

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Box Interference

Paper No. 73

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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DAVID WALLACH and CORD BRAKEBUSCH,  
Junior Party,<sup>1</sup>

v.

CRAIG A. SMITH,  
Senior Party,<sup>2</sup>

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Patent Interference No. 103,854

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HEARD: July 25, 2000

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CAROFF, DOWNEY, and ELLIS, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

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<sup>1</sup> Application 07/925,687, filed August 7, 1992, now Patent No. 5,478,925, issued December 26, 1995. Accorded Benefit of Israel, Serial No. 99120, filed August 7, 1991. Assignor to Yeda Research and Development Co., Ltd.

<sup>2</sup> Application 08/406,824, filed March 20, 1995. Accorded Benefit of Application 08/255,849, filed June 8, 1994; Application 07/860,710, filed March 30, 1992, all abandoned; and Application 07/523,635, filed May 10, 1990, now Patent No. 5,395,760, issued March 7, 1995.

FINAL DECISION

On February 8, 1999, Wallach filed a preliminary motion pursuant to 37 C.F.R. § 1.633(c)(4) to designate claims 3, 6, and 7 of U.S. Patent No. 5,478,925 as not corresponding to the count.<sup>3</sup> Paper No. 53. The motion stands unopposed.

The APJ denied the motion and ordered Wallach to show cause why judgment on the record should not be entered against them in view of the fact that junior party Wallach failed to file a preliminary statement. Paper Nos. 57 and 59.

In response to the order, Wallach filed a request for testimony (Paper No. 61) and a request for final hearing (Paper No. 60). The APJ granted these requests. Paper No. 62.

Final Hearing was held on July 25, 2000.

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<sup>3</sup> Wallach's claims 1, 3, 6 and 7 read as follows:

1. A multimer having the ability to interfere with the binding of tumor necrosis factor to its receptors and to block the effects of tumor necrosis factor, wherein said multimer comprises two or more monomers, each said monomer consisting of a soluble form of a tumor necrosis factor receptor or a salt thereof.

3. A multimer in accordance with claim 1 in trimeric form.

6. A multimer in accordance with claim 1, wherein said monomers include at least one monomer having an amino acid sequence corresponding to that of tumor necrosis factor binding protein-I and at least one monomer having an amino acid sequence corresponding to that of tumor necrosis factor binding protein-II.

7. A multimer in accordance with claim 1 said multimer being encapsulated in a liposome.

The issues presented for decision are:

1. Does Wallach claim 3 define the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute?<sup>4</sup>
2. Does Wallach claim 6 define the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute?
3. Does Wallach claim 7 define the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute?

Upon de novo review of the motion and careful consideration of the arguments and evidence before us, the motion is DENIED. Our reasons follow.

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<sup>4</sup> Count 2, the sole count in the interference, reads as follows:

2. A multimer in accordance with Claim 1 of Wallach et al., U.S. Patent 5,478,925

or

A multimer in accordance with Claim 39 of Smith, U.S. Patent Application Ser. No. 08/406,824

or

A DNA molecule in accordance with Claims 15 or 18 of Smith, U.S. Patent Application Ser. No. 08/406,824

or

A fusion protein in accordance with Claims 27 and 33 of Smith, U.S. Patent Application Ser. No. 08/406,824.

Burden of Proof

In a motion which seeks to designate a claim as not corresponding to the count, the burden is on the moving party to show, by a preponderance of the evidence,

that the claim does not define the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute [37 C.F.R. § 1.637(c)(4)(ii)].

In interference proceedings, the same patentable invention is defined by 37 C.F.R.

§ 1.601(n) as:

Invention "A" is the same patentable invention as an invention B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

In the case before us, Wallach moves to designate claims 3, 6 and 7 of their U.S. Patent 5,478,925, as not corresponding to the count. Thus, Wallach must show that the subject matter of the referenced claims is not the same as, or obvious in view of, those claims which they agree correspond to the count. Here, the burden is on Wallach to establish that the species described in claims 3 and 6 would not have been obvious in view of the genus of multimers encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count. In addition, Wallach must establish that the multimer being encapsulated by a liposome (claim 7), would not have been obvious to one of ordinary skill in the art in view of the multimer described in Smith claim 39 and Wallach claim 1, corresponding to the count in combination with Utsumi.<sup>5</sup>

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<sup>5</sup> Utsumi, et al. (Utsumi), "Preparation and Characterization of Liposomal-Lipophilic Tumor Necrosis Factor," Cancer Research, Vol. 51, pp. 3362-366 (1991).

Claim 3

As indicated above, claim 3 of the Wallach patent is directed to a trimer which comprises three (3) monomers consisting of a soluble form of any tumor necrosis factor (TNF) receptor (a.k.a., a TBP (tumor necrosis factor binding protein) trimer).

Wallach in effect acknowledges that the claimed trimer would have been prima facie obvious to one of ordinary skill in the art in view of the multimers described in Smith claim 39 and Wallach claim 1, corresponding to the count. Brief, p. 15, last para.<sup>6</sup> Thus, in order to meet their burden of establishing that the TBP trimer described in claim 3 is patentably distinct from other members of the genus of multimers encompassed by the claims corresponding to the count, Wallach urges that an unexpected result is obtained by using the trimer, as opposed to other species of the referenced genus. To that end, Wallach argues that at the time the invention was made, one of ordinary skill in the art would have had no reason to expect that TBP trimers would have “superior properties” to TBP dimers. Brief, sentence bridging pp. 16-17. According to Wallach, their patent and a publication by Peppel<sup>7</sup> “provide evidence which creates the expectation that the TBP trimer is a superior TNF antagonist to a TBP dimer.” Id., p. 17. For support, Wallach points to the disclosure in their patent that the TNF receptors (TNF-Rs) exist in aggregated form in cells exposed to TNF. Id. Wallach contends that from this discovery the inventors realized that “multimers of the soluble form of TNF-Rs would be more effective than

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<sup>6</sup> Also, at oral hearing on July 25, 2000, counsel for Wallach acknowledged that because the TBP trimer of claim 3 is a species which falls within the genus of multimers set forth in Smith claim 39 and Wallach claim 1, the species would have been prima facie obvious in view of the referenced genus.

<sup>7</sup> Peppel et al. (Peppel) “A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity,” J. Exp. Med., Vol. 174, pp. 1483-89 (1991).

monomers in inhibiting TNF activity at lower doses, since they can effectively compete with the TNF trimers for the binding sites on the aggregates of the cell surface TNF-Rs.” Id. In addition, Wallach points to Peppel which is said to disclose that TBP dimers have greater TNF inhibitory activity than TBP monomers. Peppel is further said to “theorize” that the TBP dimer blocks two of the three potential receptor binding sites of the TNF trimer. Id.

Wallach concludes that

Knowing these results of Peppel, and in light of the disclosure of Wallach, those of ordinary skill in the art would expect that a TBP trimer is significantly superior to a TBP dimer as it is able to block all three monomers of the TNF trimer, which is known to be the active form of TNF. Thus, just as Peppel proved that a TBP dimer has superior properties to TBP monomers, so one would believe from reading Peppel, in view of his reference to the binding by the TBP dimer to two of the three binding domains of TNF, that one would achieve even better TNF inhibitory activity by providing a TBP trimer which combines to all three binding sites of TNF. ... Thus, even if the genus of Wallach claim 1 and Smith claim 39 were available as prior art, the trimer of Wallach claim 3 would be patentable thereover in view of these unexpected properties [emphases added]. Brief, pp. 17-18.

We find these arguments unconvincing.

In our view, Wallach is relying on the Peppel publication as a substitute for expert testimony. That is, Wallach alleges that Peppel discloses a specific “fact” (i.e., that TBP dimers have greater TNF inhibitory activity than monomers) and based on this “fact,” one of ordinary skill in the art would have expected a TBP trimer to have “significantly superior” activity compared to the TBP dimer. However, Wallach has not provided any objective evidence, such as expert testimony, to explain (i) the contents of the Peppel publication, and (ii) what one of ordinary skill in the art would have expected with respect to the TNF inhibitory activity of a TBP trimer based on the contents of the Peppel publication. Nor has Wallach provided any evidence of a difference between the TNF inhibitory activity of TBP trimers and TBP dimers, TBP tetramers, or any other multimer encompassed by Smith claim 39 and Wallach claim 1,

corresponding to the count. Rather, on this record, all we have are arguments of counsel as to what Peppel discloses and what one of ordinary skill in the art would have expected from reading the publication. It is well established that such arguments cannot take the place of objective evidence and, thus, we accord them little evidentiary weight. In re Payne, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979); Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA), cert. denied, 434 U.S. 854 (1977); In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence”). Accordingly, we do not find Wallach’s specification, the Peppel publication and arguments of counsel sufficient to establish that TBP trimers have “significantly superior” TNF inhibitory activity compared to TBP dimers, TBP tetramers or any other multimer encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count.

Wallach contends that the statements in the brief are based on documentary evidence. Brief, pp. 20-21. Wallach argues that the disclosure in their specification “that TNF-Rs exist in aggregated form in cells exposed to TNF is supported by the experimentation in example 1 of the ... patent. This is physical evidence and not mere attorney argument.” Id., sentence bridging pp. 20-21. Wallach further contends that “[t]he data and statements of Peppel are evidence properly of record in this case and not mere attorney argument.” Id., sentence bridging pp. 21-22. We find these arguments misdirected.

Even if we assume, arguendo, that Wallach’s statements that (i) the disclosure in the specification that TNF-Rs exist in aggregated form in cells exposed to TNF, and (ii) Peppel demonstrates an increase in the effectiveness of TBP dimers compared to TBP monomers, are “facts,” the burden rests with Wallach to provide objective evidence as to what one of ordinary skill in the art would have expected based on these alleged facts. This has not been done.

These so-called “facts,” standing alone, do not demonstrate what one of ordinary skill in the art would have believed or expected with respect to the TNF binding activity of TBP trimers compared to other TBP multimers at the time the application was filed. Nor do these “facts,” standing alone, demonstrate “superior results” for the TBP trimer compared to the TBP dimer, TBP tetramer, or any other multimer encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count. It is only attorney argument which makes the conclusions presented in the brief, and such argument lacks probative value. In re Payne, 606 F.2d at 315, 203 USPQ at 256; Meitzner v. Mindick, 549 F.2d at 782, 193 USPQ at 22; In re Pearson, 494 F.2d at 1405, 181 USPQ at 646.

Wallach argues that senior party Smith does not dispute “any of the statements of material fact set forth in the Wallach preliminary motion, and therefore they may be taken as conceded.” Brief, pp. 20 and 34. We find this argument unconvincing.

Smith’s failure to oppose Wallach’s preliminary motion does not relieve the moving party of its burden of proving its case. In the case before us, the burden is on Wallach, the movant, to prove, by a preponderance of the evidence, that TBP trimers show unexpected results compared to other members of the genus of multimers described in Smith claim 39 and Wallach claim 1, corresponding to the count. 37 C.F.R. § 1.637(a). Here, as discussed above, we do not find that Wallach has met that burden. Nor does the failure of a party to oppose a motion mean that the statements therein are correct. To the contrary, the record here shows that in the settlement agreement between the parties, Smith agreed not to oppose Wallach’s preliminary motion. Paper No. 49, p. 2; Paper No. 53, p. 2. We point out that such agreements do not constitute a concession which is binding on the PTO.

Claim 6

Claim 6 is directed to a multimer which comprises at least one monomer having the amino acid sequence of TBP-I and at least one monomer having the amino acid sequence of TBP-II. Wallach refers to this type of multimer as a heteromultimer. A multimer wherein all the monomers are the same is referred to as a homomultimer. Brief, p. 29, footnote 16.

Wallach in effect acknowledges that the heteromultimers described in claim 6 would have been prima facie obvious to one of ordinary skill in the art since they are species within the genus of multimers encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count. Brief, p. 28, para. 2. However, Wallach contends that if Smith claim 39 or Wallach claim 1 were available as prior art, they would not have rendered obvious the heteromultimer described in Wallach claim 6 because the referenced claims 39 and 1 are “silent as to the nature of the TBP monomers.” Brief, p. 29. That is, according to Wallach, “one of ordinary skill in the art would [have] assume[d]” that the properties of the heteromultimer would be identical to the properties of the homomultimer, at the time the invention was made [emphasis added]. Id. Wallach points to a publication by Pinckard<sup>8</sup> and argues that based on the teachings of this reference, it is now known that

TNF induces the formation of heterocomplexes consisting of both p55 and p75 TNF receptors. This finding suggests that TBP-I and TBP-II bind to different portions of the TNF molecule, thereby creating the expectation that a heteromultimer will behave differently from a homomultimer. Indeed, one of ordinary skill in the art would expect from Pinckard that a heteromultimer will bind with greater affinity to TNF than a homomultimer. ... From a reading of Pinckard, it would be expected that the heteromultimer will have properties different from, and superior to, a homomultimer, which properties would not have been obvious to one of ordinary skill in the art at the time the present invention was made [emphases added]. Brief, pp. 29-30.

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<sup>8</sup> Pinckard et al. (Pinckard) “Ligand-Induced Formation of p55 and p75 Tumor Necrosis Factor Receptor Heterocomplexes on Intact Cells,” J. Bio. Chem., Vol. 272, pp. 10784-789 (1997).

We disagree. Here, we have the same problem with the so-called “facts” as we did with claim 3. Wallach is relying on a reference which was published six (6) years after the filing date of their application. Wallach has not provided any objective evidence as to what one of ordinary skill in the art would have expected at the time their application was filed. Nor has Wallach provided any objective evidence of an unexpected result for the claimed heteromultimers as compared to the homomultimers encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count. On this record, we have only attorney argument. As discussed above, arguments of counsel cannot take the place of objective evidence. In re Payne, 606 F.2d at 315, 203 USPQ at 256; Meitzner v. Mindick, 549 F.2d at 782, 17 USPQ at 22; In re Pearson, 494 F.2d at 1405, 181 USPQ at 646.

Wallach argues that they have provided physical evidence by means of the Pinckard publication that “TNF is capable of concomitantly interacting with p55 and p75” and, thus, their position does not rest on mere attorney argument. Brief, p. 34. We disagree.

Even if we assume, arguendo, that Pinckard’s disclosure that cultured and primary murine cells exposed to murine TNF are capable of concomitantly interacting with p55 and p75, is a “fact,”<sup>9</sup> we do not find that a “fact,” which was disclosed six years after the filing date of the Wallach specification, provides evidence as to what one of ordinary skill in the art would have expected with respect to TBP heterodimers at the time the invention was made. Moreover, we do not find that this “fact,” standing alone, demonstrates superior TNF binding activity for the

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<sup>9</sup> We point out that Wallach is relying on Pinckard’s disclosure with respect to the response exhibited by specific murine cells; i.e., cultured and primary murine cells which have been exposed to murine TNF. Untreated and human TNF-treated cells did not interact simultaneously with both p55 and p75. Since claim 6 is not directed to the murine cells described by Pinckard, it does not appear that Wallach’s arguments address a limitation present in claim 6.

heteromultimer as compared to the homomultimers encompassed by Smith claim 39 and Wallach claim 1, corresponding to the count. Again, it is only attorney argument which makes the conclusions presented in the brief, and we accord such argument little evidentiary weight. In re Payne, 606 F.2d at 315, 203 USPQ at 256; Meitzner v. Mindick, 549 F.2d at 782, 17 USPQ at 22; In re Pearson, 494 F.2d at 1405, 181 USPQ at 646.

### Claim 7

Claim 7 is directed to multimers of claim 1 wherein said multimers are “encapsulated in a liposome.” Wallach argues that because the claim “reads on a plurality of TBP monomers expressed on the surface of a liposome,” it is neither anticipated nor rendered obvious by Smith claim 39 or Wallach claim 1, corresponding to the count. Brief, p. 37. Wallach acknowledges the examiner’s position in the statement under 37 C.F.R. § 1.609(b), attached to the Interference Initial Memorandum, that it would have been obvious to one of ordinary skill in the art to formulate a TNF-R multimer in any pharmaceutical delivery vehicle known in the art, and that such delivery vehicles included liposomes as evinced by the Utsumi publication. However, Wallach urges that Utsumi discloses the use of liposomes to deliver TNF, but that there was no disclosure as to their use with TBPs. Brief, p. 38.

Wallach further argues that there is no suggestion in Utsumi of whether TBP multimers

would show affinity for liposomes. Brief, p. 39. Wallach contends that “Utsumi does not provide a reasonable expectation of success and a prima facie case of obviousness has not been made out for the liposomes vis-à-vis the multimers of claim 1.” Id., sentence bridging pp. 39-40. We find Wallach’s position untenable.

In the Decision on Motion (Paper No. 57), the APJ denied the preliminary motion with respect to claim 7 pointing out that said claim is not limited to TBP monomers expressed on the surface of a liposome or bound thereto but, rather, it is directed to a multimer which is “encapsulated in a liposome.” Paper No. 57, p. 4.

With respect to the term “encapsulated” Wallach contends that the claim must be interpreted in light of the specification. Brief, p. 39. Wallach points to col. 10, lines 12-24, of the specification which is said to disclose “that a multimer can be made by indirectly linking the monomers by being expressed on the surface of liposomes.” Id. Wallach argues that “[t]his is what was intended by the language of claim 7.” Id.

Given the polemics over the language of claim 7, we must first decide the meaning and scope of the claim before we can determine whether the subject matter would have been obvious in view of the teachings of Utsumi.

As a preliminary matter, we point out that litigation-derived testimony of an inventor and his attorney concerning claim construction is entitled to little or no probative value. Solomon v. Kimberly-Clark Corp., 2000 U.S. App. LEXIS 15317, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000)(“The testimony of an inventor is often self-serving, after-the-fact attempt to state what should have been part of his or her patent application... .”) Solomon v. Kimberly-Clark Corp., 2000 U.S. App. LEXIS 15317, 55 USPQ2d at 1283, quoting Bell & Howell Document Management Prods. v. Altek Sys., 132 F.3d 701, 706, 45 USPQ2d 1033, 1038 (Fed. Cir.

1997). See also, Roton Barrier Inc. v. The Stanley Works, 79 F.3d 1112, 1126, 37 USPQ2d 1816, 1826 (Fed. Cir. 1996) (“We have previously stated that an inventor’s ‘after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself.’”) The court has stated that the reason the inventor is not competent to construe claims after a patent has been granted is because

[C]ommonly the claims are drafted by the inventor’s patent solicitor and they may even be drafted by the patent examiner in an examiner’s amendment (subject to the approval of the inventor’s solicitor). While presumably the inventor has approved any changes to the claim scope that have occurred via amendment during the prosecution process, it is not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO. Solomon v. Kimberly-Clark Corp., 2000 U.S. App. LEXIS 15317, 55 USPQ2d at 1283-84, quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 985, 34 USPQ2d 1321, 1335 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370, 38 USPQ2d 1461 (1996).

Thus, in construing a claim we must look to the “claims, the written description, and, if in evidence, the prosecution history.” Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 976-77, 52 USPQ2d 1109, 1111 (Fed. Cir. 1999).

We turn first to the words of the claim itself. Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619-20, 34 USPQ2d 1816, 1819 (Fed. Cir. 1995). To that end, we point out that the words used in the claims are given their ordinary and accustomed meaning unless it appears from the patent and the file history that the terms were used differently by the inventors. Intellicall Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387-88, 21 USPQ2d 1386-87 (Fed. Cir. 1992). Here, when we turn to the dictionary for the ordinary and accustomed meaning of the term “encapsulated” we find that it means “enclosed by a protective coating or membrane.”<sup>10</sup> However, when we look to the portion of the specification relied upon

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<sup>10</sup> Websters II, New Riverside University Dictionary, The Riverside Publishing Co. (1988), p. 429.

by Wallach (col. 10, lines 12-24) to understand the meaning of the phrase “encapsulated in a liposome,” and to ascertain whether the term “encapsulated” was employed in its ordinary sense, or used differently by the inventors, we do not find any reference to the contested term. Thus, we do not find any definition or written description of “encapsulated” which corresponds to the dictionary meaning of the term, or otherwise, in Wallach’s specification. Accordingly, in the case before us, we do not find that reading the specification helps to resolve the issue of what the inventors intended by the meaning of the phrase “encapsulated in a liposome.”

In turning to the prosecution history, however, we find what appears to be the origin of the problematic claim language. Claims 4 and 26 of the original Wallach specification were directed to a multimer comprising a liposome. The examiner rejected these claims as being indefinite under 35 U.S.C. § 112, second paragraph. Paper No. 9, p. 5. In so doing, the examiner stated that she “interpreted these claims to mean the encapsulation of TNF-R multimers in liposomes for examining purposes” [emphasis added]. Id. In addition, the examiner rejected the claims over two references, one of which (Allen, U.S. Patent 4,837,028, issued Jun. 6, 1989) was said to describe the encapsulation of a pharmaceutical agent within a liposome in order to preserve its half-life in the blood stream and to reduce any toxic side effects [emphases added]. Id., p. 7. The examiner concluded that “it would have been obvious to one of ordinary skill in the art that TNF-BP multimers could be placed within liposomes to increase their half-life and reduce their possible side effects because the primary references teach that TNF-BPs bind TNF to prevent its activity while the remaining references teaches [sic, teach] the use of liposomes to administer agents such as TNF to retain activity, increase half life, and reduce side effects” [emphasis added]. Id. In response to these rejections, Wallach did not object to the examiner’s statements. Rather, they amended the claims to include the phrase

“encapsulated in a liposome.”<sup>11</sup> Paper Nos. 10 and 13.

Thus, from the prosecution history, we find that the phrase “encapsulated in a liposome” was used by the examiner in concordance with the ordinary and accustomed meaning of the term “encapsulated.” That is, the examiner understood the claims as being directed to multimers that were within or enclosed by a liposome. Since this term was adopted by Wallach without question, we must presume that they also adopted the examiner’s meaning thereof. Accordingly, we find that claim 7 is directed to TBP multimers which are enclosed by the liposomal membrane.

The problem now is that by amending the claim(s) to include the controversial phrase, Wallach, inadvertently or not, changed their scope. As a result, Wallach’s amendment, inadvertently or not, resulted in a claim which lacks written descriptive support in the specification as required by 35 U.S.C. § 112, first paragraph. In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981)(“The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, ... is § 112, first paragraph...”). Wallach is reminded that “[t]he purpose of this provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000). Accordingly, we do not find that Wallach’s arguments address a limitation present in claim 7.

Having concluded that claim 7 is directed to a multimer which is enclosed by a liposome, we now turn to the issue of whether said multimer would have been obvious to one of ordinary

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<sup>11</sup> Wallach deleted claim 26 by amendment in Paper No. 13, p. 2. The numbering of claim 4 was changed to claim 7 when the Wallach application issued as a patent.

skill in the art in view of the multimers set forth in Smith claim 39 and Wallach claim 1, corresponding to the count, in combination with the teachings of Utsumi. To that end, we find that Utsumi discloses that liposomes are useful as nontoxic carriers of pharmaceutical agents, in general, and that they are particularly suitable for hydrophobic drugs. Utsumi, p. 3362, col. 1, last para. Utsumi further discloses that the encapsulation of said pharmaceutical agents results in reduced toxicity and may help to target the drugs to certain organs. Id. Thus, we agree with the examiner that it would have been obvious to one of ordinary skill in the art to encapsulate a pharmaceutical agent such as a TBP multimer in a liposome in order to reduce toxicity, retain activity, and increase the half-life of said multimer.

Moreover, assuming, arguendo, that we agreed with Wallach that one of ordinary skill in the art would have understood that claim 7 is directed to a TBP multimer comprising monomers which are directly or indirectly linked to the surface of liposomes,<sup>12</sup> we would nevertheless hold that it would have been obvious to anchor a TNF-R multimer to the

surface of a liposome in view of the teachings of Utsumi. As we discussed above, Utsumi discloses that liposomes are useful as nontoxic carriers of pharmaceutical agents, in general, and that they are particularly suitable for hydrophobic drugs. Utsumi, p. 3362, col. 1, last para. Utsumi further discloses that the pharmaceutical agent, TNF, can be anchored to the liposome surface via its amino-terminus because “this is akin to the orientation of the transmembrane prohormone on the effector cell surface.” Id., p. 3365, col. 2, lines 3-6. Since a TBP multimer which comprises two or more monomers is open to the inclusion of the transmembrane portion

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<sup>12</sup> Brief, p. 39, lines 7-9 and footnote 22, referring to para. 19 of the Statement of Facts.

of the monomer (see Figure 2 of the Wallach specification), we hold that it would have been obvious to anchor said multimer to the surface of a liposome in the manner suggested by Utsumi.

With respect to Wallach's argument as to whether TBP multimers would show affinity for liposomes,<sup>13</sup> we point out that Utsumi teaches that liposomes are useful as carriers for any pharmaceutical agent. That they may be more suitable for hydrophobic drugs does not preclude their use for drugs of low hydrophobicity.

In addition, we point out that Wallach's claimed multimer comprises two or more monomers wherein each monomer consists of a soluble form of TNF-R, or a salt thereof. See claims 1 and 7. It is well established that the use of the term "comprises" in a claim, opens the claim to the inclusion of additional components. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986), cert. denied, 479 U.S. 1030 (1987); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981). Here, we find that claim 7 is open to the inclusion of the hydrophobic transmembrane and intracellular regions, or fragments thereof, of the TNF-R. Therefore, it is reasonable to conclude that the multimers encompassed by claim 7 could be readily anchored to the surface of a liposome as taught by Utsumi. Utsumi, p. 3365, col. 2, lines 3-7. Accordingly, contrary to Wallach's argument, we find that one of ordinary skill in the art would have had a reasonable expectation that the multimers described in Smith claim 39 and Wallach claim 1, corresponding to the count, could be successfully incorporated into a liposome formulation.

Accordingly, the motion is DENIED.

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<sup>13</sup> Brief, p. 39.

JUDGMENT

In view of the foregoing, judgment is entered against DAVID WALLACH and CORD BRAKEBUSCH, the junior party, who are not entitled to their U.S. Patent 5,478,925, containing claims 1 through 7, corresponding to the count.

On this record, judgment is entered in favor of CRAIG A. SMITH, the senior party, who is entitled to a patent containing claims 15 through 22 and 27 through 39, corresponding to the count.

MARC L. CAROFF )  
Administrative Patent Judge )  
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MARY F. DOWNEY ) BOARD OF PATENT  
Administrative Patent Judge ) APPEALS AND  
) INTERFERENCES  
)  
)  
JOAN ELLIS )  
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