Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte HYUN S. LILLEHOJ and
MARJORIE B. NICHOLS

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Appeal No. 1999-1396
Application No. 08/524,668[1]

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ON BRIEF

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Before ROBINSON, SCHEINER and ADAMS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 and 2, the only claims pending in the application.

[1] Application for patent filed September 8, 1995.

The claims read as follows:

1. A chicken monoclonal antibody specific for Eimeria acervulina antigens involved in host cell invasion, wherein said antigens are located on the conoid of the anterior tip of Eimeria acervulina sporozoites.

2. A chicken hybridoma which secretes the monoclonal antibody of claim 1.

The references relied on by the examiner are:

Murray et al. (Murray)	4,724,145	Feb. 9, 1988
Matsuda et al. (Matsuda)	5,411,881	May 2, 1995

Claim 1 and 2 stand rejected under 35 U.S.C. § 103 as unpatentable over Murray and Matsuda. We reverse.

BACKGROUND

Intracellular protozoan parasites belonging to the genus Eimeria infect the intestinal mucosa of livestock and poultry and impair the growth and feed utilization of the infected animals. According to the specification, "[i]dentification of parasite antigens involved in the invasion of host lymphocytes is crucial for the development of coccidial vaccines, since sporozoite invasion of host lymphocytes is the first step involved in coccidiosis." Further according to the specification, mouse monoclonal antibodies are of questionable value in "defin[ing] epitopes important in the chicken's immune response to Eimeria . . . since differences have been reported in the recognition of target antigens by immune sera from chickens, rabbits and mice." Page 2. Accordingly, the present invention is directed to "monoclonal antibodies from chicken hybridomas [] effective for identifying parasite

antigens involved in the infection and invasion of host lymphocytes . . . [and] for detecting the occurrence of parasite infection." Page 3. Claims 1 and 2 are directed to a chicken monoclonal antibody (and a chicken hybridoma secreting it) specific for antigens "located on the conoid of the anterior tip of Eimeria acervulina sporozoites."[2]

DISCUSSION

Murray describes preparation of an immunogenic extract from freeze thawed and sonicated Eimeria acervulina sporozoites. Intramuscular immunization of young chickens with the sporozoite extract protected them against subsequent oral challenge with infective E. acervulina sporulated oocysts. Example 10. Coomassie blue staining and comparison of the extract with molecular weight markers revealed 31 polypeptides ranging in size from about 300 kD to about 13 kD. None of the polypeptides were isolated from the extract, but Western Blot analysis using polyclonal rabbit anti-E. acervulina sporozoite immune serum showed that "[o]f these polypeptides, 20 are immunodominant i.e., the 20, 21.5, 22.5, 23, 24, 26, 26.5, 27, 29, 31, 34, 37, 41.5, 45, 59, 65, 68, 74, 84 and 115 kD molecular weight polypeptides." Column 1, lines 59-68, and column. 3, lines 9-25. Polyclonal rabbit anti-E. acervulina sporozoite immune serum was able to agglutinate sporozoites in vitro, and preincubation of intact sporozoites with the rabbit immune serum neutralized the infectivity of the sporozoites in chickens. Example 5, column 5, lines 26-68.

[2] According to the specification, the conoid is "a basket-like meshwork of spirally woven microtubules" which "aids in the penetration of host cells." Page 8. "[A]ntigens of the conoid" are believed to "play a role in the parasites's recognition and initial adherence to the host cells." Page 9.

Matsuda describes a method of establishing chicken monoclonal IgG-producing hybridoma cell lines.

The examiner acknowledges that Murray "does not show the use of chicken monoclonal antibodies," but concludes that (Examiner's Answer, pages 4-5)

> [i]t would have been obvious to a person of ordinary skill in the art . . . to use the method and cell line of [Matsuda] for the production of a chicken specific immunoglobulin producing hybridoma and the immunodominant antigens of [Murray] because one skill[ed] in the art would have had a reasonable expectation of success of obtaining a monoclonal antibody which would be specific to Eimeria acervulina and would have an inhibitory effect to infection as [Murray] teach[es] that the polyclonal antisera used produced the desired inhibitory effect and one skill[ed] in [the] art would have a reasonable expectation of obtaining a monoclonal antibody which could be produced in greater quantities and would be specific to a[n] immunodominant antigen involved in Eimeria acervulina invasion.

If we understand the examiner's rationale correctly, it is that it would have been obvious for one skilled in the art to raise chicken monoclonal antibodies against the immunodominant polypeptides in Murray's crude sporozoite extract (i.e., those bound by polyclonal rabbit anti-sporozoite immune serum in Murray's Western Blot) because one would have reasonably expected at least one of the chicken monoclonal antibodies to be "specific to a[n] immunodominant antigen involved in Eimeria acervulina invasion."

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. [] Close adherence to

> this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." []
>
> Most if not all inventions arise from a combination of old elements. [] Thus, every element of a claimed invention may often be found in the prior art. [] However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. [] Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted]

In other words, "there still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

At best, the statement of the rejection establishes that individual parts of the claimed invention were known in the prior art, i.e., E. acervulina was known to be immunogenic, and a protocol for making chicken monoclonal antibodies was known. It may well be, as asserted by the examiner, that a person skilled in the art would have expected a chicken monoclonal antibody raised against the polypeptides on Murray's Western blot to be "specific to a[n] immunodominant antigen." Nevertheless, the examiner has not pointed to any evidence of a suggestion to make a chicken antibody specific for Eimeria acervulina in the first place, let alone one specific for an antigen "located on the conoid of the anterior tip of Eimeria acervulina sporozoites," as required by the claims.

Here, we find no reason stemming from the prior art which would have led a person having ordinary skill in the art to the claimed invention. We find that the examiner's burden of establishing a prima facie case of obviousness has not been met. In our judgment, the only reason or suggestion to modify Murray in the manner proposed by the examiner comes from appellants' specification. Accordingly, the rejection of the claims under 35 U.S.C. § 103 is reversed.

REVERSED

Douglas W. Robinson Administrative Patent Judge	)
Toni R. Scheiner Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

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