wherein  $R^3$ ,  $R^{3'}$ , and  $R^{3''}$  are independently hydrogen,  $C_1$ - $C_6$  alkyl, or  $C_1$ - $C_6$  alkoxy.

30. The method of claim 29, wherein  $R^3$ ,  $R^{3'}$ , and  $R^{3''}$  are hydrogen.

31. The method of claim 28, wherein  $R^{4'}$  is  $C_1$ - $C_{10}$  alkyl,  $C_3$ - $C_{18}$  branched alkyl,  $C_2$ - $C_{10}$  alkenyl,  $C_2$ - $C_{10}$  alkynyl, or  $C_6$ - $C_{10}$  aryl.

32. The method of claim 31, wherein  $R^{4'}$  is phenyl, methyl, ethyl, *n*-propyl, isopropyl, *n*-butyl, *tert*-butyl, or *n*-pentyl.

33. The method of claim 28, wherein  $U^{NPL}$  is O, S, NH,  $-C(=O)$ ,  $-C(=O)-N=N-NH-$ ,  $-C(=O)-NH-N=N-$ ,  $-N=N-NH-$ ,  $-C(=N-N(R^3)_2)-$ ,  $-C(=NR^3)-$ ,  $-C(=O)O-$ ,  $-R^3S-$  or  $-R^3O-$ .

34. The method of claim 33, wherein  $U^{NPL}$  is  $-C(=O)-$ .

35. The method of claim 33, wherein  $U^{NPL}$  is absent.

36. The method of claim 16, wherein NPL is *n*-propyl, isopropyl, *n*-butyl, or *tert*-butyl.

37. The method of claim 28, wherein:

$pNPL$  is 0 to 2; and  $q1NPL$  and  $q2NPL$  are independently 0 or 1.

38. The method of claim 28, wherein the  $-(\text{CH}_2)_{p\text{NPL}}-$  alkylene chain in NPL is substituted with one or more amino groups.

39. The method of claim 16, wherein:

PL is  $-(\text{NR}^{5'})_{q1\text{PL}}-\text{U}^{\text{PL}}-(\text{CH}_2)_{p\text{PL}}-(\text{NR}^{5''})_{q2\text{PL}}-\text{V}$ , and  $\text{R}^5$ ,  $\text{R}^{5'}$ ,  $\text{R}^{5''}$ , V,  $\text{U}^{\text{PL}}$ , pPL, q1PL and q2PL are as defined in claim 16.

40. The method of claim 39, wherein  $\text{R}^5$ ,  $\text{R}^{5'}$ , and  $\text{R}^{5''}$  are independently hydrogen,  $\text{C}_1$ - $\text{C}_6$  alkyl, or  $\text{C}_1$ - $\text{C}_6$  alkoxy.

41. The method of claim 39, wherein  $\text{U}^{\text{PL}}$  is O, S, NH,  $-\text{C}(=\text{O})-$ ,  $-\text{C}(=\text{O})-\text{N}=\text{N}-\text{NH}-$ ,  $-\text{C}(=\text{O})-\text{NH}-\text{N}=\text{N}-$ ,  $-\text{N}=\text{N}-\text{NH}-$ ,  $-\text{C}(=\text{N}-\text{N}(\text{R}^5)_2)-$ ,  $-\text{C}(=\text{NR}^5)-$ ,  $-\text{C}(=\text{O})\text{O}-$ ,  $-\text{R}^5\text{S}-$  or  $-\text{R}^5\text{O}-$ .

42. The method of claim 41, wherein  $\text{U}^{\text{PL}}$  is O, S,  $-\text{C}(=\text{O})$ , or is absent.

43. The method of claim 39, wherein V is amino,  $\text{C}_1$ - $\text{C}_6$  alkylamino,  $-\text{NH}(\text{CH}_2)_p\text{NH}_2$  wherein p is 1 to 4,  $-\text{N}(\text{CH}_2\text{CH}_2\text{NH}_2)_2$ , diazamino, amidino, or guanidino.

44. The method of claim 39, wherein pPL is 2 to 4, and q1PL and q2PL are 0.

45. The method of claim 39, wherein the  $-(\text{CH}_2)_{p\text{PL}}-$  alkylene chain in PL is substituted with one or more amino groups.

46. The method of claim 16, wherein m is 1 to about 5.

47. The method of claim 16, wherein m is 1, 2 or 3.

48. The method of claim 16, wherein:

x is NR<sup>8</sup>, y is C=O, and R<sup>8</sup> is hydrogen;

A<sub>1</sub> and A<sub>2</sub> are independently optionally substituted *m*-phenylene, wherein

- (i) one of A<sub>1</sub> and A<sub>2</sub> is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is unsubstituted; or
- (ii) one of A<sub>1</sub> and A<sub>2</sub> is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is substituted with one or two polar (PL) groups;

R<sup>1</sup> is hydrogen or a polar group (PL), and R<sup>2</sup> is -x-A<sub>1</sub>-x-R<sup>1</sup>, wherein A<sub>1</sub> is as defined above and is optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;

NPL is -(NR<sup>3'</sup>)<sub>q1NPL</sub>-U<sup>NPL</sup>-(CH<sub>2</sub>)<sub>pNPL</sub>-(NR<sup>3''</sup>)<sub>q2NPL</sub>-R<sup>4'</sup>, wherein:

R<sup>3</sup>, R<sup>3'</sup>, and R<sup>3''</sup> are independently selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>6</sub> alkyl, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

R<sup>4'</sup> is selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>10</sub> alkyl, C<sub>3</sub>-C<sub>18</sub> branched alkyl, C<sub>2</sub>-C<sub>10</sub> alkenyl, C<sub>2</sub>-C<sub>10</sub> alkynyl, C<sub>3</sub>-C<sub>8</sub> cycloalkyl, C<sub>6</sub>-C<sub>10</sub> aryl, and heteroaryl, any of which is optionally substituted with one or more C<sub>1</sub>-C<sub>6</sub> alkyl or halo groups;

$U^{NPL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-R^3S-$  and  $-R^3O-$ , wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

the  $-(CH_2)_{pNPL}-$  alkylene chain is optionally substituted with one or more amino groups;

$pNPL$  is 0 to 6;

$q1NPL$  and  $q2NPL$  are 0;

PL is  $-(NR^{5'})_{q1PL}-U^{PL}-(CH_2)_{pPL}-(NR^5)_{q2PL}-V$ , wherein:

$R^5$ ,  $R^{5'}$ , and  $R^{5''}$  are independently selected from the group consisting of hydrogen,  $C_1-C_6$  alkyl, and  $C_1-C_6$  alkoxy;

$U^{PL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-R^5O-$ , and  $-R^5S-$ , wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

V is selected from the group consisting of amino, hydroxy,  $C_1-C_6$  alkylamino,  $-NH(CH_2)_pNH_2$  wherein p is 1 to 4,  $-N(CH_2CH_2NH_2)_2$ , diazamino, amidino, and guanidino;

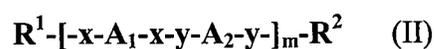
the  $-(CH_2)_{pPL}-$  alkylene chain is optionally substituted with one or more amino groups;

pPL is 0 to 6;

q1PL and q2PL are 0; and

m is 1, 2 or 3.

67. A method of treating a microbial infection in an animal in need thereof, said method comprising administering to the animal an effective amount of a pharmaceutical composition comprising an amphiphilic oligomer of Formula II:



or an acceptable salt or solvate thereof, wherein:

x is NR<sup>8</sup>, y is C=O, and R<sup>8</sup> is hydrogen;

A<sub>1</sub> and A<sub>2</sub> are independently optionally substituted *m*-phenylene and *m*- pyrimidinylene, wherein one of A<sub>1</sub> and A<sub>2</sub> is optionally substituted *m*-phenylene, and the other of A<sub>1</sub> and A<sub>2</sub> is optionally substituted pyrimidinylene, and wherein

- (i) one of A<sub>1</sub> and A<sub>2</sub> is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is unsubstituted; or
- (ii) one of A<sub>1</sub> and A<sub>2</sub> is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is substituted with one or two polar (PL) groups;

$R^1$  is hydrogen or a polar group (PL), and  $R^2$  is  $-x-A_1-x-R^1$ , wherein  $A_1$  is as defined above and is optionally substituted with one or more polar (PL) groups, one or more non-polar (NPL) groups, or a combination of one or more polar (PL) groups and one or more non-polar (NPL) groups;

NPL is  $-(NR^{3'})_{q1NPL}-U^{NPL}-(CH_2)_{pNPL}-(NR^{3''})_{q2NPL}-R^4$ , wherein:

$R^3$ ,  $R^{3'}$ , and  $R^{3''}$  are independently selected from the group consisting of hydrogen,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

$R^4$  is selected from the group consisting of hydrogen,  $C_1$ - $C_{10}$  alkyl,  $C_3$ - $C_{18}$  branched alkyl,  $C_2$ - $C_{10}$  alkenyl,  $C_2$ - $C_{10}$  alkynyl,  $C_3$ - $C_8$  cycloalkyl,  $C_6$ - $C_{10}$  aryl, and heteroaryl, any of which is optionally substituted with one or more  $C_1$ - $C_6$  alkyl or halo groups;

$U^{NPL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-R^3S-$  and  $-R^3O-$ , wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

the  $-(CH_2)_{pNPL}-$  alkylene chain is optionally substituted with one or more amino groups;

$pNPL$  is 0 to 6;

$q1NPL$  and  $q2NPL$  are 0;

PL is  $-(NR^{5'})_{q1PL}-U^{PL}-(CH_2)_{pPL}-(NR^{5'})_{q2PL}-V$ , wherein:

$R^5$ ,  $R^{5'}$ , and  $R^{5''}$  are independently selected from the group consisting of hydrogen,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

$U^{PL}$  is absent or selected from the group consisting of O, S, NH,  $-C(=O)-$ ,  $-R^5O$ , and  $-R^5S-$ , wherein groups with two chemically nonequivalent termini can adopt both possible orientations;

V is selected from the group consisting of amino, hydroxy,  $C_1$ - $C_6$  alkylamino,  $-NH(CH_2)_pNH_2$  wherein p is 1 to 4,  $-N(CH_2CH_2NH_2)_2$ , diazamino, amidino, and guanidino;

the  $-(CH_2)_{pPL}-$  alkylene chain is optionally substituted with one or more amino groups;

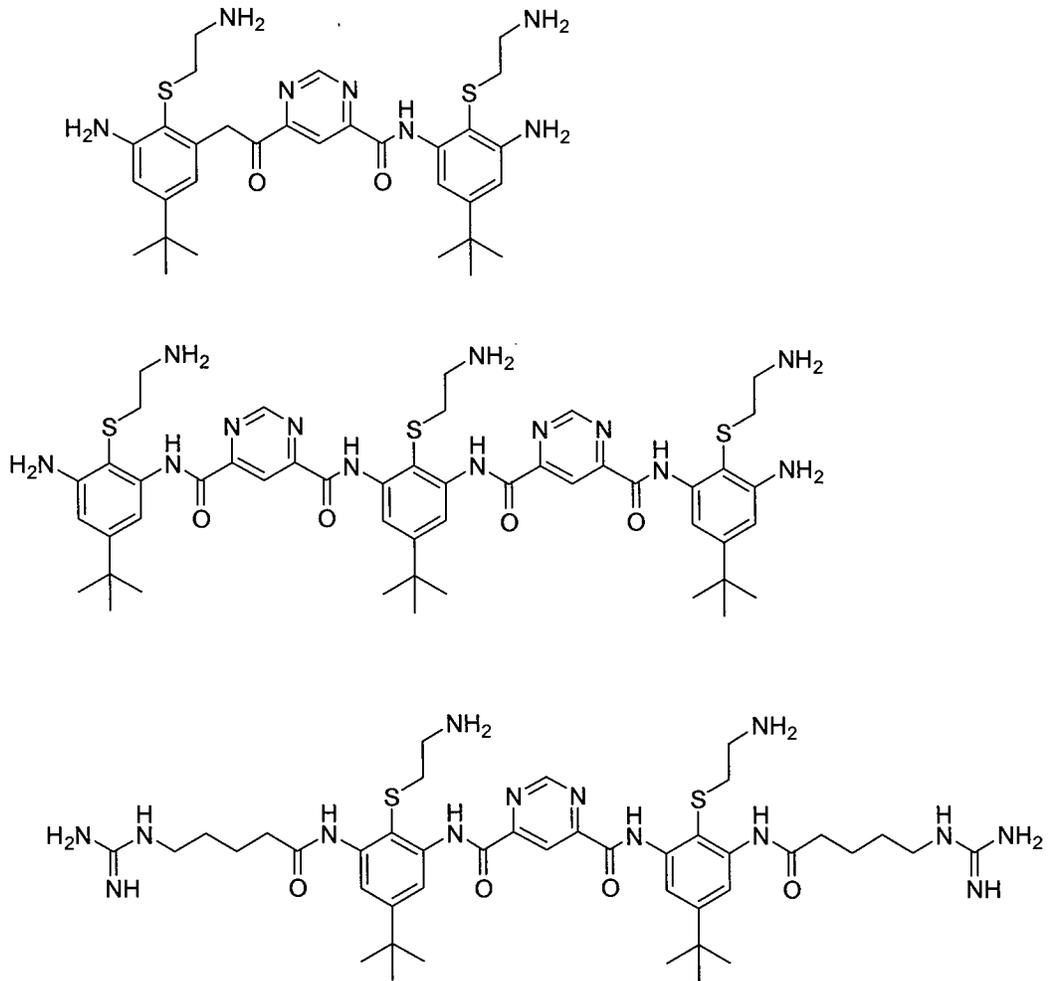
pPL is 0 to 6;

q1PL and q2PL are 0; and

m is 1, 2 or 3 ,

and a pharmaceutically acceptable carrier or diluent.

68. The method of claim 67, wherein the amphiphilic oligomer is selected from the group consisting of:



69. The method of claim 16, wherein the microbial infection is a bacterial infection, a fungal infection, or a viral infection.

70. The method of claim 16, wherein the heteroarylene is selected from the group consisting of pyridinylene, pyrimidinylene, and pyrazinylene.

71. The method of claim 16, wherein:

x is NR<sup>8</sup>, y is C=O, and R<sup>8</sup> is hydrogen;

one of A<sub>1</sub> and A<sub>2</sub> is optionally substituted *m*-phenylene, and the other of A<sub>1</sub> and A<sub>2</sub> is optionally substituted pyrimidinylene, wherein one of A<sub>1</sub> and A<sub>2</sub> is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is unsubstituted;

R<sup>1</sup> is a polar group (PL), and R<sup>2</sup> is -x-A<sub>1</sub>-x-R<sup>1</sup>;

NPL is a nonpolar group -(NR<sup>3'</sup>)<sub>q1NPL</sub>-U<sup>NPL</sup>-(CH<sub>2</sub>)<sub>pNPL</sub>-(NR<sup>3''</sup>)<sub>q2NPL</sub>-R<sup>4'</sup>, wherein:

R<sup>4'</sup> is selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, and heteroaryl, any of which is optionally substituted with one or more alkyl or halo groups;

U<sup>NPL</sup> is absent;

pNPL is 0, 1 or 2;

q1NPL and q2NPL are independently 0;

PL is a polar group -(NR<sup>5'</sup>)<sub>q1PL</sub>-U<sup>PL</sup>-(CH<sub>2</sub>)<sub>pPL</sub>-(NR<sup>5''</sup>)<sub>q2PL</sub>-V, wherein:

U<sup>PL</sup> is selected from the group consisting of O, S, and -C(=O)-;

pPL is 0 to 4;

q1PL and q2PL are independently 0;

V is selected from the group consisting of nitro, cyano, amino, hydroxy, alkoxy, alkylthio, alkylamino, dialkylamino,  $-\text{NH}(\text{CH}_2)_p\text{NH}_2$  wherein p is 1 to 4,  $-\text{N}(\text{CH}_2\text{CH}_2\text{NH}_2)_2$ , diazamino, amidino, guanidino, guanyl, semicarbazone, aryl, heterocycle and heteroaryl, any of which is optionally substituted with one or more of amino, halo, cyano, nitro, hydroxy,  $-\text{NH}(\text{CH}_2)_p\text{NH}_2$  wherein p is 1 to 4,  $-\text{N}(\text{CH}_2\text{CH}_2\text{NH}_2)_2$ , amidino, guanidino, guanyl, aminosulfonyl, aminoalkoxy, aminoalkylthio, lower acylamino, or benzyloxycarbonyl, and wherein the heterocycle is selected from the group consisting of piperidinyl, piperazinyl, imidazolidinyl, pyrrolidinyl, pyrazolidinyl, and morpholinyl; and

m is 1, 2 or 3.

72. The method of claim 16, wherein:

x is  $\text{NR}^8$ , y is  $\text{C}=\text{O}$ , and  $\text{R}^8$  is hydrogen;

one of  $\text{A}_1$  and  $\text{A}_2$  is optionally substituted *m*-phenylene, and the other of  $\text{A}_1$  and  $\text{A}_2$  is optionally substituted pyrimidinylene, wherein one of  $\text{A}_1$  and  $\text{A}_2$  is substituted with one polar (PL) group and one nonpolar (NPL) group and the other of  $\text{A}_1$  and  $\text{A}_2$  is unsubstituted;

$\text{R}^1$  is a polar group (PL), and  $\text{R}^2$  is  $-\text{x}-\text{A}_1-\text{x}-\text{R}^1$ ;

NPL is a nonpolar group  $-(NR^{3'})_{q1NPL}-U^{NPL}-(CH_2)_{pNPL}-(NR^{3''})_{q2NPL}-R^{4'}$ , wherein:

$R^{4'}$  is selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, and heteroaryl, any of which is optionally substituted with one or more alkyl or halo groups;

$U^{NPL}$  is absent;

$pNPL$  is 0, 1 or 2;

$q1NPL$  and  $q2NPL$  are independently 0;

PL is a polar group  $-(NR^{5'})_{q1PL}-U^{PL}-(CH_2)_{pPL}-(NR^{5''})_{q2PL}-V$ , wherein:

$U^{PL}$  is selected from the group consisting of O, S, and  $-C(=O)-$ ;

$pPL$  is 0 to 4;

$q1PL$  and  $q2PL$  are independently 0;

$V$  is selected from the group consisting of amino and guanidino; and

$m$  is 1, 2 or 3.

73. The method of claim 16, wherein:

$x$  is  $NR^8$ ,  $y$  is  $C=O$ , and  $R^8$  is hydrogen;

one of  $A_1$  and  $A_2$  is optionally substituted *o*-, *m*-, or *p*-phenylene, and the other of  $A_1$  and  $A_2$  is optionally substituted heteroarylene, wherein one of  $A_1$  and  $A_2$  is substituted with

one polar (PL) group and one nonpolar (NPL) group and the other of A<sub>1</sub> and A<sub>2</sub> is unsubstituted, and wherein the heteroarylene is selected from the group consisting of pyridinylene, pyrimidinylene, or pyrazinylene;

R<sup>1</sup> is a polar group (PL), and R<sup>2</sup> is -X-A<sub>1</sub>-X-R<sup>1</sup>;

NPL is a nonpolar group  $-(NR^{3'})_{q1NPL}-U^{NPL}-(CH_2)_{pNPL}-(NR^{3''})_{q2NPL}-R^{4'}$ , wherein:

R<sup>4'</sup> is selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, and heteroaryl, any of which is optionally substituted with one or more alkyl or halo groups;

U<sup>NPL</sup> is absent;

pNPL is 0, 1 or 2;

q1NPL and q2NPL are independently 0;

PL is a polar group  $-(NR^{5'})_{q1PL}-U^{PL}-(CH_2)_{pPL}-(NR^{5''})_{q2PL}-V$ , wherein:

U<sup>PL</sup> is selected from the group consisting of O, S, and -C(=O)-;

pPL is 0 to 4;

q1PL and q2PL are independently 0;

V is selected from the group consisting of amino and guanidino; and

m is 1, 2 or 3.

**IX. Evidence Appendix (37 C.F.R. § 41.37(c)(1)(ix))**

Copies of the evidence relied upon by Appellants in this Appeal Brief are provided. The Table below sets forth the location of the evidence in the Record:

<b>Exhibit</b>	<b>Title of Exhibit</b>	<b>Location in the Record</b>
Exhibit 1	U.S. Patent No. 7,173,102 B2	Cited by the Examiner in the Office Actions mailed March 29, 2007, October 30, 2007, July 28, 2008, and February 2, 2009
Exhibit 2	Dorland's Medical Dictionary for Healthcare Consumers	Exhibit A to Reply to Office Action filed October 27, 2008
Exhibit 3	Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP	Exhibit A to Supplemental Reply to Office Action filed June 25, 2008
Exhibit 4	Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D.	Exhibit B to Supplemental Reply to Office Action filed June 25, 2008

**X. *Related Proceedings Appendix (37 C.F.R. § 41.37(c)(1)(x))***

A copy of each decision rendered in a related in proceeding identified pursuant to paragraph (c)(1)(ii) of this section is provided below:

Decision 1: Notice of Panel Decision from Pre-Appeal Brief Review for Appl. No. 10/801,951, mailed June 23, 2009.