Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte JEFFREY A. HUBBELL, MARCUS TEXTOR,
DONALD L. ELBERT, STEPHANIE FINKEN,
ROLF HOFER, NICHOLAS D. SPENCER, and
LAURENCE RUIZ-TAYLOR

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Appeal No. 2003-1783
Application No. 09/560,472

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HEARD: January 8, 2004

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Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 5-6, 8-10, 12-18, 20-23, 61 and 64-66, which are all of the claims pending in this application.

Claims 5, 13, 15 and 20 are illustrative of the claims on appeal and read as set forth below:

5. A method for reducing non-specific adsorption of inorganic ions, peptides, proteins, and saccharides to a surface of a device comprising

applying to or coating onto a surface of an analytical or sensing device, wherein the surface comprises a material selected from the group consisting of metals, metal oxides, and charged polymers,

a non-interactive polyionic multifunctional copolymer, wherein the non-interactive polyionic multifunctional copolymer comprises non-interactive polymer sidechains covalently grafted onto a charged polyionic polymeric backbone which has an anionic charge at a pH greater than 4, wherein the polyionic polymeric backbone interacts with the surface at a pH greater than 4.

13. The method of claim 9 [the method of claim 5 where some or all of the non-interactive polymer sidechains are partially or fully functionalized at or near the free terminal position of the non-interactive polymer sidechains with a functional molecule.]

comprising exposing the copolymer to analyte which is bound by the functional molecule in a fluid phase, followed by adsorption of the copolymer onto the substrate or surface.

15. A method for making a biosensing or analytical device having reduced non-specific adsorption of inorganic ions, peptides, proteins, and saccharides comprising

applying to or coating onto a surface of the biosensing or analytical device non-interactive polyionic multifunctional copolymers,

wherein the non-interactive polyionic multifunctional copolymers comprise non-interactive polymer sidechains covalently grafted onto a charged polyionic polymeric backbone, and

wherein the surface comprises a material selected from the group consisting of metals, metal oxides, and charged polymers, and

the surface of the device has a charge opposite to the charge of the charged polyionic polymeric backbone, and

wherein some of the non-interactive polymer side chains comprise a functional moiety and some of the non-interactive polymer side chains do not comprise a functional moiety.

20. The method of claim 15 wherein the surface is patterned with areas with adsorbed polyionic copolymers not comprising functional groups and areas with adsorbed polyionic copolymers comprising functional groups.

The references are relied upon by the examiner are:

Hubbell et al. (Hubbell) WO 98/47948 Oct. 29, 1998

Humphries, et al. (Humphries), "The use of graft copolymers to inhibit the adhesion of bacteria to solid surfaces," FEMS Microbiology Ecology, Vol. 45, pp. 297-304 (1987)

Claim Groupings

According to appellants, the claims do not stand or fall together and the claims should be grouped as follows: (1) claims 5, 6, 8, 12, 61 and 64; (2) claims 13 and 14; (3) claims 9, 10, 15, 16 and 18, and (4) claims 20-23 and 66. Reply Brief, page 3. We decide this appeal with respect to the prior art rejections before us on the basis of representative claims 1, 13, 15 and 20 as designated for each of the above noted groups, respectively. In Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

Grounds of Rejection

Claim 5 stands rejected under 35 U.S.C. § 112, second paragraph, as being incomplete and omitting essential steps.

Claims 5-6, 8-10, 12-18, 20-23, 61 and 64-66 stand rejected under 35 U.S.C. § 102(a) as anticipated by Hubbell.

Claims 5-6, 8-10, 12-18, 20-23, 61 and 64-66 stand rejected under 35 U.S.C. § 102(b) as anticipated by Humphries.

We reverse the rejection under 35 U.S.C. § 112, second paragraph, and reverse the rejection under 35 U.S.C. § 102(a) over Hubbell. We affirm the rejection of claims 5, 6, 8, 12, 61, 64 and 65 under 35 U.S.C. § 102(b) over Humphries. We reverse the rejections of claims 13 and 14; claims 15-19, and claims 20-23 and 66 over Humphries.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

35 U.S.C. § 112, second paragraph

Claim 5 stands rejected under 35 U.S.C. § 112, second paragraph, as being incomplete and omitting essential steps.

The examiner argues that claim 5 is indefinite because there is no correlation between the preamble of the method claim and the body of the claim. Specifically, the examiner argues that the claim is a method claim for reducing adsorption but there is no correlation step reciting how this is done. Appellants argue that the claim clearly recites

the interaction between the copolymer and the surface. Brief, page 9. However, the examiner maintains the argument that there must be a correlation between the preamble and the body of the claim as to how the reduction in adsorption. Answer, page 5.

As set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

> The statute requires 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." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

Furthermore, claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

We do not agree with the examiner that the failure of claim 5 to recite the way in which the non-specific adsorption is reduced renders the claim indefinite. The claim language must be interpreted in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art. We agree with appellants that one possessing the ordinary skill in the pertinent art would understand that claim 5 requires that the

polyionic polymeric backbone interact with the surface and the interaction between the charged polyionic backbone attaches the copolymer to the surface in a manner which prevents the non-specific adsorption of ions or molecules to the surface.

We do not find the examiner has provided a sufficient basis upon which we should find the claim language indefinite. The rejection of claim 5 under 35 U.S.C. § 112, second paragraph, as being incomplete and omitting essential steps, is reversed.

35 U.S.C. § 102(b)

Claims 5-6, 8-10, 12-18, 20-23, 61 and 64-66 stand rejected under 35 U.S.C. § 102(b) as anticipated by Humphries.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The examiner relies on Humphries for its disclosure of graft copolymers that inhibit adhesion of bacteria to substrates. The copolymers have polyethylene glycol side chains and a backbone that is either uncharged, acidic or basic. The substrates disclosed in Humphries are microscopic slides (glass), steel, and hydroxyapatite. The copolymers are attached to the surface through covalent binding. Answer, page 5.

In response to this rejection, appellants argue that Humphries does not disclose

biosensing or analytical devices. The examiner addresses this argument indicating that the microscope slides disclosed in Humphries are analytical in nature. Answer, page 7. In addition, Humphries discloses the coating of stainless steel discs. The amount of bacteria which adhered to the discs was determined by computerized image analysis. Humphries, page 300. Thus, the stainless steel discs for computerized image analysis and microscope slides described in Humphries would reasonably appear to be analytical devices for the specific detection of biologically or medically relevant molecules in congruence with the definition of analytical device in appellants' specification, page 47.

Appellants also argue that "Humphries does not provide any teaching regarding methods of reducing nonspecific adsorption of *inorganic ions, peptides, proteins, and saccharides*." Brief, page 12. The examiner responds, arguing that because this language is present in the preamble of the claim that it is not given patentable weight because the process steps or structural limitations are able to stand alone, citing Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Answer, page 8. The examiner also argues that "Applicant's [sic] intended use would be an inherent function of the Humphries method, since the reference teaches all the steps of the claimed method and would be capable of performing this function." Id.

"If the claim preamble, when read in the context of the entire claim, recites

limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim. . . . If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

We agree with the examiner that, in the present case, the preamble language does not give life, meaning, and vitality to the claim and that the body of the claim fully and intrinsically sets forth the complete invention. We do not give patentable weight to the preamble language *inorganic ions, peptides, proteins, and saccharides*.

Moreover, appellants' specification, page 14, line 12, indicates that a suitable polyanionic block includes poly(meth)acrylic acid. Appellants' specification, page 11, lines 18-30, states that non-interactive polymers include polyethylene glycol. Similarly, Humphries, page 300, Table 1, compound 11 describes the same polymethacrylic acid polyanion with polyethylene glycol side chains. Assuming, arguendo, that patentable weight is given to the preamble claim language, we find no distinction between the claimed subject matter and that of Humphries. As stated in In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963), "From the standpoint of patent law, a

compound and all of its properties are inseparable; they are one and the same." If the compounds disclosed in the specification possess the property of reducing non-specific adsorption of inorganic ions, peptides, proteins, and saccharides to a surface of a device, the exact same compound disclosed in Humphries must also necessarily possess this property. Furthermore, Humphries clearly indicates that its graft copolymers inhibit the adhesion of bacteria to solid surfaces. Humphries, page 297.

The rejection of representative claim 5 is affirmed. Dependent claims 6, 8, 12, 61, 64 and 65 fall with representative claim 5.

However, independent claim 15 stands on a different footing than claim 5 and includes the limitation that the non-interactive polymer sidechain include a functional moiety. In addition, claim 13 requires that an analyte is bound by the functional molecule in a fluid phase. We do not find that the examiner has presented sufficient evidence or indicated where Humphries describes a functional moiety as claimed in claims 13 or 15. The rejection of claims 13 and 14 and claims 9, 10, 15, 16 and 18, over Humphries is reversed.

Likewise, we do not find the examiner has presented evidence or indicated where Humphries discloses a patterned surface in accordance with claim 20. The rejection of claims 20-23 and 66 over Humphries is reversed.

35 U.S.C. § 102(a)

Claims 5-6, 8-10, 12-18, 20-23, 61 and 64-66 stand rejected under 35 U.S.C. § 102(a) as anticipated by Hubbell.

According to the examiner (Answer, page 4), Hubbell discloses

> multifunctional polymeric coatings for coating biological and non-biological surfaces (including metallic surfaces), which minimize or prevent adhesion (abstract). Embodiments include polyethylene glycol/polylysine (PEG/PLL) copolymers, in which PLL is a dendrimer attached to an end of the PEG (abstract). The lysine dendrimer, which usually contains 16-128 amine groups, is covalently grafted to one of the PEG block. The multi-layer polymeric material is formed by end ionic interactions of a polycation and a polyanion. The polymeric material is applied in fluid phase to a surface. The PEG/PLL copolymers can be brush copolymers with a backbone of polylysine. Suitable polycationic blocks include polyamino acids having net positive charge at neutral pH, positive charge polysaccharides, and positively charged synthetic polymers (page 7)... It is inherent that surface on which the copolymer is attached may have a positive or negative charge, as multiple copolymer layers of either charge may be attached to the substrate surface.

The examiner urges that Hubbell page 18, lines 24-30 "clearly states that the terminal amine of polyglutamic acid (one example of a polyanion) can be reacted with PEWG [sic] modified with CDI to produce a copolymer structure." Answer, page 6.

Appellants, on the other hand, argue that Hubbell does not teach or suggest coating a positively charged surface or a copolymer containing a polyanionic backbone and non-interactive polymer sidechains. Brief, pages 9-10. Appellants specifically argue that Hubbell teaches at page 18, line 24, that the "polycationic material will then be hydrolyzed to form a 'non-binding polyanion'", and therefore "Hubbell teaches that a copolymer with a polyanionic backbone cannot be used to bind to and coat a surface."

Brief, page 11. We do not find that the examiner has adequately addressed or responded to appellants' argument and characterization of the disclosure of Hubbell, page 18.

While Hubbell describes polycationic/polyanion layered structures of polyethylene imine/polyacrylic acid and of polylysine/alginate at pages 28-29, Hubbell does not appear to specifically describe compositions such as these which contain non-interactive polymer side chains, or functional groups as set forth in claims 5 and 15, respectively, as required by 35 U.S.C. § 102.

In view of the above, the rejection of the claims over Hubbell is reversed.

CONCLUSION

We reverse the rejection under 35 U.S.C. § 112, second paragraph, and reverse the rejection under 35 U.S.C. § 102(a) over Hubbell. We affirm the rejection of claims 5, 6, 8, 12, 61, 64 and 65 under 35 U.S.C. § 102(b) over Humphries. We reverse the rejections of claims 13 and 14; claims 9, 10, 15, 16 and 18, and claims 20-23 and 66 over Humphries.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

TONI R. SCHEINER Administrative Patent Judge	) BOARD OF PATENT
DEMETRA J. MILLS Administrative Patent Judge	) APPEALS AND
ERIC GRIMES Administrative Patent Judge	) INTERFERENCES

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