

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 71

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte LAWRENCE E. D'ANTONIO

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Appeal No. 1998-1987  
Application No. 07/915,783

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HEARD July 24, 2001

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Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.  
GRIMES, 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 11-16, 18, 27, 29, 68-80, 84-88, and 90-100.<sup>1</sup> Claims 68, 18, and 84 are representative and read as follows:

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<sup>1</sup> Although the file record is somewhat unclear as to the status of some of the claims, Appellant and the examiner agree that claims 1-9, 20-22, 28, 31-33, 38, 39, 52, 60, and 62-67 were withdrawn from consideration following a restriction requirement. See the Appeal Brief, page 1, and the Examiner's Answer, page 2 ("The statement of the status of claims contained in the brief is now correct."). In addition, Appellant withdrew his appeal of claims 81-83. See the "Partial Withdrawal of Appeal" attached to Paper No. 55, filed October 31, 1997. Therefore, the appeal with respect to claims 81-83 is dismissed.

68. A water-insoluble composition having the characteristic of inducing in animals immunological reactivity to plasmodial parasites, said composition comprising recovered parasite antigenic factor(s) selected from the group consisting of intact starting plasmodial parasites released from a quantity of red blood cells, intact red blood cells containing a blood stage of said starting plasmodial parasite, merozoites which released themselves from red blood cells, tissues having blood infected with said starting plasmodial parasite, and tissues having starting plasmodial parasite infected blood, said group being treated as follows:
- a) forming a suspension in water of said intact starting plasmodial parasite released from a quantity of red blood cells, intact red blood cells containing the blood stage of the starting plasmodial parasite, merozoites which released themselves from red blood cells, tissue having blood with said starting plasmodial parasite, and tissues having starting plasmodial parasite infected blood, which together contain said antigenic factor(s), form an aqueous medium;
  - b) adding a non-ionic detergent to the suspension to disperse the antigenic factor(s); and
  - c) separating and recovering the antigenic factor(s) from the aqueous medium.
18. The composition of Claim 68, wherein the detergent is selected from the group consisting of MEGA-9, n-heptyl -D-thioglucoside, Triton X-100 and Nonident P-40.
84. A process for making a composition comprising recovered parasite antigenic factor(s), said process comprising:
- a) forming a suspension in an aqueous medium of at least one of the following: (i) intact plasmodial parasite released from a quantity of red blood cells, (ii) intact red blood cells containing the blood stage of the plasmodial parasite, (iii) merozoites which released themselves from red blood cells, (iv) tissues having blood infected with said plasmodial parasite, and (v) tissues having plasmodial parasite infected blood, said suspension having said antigenic factor(s)

- said antigenic factors being insoluble in the aqueous medium;
- b) adding a non-ionic detergent to the suspension to disperse the antigenic, insoluble factor(s);
  - c) separating the dispersed antigenic, insoluble factors from the non-ionic detergent; and
  - d) recovering said dispersed antigenic, insoluble factor(s).

The examiner relies on the following references:

D'Antonio 4,859,464 Aug. 22, 1989

Ludford et al. (Ludford), "Babesia argentina, plasmodium vivax and P. falciparum: Antigenic cross-reactions," Experimental Parasitology, Vol. 32, pp. 317-326 (1972)

Schmidt-Ullrich et al. (Schmidt-Ullrich), "Plasmodium knowlesi-induced antigens in membranes of parasitized rhesus monkey erythrocytes," Proc. Natl. Acad. Sci., Vol. 75, No. 10, pp.4949-4953 (1978)

Kilejian, "Stage-specific proteins and glycoproteins of Plasmodium falciparum: Identification of antigens unique to schizonts and merozoites," Proc. Natl. Acad. Sci., Vol. 77, No. 6, pp. 3695-3699 (1980)

Epstein et al. (Epstein), "Monoclonal antibodies against a specific surface determinant on malarial (Plasmodium knowlesi) merozoites block erythrocyte invasion," Journal of Immunology, Vol. 127, No. 1, pp. 212-217 (1981)

Newbold et al. (Newbold), "Identification of a schizont- and species- specific surface glycoprotein on erythrocytes infected with rodent malarias," Molecular and Biochemical Parasitology, Vol. 5, pp. 45-54 (1982)

Howard et al. (Howard), "Solubilization and immunoprecipitation of <sup>125</sup>I-labelled antigens from Plasmodium knowlesi schizont-infected erythrocytes using non-ionic, anionic and zwitterionic detergents," Parasitology, Vol. 88, pp. 27-36 (1984)

Perrin et al. (Perrin), "Malaria : immunity, vaccination and immunodiagnosis," Experientia, Vol. 40, pp. 1343-1350 (1984)

Butcher, "Mechanisms of immunity to malaria and the possibilities of a blood-stage vaccine: a critical appraisal," Parasitology, Vol. 98, pp. 315-327 (1989)

Mitchell, "An update on candidate malaria vaccines," Parasitology, Vol. 98, pp. 829-847 (1989)

Claims 11-16, 18, 27, 29, 68-80, 84-88, and 90-100 stand rejected under the judicially created doctrine of obviousness-type double patenting.

Claims 11-16, 18, 27, 29, and 68-80 stand rejected under 35 U.S.C. § 112, first paragraph, as unsupported by an enabling disclosure.

Claims 11-16, 18, 27, 29, 68-80, 84-88, and 90-100 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled throughout their full scope.

Claims 11-16, 18, 27, 29, and 68-80 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively under 35 U.S.C. § 103 as obvious over, either of Schmidt-Ullrich or Kilejian.

Claims 11-16, 18, 27, 29, and 68-80 stand rejected under 35 U.S.C. § 102(a) as anticipated by, or alternatively under 35 U.S.C. § 103 as obvious over, Epstein.

Claims 18 and 68 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively under 35 U.S.C. § 103 as obvious over, any one of Howard, Newbold, or Epstein.

Claims 84–88 and 90-100 stand rejected under 35 U.S.C. § 103 as obvious over either of Schmidt-Ullrich or Kilejian.

We affirm the obviousness-type double patenting rejection and all of the §§ 102/103 rejections. We reverse both rejections for nonenablement, as well as the rejection based solely on § 103.

### Background

The specification discloses a method for solubilizing and recovering antigens from protozoan parasites such as malaria-causing Plasmodium species. In the disclosed method, parasite-containing material (e.g., parasite-infected blood or tissue) is suspended in an aqueous solution and detergent is added. Specification, pages 5-6. The detergent solubilizes the parasite antigens so that they can be isolated from residual materials. The specification states that the antigen-containing compositions produced by the disclosed method are potentially useful as vaccines or as diagnostic agents. Id., page 3.

### Discussion

The claims are directed to compositions comprising plasmodial antigens, and methods of making and using such compositions. Appellant indicates that all of the claims stand or fall with claim 68, with respect to most of the rejections, or with claim 84, with respect to the rejection based solely on 35 U.S.C. § 103. See the Appeal Brief, pages 7-9. We therefore limit our analysis to these claims.

#### 1. The obviousness-type double patenting rejection.

Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. It requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later.

In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998) (citation omitted). “Without a patentable distinction—because the pending claim defines merely an obvious variation of the patented claim—the patentee may overcome the double patenting rejection by filing a terminal disclaimer.” In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993). “[W]ithout a terminal disclaimer, the [previously issued] species claims preclude issuance of the generic application.” Id.

The examiner rejected all of the claims on appeal as unpatentable over claims 1-15 of Appellant’s U.S. Patent 4,859,464. The claims of the ‘464 patent are directed to, inter alia, compositions comprising plasmodial antigens derived by solubilization with the non-ionic detergent n-octyl- $\beta$ -D-glucopyranoside. The ‘464 patent claims are therefore a species of the instantly claimed genus (which encompasses compositions derived by solubilization with any non-ionic detergent).

Appellant has not disputed the merits of this rejection and has agreed to file a terminal disclaimer to overcome it. See Paper No. 33, filed August 30, 1994, page 10; Appeal Brief, page 41. Since Appellant has not argued that the rejection is improper, we affirm it.

2. The “lack of utility” enablement rejection.

The examiner rejected claims 11-16, 18, 27, 29, and 68-80 under 35 U.S.C. § 112, first paragraph, as nonenabled. The basis of the examiner’s rejection is that the claimed compositions had not been shown to be therapeutically effective as of the effective filing date of the instant application.

See the Examiner's Answer, pages 6-8. The examiner acknowledges that "[t]he specification sets forth data showing immunization of mice with recovered blood stage antigens from P. berghi." Id., page 6. However, she concludes that these data are insufficient to enable the claims because later-published references (Butcher and Mitchell) show that malaria vaccines were still an elusive goal as late as 1989. The examiner also cites these references for their statements that "with the exception of the work carried out in man, the validity of all experimental systems is open to challenge" (Mitchell), and "any [animal] model of malaria has some difficulties" (Butcher). She concludes that

Applicant[']s claims must be assessed at the time of filing, and the teachings of Mitchell and Butcher indicate that there is no malaria vaccine per se, or one which effectively causes "resistance" to the malaria parasite, and that extrapolation from murine data, to similar efficacy in all animals, particularly humans[,] cannot be done.

Examiner's Answer, page 8.

The examiner's statement of the rejection makes clear that the instant rejection, although framed as nonenablement, is actually based on lack of an adequate disclosed utility for the claimed compositions. That is, the examiner finds the specification's data to be unconvincing of therapeutic efficacy and therefore concludes that the specification does not adequately teach how to use the claimed compositions. We disagree.

The examiner bears the initial burden of showing nonenablement or lack of utility. See In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to

those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” (emphasis in original)). See also In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974) (“[A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.”).

“[P]roof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility.” In re Brana, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995) (citing In re Krimmel, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961)). “[O]ne who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.” Brana, 51 F.3d at 1567, 34 USPQ2d at 1442 (quoting Krimmel, 292 F.2d at 953, 130 USPQ at 219).

In this case, the specification discloses that the claimed compositions have a significant therapeutic effect when administered to mice. See pages 24-31. The examiner’s position to the contrary notwithstanding, mice appear to be

an art-accepted experimental animal for malaria vaccine research. See Perrin, pages 1345 and 1346 (discussing immunization of mice with various plasmodial antigens); Butcher, page 318 (showing the results of three vaccination trials conducted in mice, together with results from other animals) and 321-22 (discussing the advantages and disadvantages of various animal models, including mice).

Thus, the specification appears to provide “proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals.” Brana, 51 F.3d at 1567, 34 USPQ2d at 1442. This “is sufficient to establish utility,” id., unless the examiner provides convincing evidence or scientific reasoning to the contrary. The examiner, however, provides only vague doubts about whether the claimed compositions will ultimately prove to be effective. On this record, we cannot say that the claims lack utility and we therefore reverse the rejection of claims 11-16, 18, 27, 29, and 68-80 for nonenablement.

### 3. The “undue experimentation” enablement rejection.

In a separate rejection, the examiner rejected all of the pending claims as nonenabled, on the basis that undue experimentation would be required to practice the claims throughout their full scope. The examiner points to Howard as showing that different detergents extract different antigens from malarial parasites. The examiner concludes that “the disclosure is enabling only for claims limited to antigenic factors obtained using the exemplified non-ionic detergents.” Examiner’s Answer, page 9.

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

We conclude that this burden has not been met in this case. The specification exemplifies preparation of plasmodial antigens using the following non-ionic detergents: n-octyl- $\beta$ -D-glucopyranoside (pages 20-24), Triton X-100 (pages 27-28), nonanoyl-N-methylglucamide (page 29), and N-heptyl- $\beta$ -D-thiogluconide (page 29). The specification discloses testing of the various antigen preparations for immunoprotective effect and concludes that “active protective parasite antigens may be recovered following solubilization with different non-ionic detergents.” Page 31.

Thus, the specification “contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented.” Marzocchi, 439 F.2d at 223, 169 USPQ at 369. Therefore, it “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” Id. The evidence relied on

by the examiner is insufficient. The mere fact that different detergents would be expected to solubilize a different set of antigens is insufficient evidence of nonenablement where, as here, the specification shows that the antigens actually solubilized by different detergents are all effective in producing an immunoprotective effect. We therefore reverse the second rejection for nonenablement.

4. The §§ 102/103 rejections.

The examiner rejected claims 11-16, 18, 27, 29, and 68-80 as anticipated by, or alternatively as obvious in view of, either Schmidt-Ullrich or Kilejian. The examiner also rejected the same set of claims as anticipated by or obvious over Epstein. Finally, the examiner rejected claims 18 and 68 as anticipated by or obvious over any of Howard, Newbold, or Epstein.

We will consider these rejections together. The examiner's rationale is similar for each, and in each case the claims stand or fall with claim 68. In addition, we find it necessary to consider only the references by Kilejian and Epstein. Since the relevant disclosures of Kilejian and Epstein are similar, we can efficiently discuss both references together.

We begin with claim construction. See Key Pharms. Inc. v. Hercon Labs. Corp., 161 F.3d 709, 714, 48 USPQ2d 1911, 1915 (Fed. Cir. 1998) (“[A] determination of anticipation, as well as obviousness, involves two steps. First is construing the claim.”). Claim 68 is directed to a water-insoluble composition comprising plasmodial antigens, which induces “immunological reactivity to plasmodial parasites,” and which is produced by the following process: “forming

a suspension in water” of a parasite-containing material,<sup>2</sup> “adding a non-ionic detergent to the suspension,” and “separating and recovering the antigenic factor(s) from the aqueous medium.” Claim 68 requires no particular purification step(s) or degree of purification in the claimed compositions.

Both Kilejian and Epstein teach immunoprecipitation of antigens from plasmodial parasites. In the process disclosed by Kilejian, plasmodial merozoites and a “membrane-enriched fraction prepared from schizonts” were used to immunize rabbits. Page 3695, right-hand column. After the rabbits had developed plasmodial-specific antibodies, antisera (“immune sera”) were collected. Id. The antibody-containing immune sera were then mixed with “protein A covalently coupled with Sepharose CL-4B,” to form antibody/protein A/Sepharose beads. Page 3696, sentence bridging the columns. In the meantime, Plasmodium falciparum “parasites were solubilized in . . . 1% Nonidet P-40 (NP-40) in phosphate-buffered saline.” Id., left-hand column.<sup>3</sup> The “NP-40 extract (200 µl; 400-600 µg of protein) was added to the washed beads. . . . Unbound extract was removed by three washes with 0.5 M LiCl/10 mM Tris-HCl, pH 8, and one wash with 1% NP-40 buffer. Immunocomplexes were eluted.” Id., right-hand column.

Epstein discloses a similar immunoprecipitation protocol. Mice were immunized with merozoites and used to produce plasmodial-specific monoclonal

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<sup>2</sup> Specifically, “intact starting plasmodial parasite released from a quantity of red blood cells, intact red blood cells containing the blood stage of the starting plasmodial parasite, merozoites which released themselves from red blood cells, tissues having blood infected with said starting plasmodial parasite, [or] tissues having starting plasmodial parasite infected blood.” Claim 68.

antibodies. See page 212, right-hand column. Meanwhile, Plasmodium knowlesi antigen was prepared by extracting parasite-infected red blood cells by “suspend[ing] in 1 ml PBS [phosphate-buffered saline] containing 1% Triton X-100 . . . [and] incubat[ing] on ice for 1 hr with intermittent vigorous vortexing.” Page 213, paragraph bridging the columns.<sup>4</sup> The resulting soluble extract was “mixed with ascites fluid containing the monoclonal antibody.”<sup>5</sup> Id., right-hand column. After the monoclonal antibody had been allowed to bind the plasmodial antigens in the extract, “goat anti-mouse Ig-conjugated Sepharose 4B or protein A-Sepharose 4B” was added. After the immune complexes (i.e., plasmodial antigen plus monoclonal antibody) had been allowed to bind, the Sepharose gels were washed to eliminate unbound extract and “[i]mmune complexes were eluted from the Sepharose.” Id.

Thus, both references disclose compositions comprising Sepharose beads with protein A attached and an antibody/plasmodial antigen immune complex bound to the protein A. These compositions are water-insoluble, since both Kilejian and Epstein recover the Sepharose-containing composition by centrifugation. See Kilejian at page 3696 (“[Sepharose] beads were pelleted and washed once with the buffer. . . . Unbound extract was removed by three washes with 0.5 M LiCl/10 mM Tris-HCl, pH 8, and one wash with 1% Nonidet P-40 buffer.”); Epstein at page 213 (“[Sepharose] gels with bound immune complexes were washed twice with 5 ml [NETT] buffer. . . containing 10% FBS, followed by

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<sup>3</sup> Nonidet P-40 is a non-ionic detergent. See, e.g., claim 18.

<sup>4</sup> Triton X-100 is a non-ionic detergent. See, e.g., claim 18.

1 wash with NETT buffer containing 0.5 M NaCl and 2 washes with NETT buffer. Gels were spun at 200 x G for 2 min for each wash.”).

The disclosed compositions also comprise plasmodial antigens that are solubilized with a non-ionic detergent (i.e., Nonidet P-40 or Triton X-100). See Kilejian at page 3696 (“[P]arasites were solubilized . . . in 4 vol of 1% Nonidet P-40.”); Epstein at page 213 (“[C]ells were extracted with 1% Triton X-100.”).

Finally, the compositions would reasonably be expected to induce immunological reactivity to plasmodial parasites, because they comprise plasmodial antigens. The plasmodial antigens in each of the disclosed compositions were isolated based on binding of the antigen to antibodies that were raised to intact merozoites. See Kilejian, page 3695 (“Rabbit A was immunized with merozoites.”); Epstein, page 212 (“mice . . . were immunized with freshly prepared merozoites.”). Thus, the antigens in the compositions disclosed by Kilejian and Epstein would reasonably be expected to contain at least one epitope that is displayed by the intact (merozoite-stage) parasite. Since the antigens would be expected to comprise epitopes that are shared by the intact parasites, they would be expected to induce immunological reactivity to the intact parasites.

The antigen-isolation process disclosed by Kilejian and Epstein differs in one respect from that recited in the instant claims: the claims recite a process comprising “forming a suspension in water” of the parasite-containing material,

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<sup>5</sup> The extract was “preadsorbed with . . . protein A-Sepharose CL-4B” but this step was only “[t]o reduce nonspecific binding of antigen to the immunoabsorbant.” Id.

then in a second step “adding a non-ionic detergent to the suspension.” In Kilejian and Epstein, the non-ionic detergent (together with phosphate buffer and other components) is added to water and then this detergent solution is used to extract the plasmodial parasites.

This slight difference does not distinguish the claimed composition from those disclosed in the prior art. The claims subject to the instant rejections are all directed to products, not processes. “The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). There is no evidence in the record that the same non-ionic detergent will solubilize different antigens from plasmodial parasites depending on whether it is present in the extraction buffer, rather than being added in a second step after the plasmodial parasites are suspended in water. The prior art compositions thus reasonably appear to meet all of the limitations of claim 68. The Kilejian and Epstein references therefore support a prima facie case of anticipation.

Appellant argues that both Kilejian and Epstein fail to teach the claimed compositions. Appellant argues that the references are deficient because they

- “1) Used a detergent to extract parasite antigens,
- 2) None removed detergents from their extracts,
- 3) None showed that the extracted antigens were insoluble or would aggregate in insoluble form after detergent removal, and

- 4) None showed that they had extracted and/or recovered protective antigens.”

Appeal Brief, pages 48-49. We will address these arguments seriatim.

First, Appellant argues that Kilejian and Epstein “[u]sed a detergent to extract parasite antigens.” It is unclear what point Appellant is trying to make; claim 68 requires that the plasmodial antigens in the claimed composition be solubilized using a non-ionic detergent. This argument is therefore not persuasive.

Second, Appellant argues that neither Kilejian nor Epstein “removed detergents from their extracts.” This argument is also unpersuasive, since claim 68 is not limited to compositions from which the detergent has been removed.

Third, Appellant argues that neither Kilejian nor Epstein “showed that the extracted antigens were insoluble or would aggregate in insoluble form after detergent removal.” Again, Appellant is relying on a limitation that is not present in the claims. Claim 68 does not require that all or even any of the plasmodial antigens themselves be water-insoluble, it requires that the overall composition comprising the antigens be water-insoluble. This limitation is met by the immunoprecipitates disclosed by both Kilejian and Epstein, which comprise plasmodial antigens, antibodies, protein A, and Sepharose beads. Whether or not the plasmodial antigens themselves are water-insoluble, the immunoprecipitated compositions as a whole are water-insoluble, as shown by the fact that the immunoprecipitates were recovered by centrifugation.

Finally, Appellant argues that neither Kilejian nor Epstein “showed that they had extracted and/or recovered protective antigens.” Again, claim 68 does not require that either the plasmodial antigen in the claimed composition or the composition itself generate an immune response that is protective against later challenge. All the claim requires is that the composition induce “immunological reactivity.” This property would be reasonably expected from the prior art compositions, because the plasmodial antigens that were immunoprecipitated were recognized and bound by antibodies raised to intact merozoites. Therefore, the plasmodial antigens display epitopes shared by intact merozoites and would reasonably be expected to generate the same antibody response, i.e., they would be expected to induce the same immunological reactivity.

Appellant presents a similar argument with respect to the rejection based on Kilejian, in which he argues that “[i]t should be borne in mind that the key to the composition having immunological reactivity of the present invention is recited in independent claims 68 [and others] and is that the composition includes ‘solubilized (dispersed) protective antigenic factors.’” Appeal Brief, page 40 (emphasis in original). The phrase “quoted” by Appellant from claim 68 in fact does not appear in the claim. The claim is not limited to a composition comprising “protective antigenic factors,” but requires only that the composition include one or more “recovered parasite antigenic factor(s).” Since the claim is not limited to a composition comprising protective antigens, the alleged lack of protective antigens in the prior art cannot be relied on to establish the novelty of the claimed composition.

“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Appellant has not shown that the prior art compositions fail to meet any of the limitations of claim 68. We therefore affirm the rejections under 35 U.S.C. § 102 based on Kilejian and Epstein. Since we find that Kilejian and Epstein anticipate claim 68, we do not reach the alternative basis under 35 U.S.C. § 103. We also find it unnecessary to consider the disclosures of Schmidt-Ullrich, Howard, and Newbold, which were relied on as alternatives to Kilejian or Epstein.

5. The § 103 rejection.

The examiner rejected claims 84-88 and 90-100 as obvious in view of the disclosure of either Kilejian or Schmidt-Ullrich. The examiner reasons that the references teach processes of obtaining plasmodial parasite antigens using non-ionic detergent, and that the process steps recited in the claims “appear to be conventional extraction steps and known to persons of skill in the art at the time the invention was made.” Examiner’s Answer, pages 14-15. Therefore, the examiner concludes that the claimed process would have been obvious in view of the references.

“It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references.” Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d

1626, 1629 (Fed. Cir. 1996). “Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992)

The process of claim 84 requires, inter alia, “forming a suspension in an aqueous medium of” plasmodium-containing material, and “adding a non-ionic detergent into the suspension to disperse the antigenic, insoluble factor(s).” Thus, the claim requires first forming a suspension containing plasmodial antigens, then adding a non-ionic detergent to that suspension. Neither Kilejian nor Schmidt-Ullrich disclose such a two-step process; in both prior art references, a pre-mixed solution containing non-ionic detergent is used to extract and solubilize the plasmodial antigens. The examiner has pointed to nothing in the prior art that would have motivated those skilled in the art to modify the prior art process as required to meet the limitations of the claims. Since the cited references would not have motivated those skilled in the art to carry out the claimed process, the references do not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

Summary

We affirm the rejection for obviousness-type double patenting because Appellant has not contested it. We also affirm the rejections under 35 U.S.C. § 102 because the prior art products reasonably appear to meet all the limitations of claim 68. However, we reverse the rejections under 35 U.S.C. § 112, first paragraph, because the examiner has not shown that the claimed products lack utility or that undue experimentation would be required to practice the full scope of the claims. We also reverse the rejection of claims 84-88 and 90-100 under 35 U.S.C. § 103 because the prior art would not have motivated those skilled in the art to carry out the claimed process. Therefore, claims 84-88 and 90-100 are not subject to any outstanding rejection.

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

WILLIAM F. SMITH	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
DEMETRA J. MILLS	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
ERIC GRIMES	)	
Administrative Patent Judge	)	

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D. PETER HOCHBERG CO., L.P.A.  
ONE BAKER BLDG.  
1940 EAST 6<sup>TH</sup> ST., 6<sup>TH</sup> FL.  
CLEVELAND, OH 44114

EG/jlb