Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROY CONIGLIONE and JOHN L. RUSSELL, JR.

Appeal No. 2000-1775
Application No. 08/563,087

ON BRIEF

Before ELLIS, MILLS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 37 C.F.R. § 134 from the examiner's final rejection of claims 4-8, 10, 11, 13, 22, 25-27, 31 and 36-41. Claims 9, 12, 14-21, 23, 28, 30 and 32-35 have been withdrawn from consideration by the examiner pursuant to 37 C.F.R. §

Claims 4 and 25 are representative of the claims on appeal and read as follows:[1]

4. A therapeutic source comprising a radioactive composite consisting essentially of (a) a polymeric matrix and (b) a radioactive powder consisting essentially of microscopic radioactive particles at least 0.002 microns in average dimension randomly and essentially uniformly dispersed within said polymeric matrix;
wherein said polymeric matrix is a biocompatible polymer.

25. A method of making a therapeutic source of claim 4, comprising the steps of:
(a) mixing a radioactive powder dispersed in a solvent, with a biocompatible polymer;
(b) removing the solvent to form a mixture;
(c) extruding the mixture to form an extruded mixture; and
(d) cutting said extruded mixture to form said therapeutic source;
whereby said therapeutic source is adapted to deliver a therapeutic dose of radiation.

The references relied upon by the examiner are:

Stavrianopoulos	4,849,208	Jul. 18, 1989
Suthanthiran et al. (Suthanthiran)	5,163,896	Nov. 17, 1992
Carden, Jr. (Carden)	5,405,309	Apr. 11, 1995

The examiner has rejected all of the claims under 35 U.S.C. § 103 as being

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[1]On Sept. 12, 1997, the examiner entered a final rejection of claims 4-8, 10, 11, 13, 22, 25-27, 31 and 36-41 over the combined teachings of Suthanthiran,

unpatentable over Suthanthiran, Stavrianopoulos and Carden.[2]

We reverse.

Discussion

The examiner has predicated his conclusion of obviousness on the combined teachings Suthanthiran, Stavrianopoulos and Carden. To that end, we find the following.

1. Suthanthiran discloses the construction of a radioactive seed (pellet) which is said to be useful as a therapeutic agent. Suthanthiran, col. 1, lines 8-9. The radioactive pellet comprises a marker rod or a metal substrate, preferably made of tungsten or a tungsten alloy. Id., col. 2, lines 52-63. The metal substrate/marker is coated with a radioactive-absorbing material (which is capable of binding a fluid radioactive material), in a binder material. Id., lines 64-68. The radioactive-absorbing materials include

> carbon, activated carbon or charcoal, and ion-exchange resins such as sulfonated polystyrene resins which are available from the Dow Chemical Co. under the trade-name DOWEX, methylene-sulfuric phenolic resins, phosphoric polystyrene resins, polystyrene resins containing quaternary ammonium groups immodiacetic polystyrene resins, and polystyrene resins containing polyamine groups. Id., col. 3, lines 1-9.

However, the preferred material for the radioactive-absorbing material is said to be a polyamino acid. Id., col. 3, lines 10-11. The polyamino acid may be combined with the binder material and applied to the substrate/marker before or after impregnation with the radioactive material. Id., col. 3, lines 11-14.

Suthanthiran further discloses that the binder material is one which is capable of binding the substrate or marker and absorbing the radioactive-absorbing material. Id., col. 4, lines 18-22. Preferred binders are said to be water insoluble so that aqueous solutions of radioactive materials can be used to impregnate the radio-absorbing material. Id., col. 4, lines 22-25. Water-insoluble binders are said to include "cellulose esters such as cellulose acetate, cellulose propionate, cellulose butyrate, and the like ... [as well as] ... hydrogenated rosin esters, alkyd resins, silicone resins, polystyrene-olefin copolymers, polystyrene-vinyl toluene copolymers, phenyl methyl silicone resin, phenolformaldehyde resins, and the like." Id., col. 4, lines 38-40 and 51-55. Suthanthiran still further discloses that when the radioactive materials are soluble or suspendable in organic solvents, the binder may be water soluble, but insoluble in the organic solvent. Id., col. 4, lines 61-64. Water-soluble binders may include water-soluble materials; e.g., "disaccharides such as sucrose, maltose and the like,

2. Stavrianopoulos discloses methods of attaching metal chelating groups[3] and biotin to polymers, "especially biopolymers such as polynucleotides, polypeptides or polysaccharides." Stavrianopoulos, the abstract, col. 1, lines 10-17; col. 3, lines 24-28. The covalent conjugates produced by the disclosed methods are said to be useful in in vivo or in vitro diagnostic assays or therapies. Id., col. 5, lines 3-14. Stavrianopoulos further discloses that synthetic polymers having at least one modifiable reactive group can be attached to the biopolymers or small molecules of the invention. Id., col. 5, lines 14-17. The presence of synthetic polymers on the biopolymers is said to provide additional radiometals per biopolymer or small molecule and, thus, serve to enhance the signal. Id., col. 5, lines 17-20. Examples of synthetic polymers are said to include, but are not limited to, "polyethylene, polyacrylamide, polyurethane, polystyrene, polyethylene glycol, polybutadiene, polyvinyl alcohols and halides and copolymers thereof." Id., col. 6, lines 19-22.

3. Carden discloses a method of making a radioactive seed having a pre-determined radiation level for implantation into a tumor in a living body. Carden, col. 4, lines 26-30. The method is said to involve electroplating palladium 103 (Pd-103) onto at least one pellet of an electroconductive material made of carbon, usually in the form of graphite and aluminum. Id., col. 4, lines 26-49; col. 7, lines 3-11. The pellet is said

to be encapsulated with a shell of biocompatible material that is penetrable by X-rays in the 20-23 kev range, such as titanium. Id., col. 4, lines 47-49; col. 7, lines 38-40.

In order to fully capture the examiner's position in rejecting the claims before us, we reproduce the examiner's reasons as to why the invention would have been obvious to those having ordinary skill in the art, in its entirety. According to the examiner,

> Although Suthanthiran '896 may not specifically disclose a therapeutic source (and methods or [sic, of?] preparing or using thereof) comprising Pd-103 in the form of small radioactive particles, it would have been obvious to one of ordinary skill in the art to use Pd-103 as the radionuclide in the radioactive source (and methods of preparation thereof) disclosed by Suthanthiran '896 because Suthanthiran teaches Pd-103, which may be in particle form, as a possible radionuclide and Carden Jr. teaches that the use of a Pd-103 in a particle is valuable in radiotherapeutic seeds and provides the advantages of allowing the specific activity of Pd-103 to be adjusted and preventing free Pd-103 to be mobilized into the body fluids. Additionally, although Suthanthiran '896 may not specifically disclose a therapeutic source comprising a polyurethane polymeric matrix, it would have been obvious to one of ordinary skill in the art to use polyurethane in the therapeutic source (and methods of preparing and using thereof) because Suthanthiran '896 teaches that various known polymers may be used and Stavrianopoulos teaches that the synthetic polymers, such as polyurethane, provide the advantage of allowing numerous radiometals per polymer, resulting in a strong signal (e.g., or radiotherapeutic emission) being produced, thus optimizing methods of radiotherapy, etc. [Answer, pp. 7-8].

Here, we agree with the appellants (Brief, p. 4, para. 3) that it is not possible to ascertain from such a rejection how each of the claims, with their different limitations, are taught or suggested by the applied prior art. We acknowledge that the examiner

particles ranging in size, from about 1.0 microns to about 100 microns, which are randomly and essentially uniformly dispersed throughout a polymeric binding material"; (ii) Suthanthiran discloses that "the radioactive absorbing material is of a particulate form and may be in the size range of 1.0 to 100 microns"; (iii) "Suthanthiran '896 teaches that the binder materials are preferably polymeric matrices which are inherently, biocompatible, ... binder material, such as, polysaccharides, cellulose, etc. would meet the broad limitation of 'a biocompatible polymeric matrix'"; etc. Answer, pp. 5-6. However, such recitations, if not tied to reasons, do not constitute a prima facie case of obviousness. That is, the mere fact that a reference or references might teach different aspects of the claimed invention, does not render said invention obvious. Rather, it is the examiner's responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally available in the art would have led one of ordinary skill in the art to combine the various teachings of the reference(s) to arrive at the claimed invention. Pro-Mold & Tool Co. v. Great Lakes Plastics Inc., 745 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). Given the diverse subject matter of the claims before us, the burden is on the examiner to make such a showing for each of the claims and their respective limitations. This the examiner has not done.

emphasized in the examiner's rejection. See, the quote above from pages 7-8 of the Answer. We point out that claim 4 requires a radioactive composite consisting essentially of (i) a polymeric matrix which is biocompatible polymer; and (ii) a radioactive powder consisting essentially of radioactive particles of at least 0.002 microns wherein said particles are "randomly and essentially uniformly dispersed within said polymeric matrix." We find that the examiner's rejection fails to address these limitations.

Where is the rejection of claim 4? In the discussion of the various teachings of the references? In the response to the appellants' arguments?

In his discussion of the teachings of Suthanthiran we find that the examiner states that (i) the radioactive-absorbing material particles disclosed in the patent (col. 5, lines 4-8) would meet the limitation of the radioactive powder consisting essentially of microscopic radioactive particles at least 0.002 microns in average dimension randomly and essentially uniformly dispersed within the polymeric matrix required by part (b) of claim 4 (Answer, p. 5); and (ii) the binders taught in col. 4 of Suthanthiran, meet the limitation of part (a) (Answer, p. 5, pointing to col. 4, lines 19+, for support). However, as discussed above, various teachings of a reference which are not connected to reasons of obviousness, do not constitute a prima facie case of obviousness. We

obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984).

Moreover, even if we assume, arguendo, that the examiner had properly included the teachings of Suthanthiran with respect to the polymeric binder and radioactive particles in his reasons for finding the invention obvious, we would have found the argument unpersuasive for several reasons.

First, it is not clear whether the examiner intended the limitation of radioactive particles of at least 0.002 micron in average dimension (claim 4, part (b)) to be met by the teachings of Suthanthiran with respect to the combination of the radioactive material and the radioactive-absorbing particles that range in size from about 1.0 micron to about 100 microns,[4] or the radioactive-absorbing material particles alone. The examiner only refers to the radioactive-absorbing material particles, which do not satisfy the requirements of part (b) of claim 4.

Second, we do not find that Suthanthiran teaches that the binder can be material such as "polysaccharides, cellulose, etc." in the section of the patent relied upon by the

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[4] We find that in numerous locations in the Answer, the examiner states that the radioactive-absorbing material particles meet the limitation of part (b) of claim 4. We

examiner. Rather, we find that Suthanthiran teaches water insoluble binder materials include cellulose esters (col. 4, lines 37-50), and that the water-soluble binders can include materials which are water-soluble, such as disaccharides, polysaccharides, glycogen and inorganic compositions (col. 4, line 68- col. 5, line 3).

To that end, we do not agree that the binders disclosed by Suthanthiran are biocompatible polymers within the scope of representative claim 4. Answer, p. 5. As pointed out by the appellants, the specification clearly defines what is meant by this term. Attention is directed to page 7, lines 10-12, of the specification which states:

> the term "polymeric" means composed of organic polymers, including silicones, whether naturally occurring or synthetic, and whether homopolymers or copolymers;

and, to page 13, lines 21-25, which discloses that biocompatible means that the polymer is "chemically inert in bodily fluids and evokes no toxic response when released into the body." Attention is further directed to Tables 1 and 2 of the specification which are said to list some suitable, biocompatible materials. Specification, p. 9, lines 1-4 and pp. 47-48. The examiner has not provided any evidence to support his finding that Suthanthiran teaches the use of a binder material which is a polymeric matrix wherein said matrix is a biocompatible polymer. The examiner is cautioned that a prima facie case of obviousness must be based on fact, not unsupported generalities. In re Freed,

we would have found an obviousness rejection based only on the teachings of Suthanthiran to be unsustainable. Moreover, if we go a step further and assume, arguendo, that the examiner intended that it would have been obvious for one of ordinary skill in the art to substitute the binder material taught by Suthanthiran with the polyurethane disclosed by Stavrianopoulos to satisfy the requirement of a polymeric matrix which is a biocompatible polymer (claim 4(a)), which we do not,[5] we would still find no teaching or suggestion in either reference which would have motivated such persons to arrive at the appellants' invention. First, the examiner has not provided any reasons as to why one of ordinary skill would have selected polyurethane from the numerous synthetic polymers taught by Stavrianopoulos. See, Stavrianopoulos, col. 6, lines 12-26.

Second, contrary to the examiner's argument, we do not find that the references are in the same field of endeavor. Answer, p. 7. Stavrianopoulos teaches the labeling of biopolymers or small molecules, such as polynucleotides, polysaccharides or polypeptides with metal chelating groups or biotin. As discussed above, such biopolymers are not biocompatible polymers within the meaning of the appellants' invention. In addition, although the examiner contends that it would have been obvious to use the polyurethane in the "therapeutic source" disclosed by Suthanthiran, to

polyurethane is to be used. Answer, pp. 7-8. That is, is the polyurethane to be used in addition to the radioactive-absorbing material particles and the binder materials, or is it to replace one of said materials? Surprisingly, in the response to the appellants' arguments with respect to claim 4,[6] the examiner provides some guidance in this regard. There, we find that the examiner argues that the polyurethane may be used as the polymeric binding material.[7] Answer, p. 14. We point out, however, that Suthanthiran discloses that the binding material is that which binds the radioactive-absorbing material particles to the substrate/marker. Thus, as we understand the examiner's position, he is urging that the combination of references would have suggested a radioactive composite which comprises polyurethane and the radioactive-absorbing material (which, preferably, is a polyamino acid), but not necessarily the radioactive material. Not only does this model does not satisfy the limits of any claim, but it is not realistic since the examiner has not established that the polyurethane "binder" could absorb the radioactive-absorbing material particles and bind said material to the metal substrate/marker. The latter is necessary otherwise there is no reason to employ polyurethane in the radioactive seed taught by Suthanthiran.

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[6] See our comments in footnote 3.

Nor is the examiner's position consistent with the teachings of Stavrianopoulos which teaches that the synthetic polymers are attached to the biomolecules because their reactive group is capable of binding additional metal chelating groups or biotin to said biomolecules. In other words, the use of the synthetic polymers taught by Stavrianopoulos as binders is to bind the metal chelating agents to a biomolecule. The binding material taught by Suthanthiran is to bind the radioactive-absorbing material to a metal substrate or marker. Thus, the "binders" of the two patents are not analogous. Therefore, they are not, as the examiner suggests, interchangeable.

Since we find that the examiner has failed to establish a prima facie case of obviousness with respect to the limitations required by independent claim 4, based on the shortcomings of the primary reference Suthanthiran, it reasonably follows that we cannot sustain the rejection with respect to the remaining dependent composition and method claims, each of which contains the limitations of claim 4. Moreover, we point out that the examiner's has given them [the method claims] only cursory mention in the rejection and has not addressed any of the limitations recited therein.[8]

In view of the foregoing, we agree with the appellants that the rejection falls into

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[8] To the extent that the examiner intends his comments on pages 19-21 of the

the category of what is commonly known as hindsight reconstruction of the claimed invention, wherein the appellants' invention is used as a template and elements from the references are selected to fill in the gaps. Such hindsight reconstruction of the appellants' invention is impermissible. In re Gorman, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher").

Accordingly, the rejection is reversed.

REVERSED

JOAN ELLIS)
Administrative Patent Judge)

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Appeal No. 2000-1775
Application 08/563,087

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