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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM F. DEGRADO, GREGORY N. TEW, MICHAEL L. KLEIN, DAHUI LIU, JING YUAN, and SUNGWOOK CHOI,

Appellants.

Appeal 2010-005832
Application 10/801,951
Technology Center 1600

Before ROBERT L. STOLL, *Commissioner for Patents*, JAMES T. MOORE, *Vice Chief Administrative Patent Judge,* and RICHARD E. SCHAFER, *Administrative Patent Judge*.

SCHAFER, *Administrative Patent Judge*

ORDER FOR FURTHER BRIEFING

Under the provisions of 37 CFR § 41.50(d), Applicants are required to brief the following questions:

1. Whether Applicants may be required to restrict their claims to a single invention under the provisions of 35 U.S.C. § 121 and

2. Whether Claim 16 is a proper "Markush Claim."

Applicant's brief is due no later than June 6, 2011.

Background

The subject matter of Claim 16 relates to a method for treating microbial infections by administering any of a large variety of compositions. The compositions must include at least one amphiphilic oligomer. Oligomers are compounds having a small number of monomer units. For example, an oligomer might have four monomers while a polymer would have thousands. Amphiphilic compounds are a large known class of compounds that are both hydrophilic (water attracting) and lipophilic (fat attracting). Such compounds typically include hydrophilic and lipophilic moieties. Soaps and detergents are amphiphilic compounds.

Applicants define the amphiphilic oligomers within the scope of the claims by Formula II:

$$\mathbf{R^1\text{-}[\text{-}x\text{-}A_1\text{-}x\text{-}y\text{-}A_2\text{-}y\text{-}]_m\text{-}R^2} \qquad \mathbf{(II)}$$

Each of R^1, R^2, x, y, A_1, A_2 and m are separately defined in the claim as follows:

> x is NR^8, $-N(R^8)N(R^8)-$, or $-C(R^7R^{7'})NR^8-$, and y is C=O;
> wherein R^8 is hydrogen or alkyl; R^7 and $R^{7'}$ are independently hydrogen or alkyl, or R^7 and $R^{7'}$ together are $-(CH_2)_{p-}$, wherein p is 4 to 8;
>
> A_l and A_2 are independently optionally substituted *o*-, *m*-, or *p*-phenylene or one of A_l and A_2 is optionally substituted *o*-, *m*-, or *p*-phenylene and the other of A_l and A_2 is optionally

substituted heteroarylene, wherein A_l and 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;

R^1 is

(i) 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 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

(iv) 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), $S(=0)_2$, NR^3, -C(=O)-, -C(=O)-N=N-NR^3-, -C(=O)-NR^3-N=N-, -N=N-NR^3-, -C(=N-$N(R^3)_2$)-, -C(=NR^3)-, -C(=O)O-, -C(=O)S-, -C(=S)-, -O-$P(=O)_2$O-, -R^3O-, -R^3S-, -S-C=N- and -C(=O)-NR^3-O-, 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, 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 -$(NR^{5'})_{q1PL}$-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, alkyl, and alkoxy;

U^{PL} is absent or selected from the group consisting of O, S, S(=O), $S(=O)_2$, NR^5, -C(=O)-, -C(=O)-N=N-NR^5-, -C(=O)-NR^5-N=N-, -N=N-NR^5-, -C(=N-$N(R^5)_2$)-, -C(=NR^5)-, -C(=O)O-, -C(=O)S-, -C(=S)-, -O-$P(=O)_2$O-, -R^5O-, -R^5S-, -S-C=N- and -C(=O)-NR^5-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, $-NH(CH_2)_pNH_2$ wherein p is 1 to 4, $-N(CH_2CH_2NH_2)_2$, 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, $-NH(CH_2)_pNH_2$ wherein p is 1 to 4, $-N(CH_2CH_2NH_2)_2$, amidino, guanidino, guanyl, aminosulfonyl, aminoalkoxy, aminoalkythio, lower acylamino, or benzyloxycarbonyl;

the $-(CH_2)_{pPL}$-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.

(App. Br. 27-31, Claims App'x.)

We conservatively estimate that Claim 16, in its current form, encompasses in excess of 400 billion oligomers.

Prosecution History

As originally filed, the application had 65 claims, not counting multidependent claims. Of the seven independent claims, five are directed to methods of treating microbial infections by administering specified groups of oligomers. The two remaining independent claims are directed to the specified groups of the oligomers. None of the original claims required that the oligomers be amphiphilic.

Upon initial review, an Examiner identified fifteen independent and distinct inventions (Groups I-XV) and required Applicants to elect one of them. Paper entered April 10, 2006, pp. 2-4. The Examiner found that

inventions I-XV were directed to unrelated inventions. Paper entered April 10, 2006, pp. 2-3. The Examiner further required that Applicants select a single disclosed species of oligomer from the elected group. Paper entered April 10, 2006, pp. 4-6.

Applicants responded, electing the invention of Group III (Claims 16-48) and further electing the third oligomer disclosed on page 100 of their written description. Paper filed June 12, 2006, pp. 1-2. We will refer to this oligomer as "Oligomer 3." The structural formula of this oligomer is shown in the margin.[1] Applicants traversed the requirement only to the extent that Groups III and IV (Claims 49-51) were not patentably distinct from each other and should be examined together. Paper filed June 12, 2006, p. 2. Applicants did not otherwise traverse the restriction and election of species requirements.

The Examiner performed a preliminary search of the prior art[2] and entered an additional restriction requirement for the Group III invention, Claims 16-48. He identified twenty-eight independent classes of oligomers (Groups I-XXVIII). Paper entered September 6, 2006, pp. 1-5. The inventions in each group were found to be unrelated. Paper entered September 6, 2006, p. 6. The Examiner required that the invention be restricted to one of the 28 groups and also required Applicants to elect a

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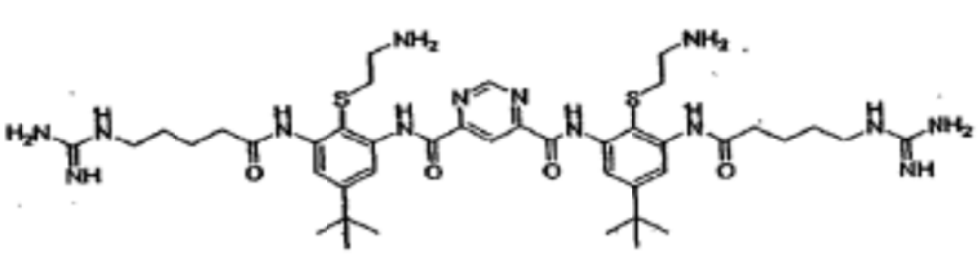
[1] Compound 3:



[2] Application 10/801,951, paper entered August 28, 2006.

single disclosed species from within the elected group. Paper entered September 6, 2006, p. 7. The claims other than 16-48 were withdrawn from further consideration. Paper entered September 6, 2006, p. 1.

In response, Applicants amended Claim 16 to require that the oligomers be "amphiphilic." Paper filed October 24, 2006, p. 10. According to Applicants, amphiphilicity gave the oligomers its anti-microbial property. Paper filed October 24, 2006, p. 53. Applicants traversed the restriction and election requirement because it (1) ignored the amphiphilicity feature of the invention, (2) as burdensome to applicants and (3) not allowing a meaningful restriction of "any of Applicants' inventions." Paper filed October 24, 2006, p. 54. Applicants also stated they could not elect one of the 28 identified groups because none

> permit the property of amphiphilicity, which is the central feature of Applicants' invention.

Paper filed October 24, 2006, p. 53. Applicant requested that the Examiner indicate which group reads upon the species of Oligomer 3 and explain how that group reads on that compound. Paper filed October 24, 2006, pp. 53-54.

Applicants, also argued that requiring a restriction between independent inventions present in a single claim was improper under *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978) and *In re Haa*s, 580 F.2d 461 (C.C.P.A. 1978). Also referencing MPEP ¶ 803.02, they argued that the Office must examine all claims exactly as Applicants presented them unless they lack "unity of invention." Paper filed October 24, 2006, pp. 54-55. According to Applicants, the amphiphilic oligomers of Claims 16-48 demonstrated unity of invention because they share the common utility of

antimicrobial activity and the structural feature of amphiphilicity. Paper filed October 24, 2006, p. 55.

Applicants additionally asserted that to the extent the claims encompass multiple independent and distinct inventions the Office must examine each invention when the number of inventions does not present a serious burden in searching and examining the claims. Paper filed October 24, 2006, p. 55. According to Applicants, the Examiner's 28 Groups could be divided by their respective PTO classifications into 7 sets each including 4 of the groups. Thus, according to Applicants, there would be no burden on the Office "because a search concerning the patentability of the invention of one group is likely to uncover art of interest to the other group." Paper filed October 24, 2006, p. 55.

In light of the amendment limiting the oligomers to amphiphilic compounds, the Examiner withdrew the second restriction requirement, and entered a new requirement identifying 21 unrelated inventions (Groups I-XXI). Paper entered December 28, 2006, pp. 2-6. The Examiner again noted that the claims were directed to a multitude of unrelated compounds having different structures, reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility, and modes of action. Paper entered December 28, 2006, pp. 5-6. The Examiner also found that the search for one of the compounds in one group would not lead to information regarding compounds in the other groups. Paper entered December 28, 2006, p. 6. The Examiner also again required election of a single species within the selected group. Paper entered December 28, 2006, p. 6.

Applicants responded electing, with traverse, the Group III invention, Claim 16-48, and further elected the species of Oligomer 3 for the purpose of initial examination. Applicants argued that the property of amphiphilicity

common to all the claimed compounds and their effectiveness for treating microbial infections precluded any requirement for restriction. Paper filed January 29, 2007, p. 2. Applicants further argued that Groups I, II and III, should be examined together because (1) they include a common structural feature, (2) the oligomers in those groups would be classified in the same class and subclass, and (3) there would be no "serious burden" to the Office. Paper filed January 29, 2007, pp. 2-3. Applicants also again argued the impropriety of restricting between multiple inventions in a single claim, noting that § 121 "does not grant the PTO the authority to refuse to examine a single claimed invention." Paper filed January 29, 2007, p. 3.

The Examiner maintained the restriction requirement and made it final. Paper entered March 29, 2007. The Examiner noted that the different groups were based on different common structural features and the searches of the non-patent literature would be different, notwithstanding common classifications of some of the groups. Prosecution of the application proceeded to the merits.

The Official record of this application does not show that a petition was filed to the Examiner's final restriction requirement.

DISCUSSION

35 U.S.C. § 121 and Multiple Independent and Distinct Inventions in a Single Claim

Section 121 of Title 35 provides in relevant part (emphasis added):

> If two or more independent and distinct inventions are claimed in one *application*, the Director may require the *application to be restricted to one of the inventions*.

The plain language of the statute appears to empower the Director to require any "application to be restricted to one of the inventions." Limiting an application to a single invention necessarily would require limiting the claims of that application to a single invention. Case law interpreting this section, however, has held that the provisions of the second paragraph of 35 U.S.C. § 112 are superior to the Director's discretion under § 121 to restrict the applicationto a single invention where independent and distinct inventions are presented in a single claim. The Court held that in requiring that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the *subject matter* which the applicant regards as his *invention*," 35 U.S.C. § 112, 2nd paragraph, allows the inventor to claim the invention in the way he chooses (subject to the other requirements of law), including claiming multiple independent and distinct inventions in a single claim. *In re Weber*, 580 F.2d 455, 458 (CCPA 1978). The court noted that, as a general proposition, an applicant has a right to have each claim examined on the merits in the form the applicant considers best defines the invention. *Id.* The court reasoned that if a single claim could be divided up and presented in several applications, applicant's claim in the form the applicant sought best to protect the invention would never be considered on the merits. *Id.* Notwithstanding the clear discretion provided by § 121 allowing the Director to require that the "application" be restricted

to a single invention, the court held that the Director had no authority to either reject claims or require restriction on the basis that independent and distinct inventions are covered in a single claim. *Id.*

We require that Applicants brief the apparent conflict between the plain language of § 121 and the *Weber* and *Haas* opinions. As part of the briefing applicants are required to address whether the language of the second paragraph of § 112, requiring "one or more claims . . . claiming the subject matter the applicant regards as his invention" necessarily precludes the Director from exercising his statutory discretion "to require the *application* to be restricted to one of the inventions" when more than one independent and distinct inventions are encompassed within a single claim.

Proper "Markush" Claims

We also require additional briefing on whether Claims 16-48 are proper Markush Claims. *In re Harnisch*, 631 F.2d 716 (C.C.P.A. 1980) notes that the body of law relating to Markush-type claims is concerned with the concept of "unity of invention." *Harnisch*, 631 F.2d at 721. The court used unity of invention to refer to the situation where unrelated, i.e., independent and distinct, inventions are captured in a single claim. *Harnisch*, 631 F.2d at 722. A Markush claim is improper if the inventions (1) do not share a common use; or (2) do not share a "single structural similarity," that is, a substantial structural feature disclosed as being essential to the common utility. *Harnisch*, 631 F.2d at 722; *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (Bd. Pat. App. & Int. 1984). The Examiner held that Claims 16-48 encompassed 21 unrelated inventions. Paper entered December 28, 2006, pp. 2-6. That determination was based upon the markedly different chemical structures between the oligomers in the different groups.

Applicants are required to brief whether the recitation of a broad general formula covering a very large group of compounds, the recitation of a general chemical property (amphiphilicity) that may be possessed by those compounds, and the recitation of the single broad step of "administering an effective amount" is per se sufficient to create "unity of invention" as that concept was used by the *Harnisch* court. Applicants are also required to brief whether, considering only the oligomers as defined by Formula II in Claim 16, the 21 groups identified by the Examiner are unrelated inventions. Stated another way, do those groups share any additional structural or functional features that would establish unity of invention?

ORDER

On or before June 6, 2011, Applicants shall file a brief addressing the two issues described above. 37 CFR § 41.50(d).