

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 15

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte ALAN ROY DEARN

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Appeal No. 2002-1254  
Application No. 09/411,381

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ON BRIEF

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Before SCHEINER, ADAMS, 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 20-31, all of the claims remaining. Claims 20, 21, 23, 26 and 28 are representative and read as follows:

20. Small particles of atovaquone wherein at least 90% of the particles of atovaquone have a volume diameter in the range 0.1-3 $\mu$ m.

21. Small particles of atovaquone wherein the particles of atovaquone have been microfluidized.

23. A pharmaceutical composition comprising particles of atovaquone and one or more pharmaceutically acceptable carriers therefor wherein at least 90% of the particles have a volume diameter in the range of 0.1-3 $\mu$ m.

26. A pharmaceutical composition according to claim 23 wherein the pharmaceutically acceptable carriers include a suspending agent.

28. A pharmaceutical composition according to claim 26, wherein the suspending agent is xanthan gum.

The examiner relies on the following reference:

Latter et al. (Latter)	4,981,874	Jan. 01, 1991
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Claims 20-27, 30, and 31 stand rejected under 35 U.S.C. § 102(b) as anticipated by Latter.

Claims 28 and 29 stand rejected under 35 U.S.C. § 103 as obvious in view of Latter.

We reverse.

#### Background

Atovaquone is a known compound used for treatment of Pneumocystis carinii pneumonia. See the specification, page 1. However, “[t]he efficacy of atovaquone as a therapeutic agent is limited by its bioavailability.” Id., page 2. The specification discloses that “conventional methods of reducing the particle size of atovaquone were found to be unsuccessful in producing particles of the size required to improve bioavailability.” Id. However, “microfluidised particles of atovaquone . . . have improved bioavailability of the compound. It is believed that this is due to the small size and narrow range of sizes of the microfluidised atovaquone particles.” Id. Microfluidization is a mixing process “in which fluid streams interact at very high velocities and pressures.” Id. It is used “primarily . . . in the food and pharmaceutical industries, for the preparation of e.g. emulsion

and liposomal systems and has . . . been used for cell-rupture purposes in biotechnology applications.” Id.

### Discussion

Claims 20 and 21 are directed to particles of atovaquone where at least 90% of the particles have a volume diameter between 0.1 and 3  $\mu\text{m}$  (claim 20), or in which the particles have been microfluidized (claim 21). The examiner rejected claims 20-27, 30, and 31 as anticipated by Latter, on the basis that

Latter et al. teach atovaquone having a diameter of 0.5 to 7 microns (col. 2, line[s] 32-47; col. 5, lines 19-23). The reference teaches (1) the compound exhibits good activity against Pneumocystis carinii pneumonia infections . . . and (2) various formulation[s] including suspensions. . . . The compound, composition and method of use taught by the reference are encompassed by the instant claims.

Examiner’s Answer, page 3.

As the examiner noted, Latter discloses treatment of Pneumocystis carinii pneumonia with atovaquone. (Latter refers to atovaquone by its chemical name. Compare Latter, col. 2, lines 32-33, with the instant specification, page 1, first paragraph.) Latter also discloses that “[f]ormulations suitable for pulmonary administration via the buccal cavity are presented such that particles containing the active ingredient and desirably having a diameter in the range of 0.5 to 7 microns are delivered into the bronchial tree of the recipient.” Col. 5, lines 19-23. Latter also discloses exemplary formulations for “Nebulisation,” “Aerosol Formulation,” and “Powder Inhalation,” all of which contain “micronised” atovaquone. See col. 8, line 60 to column 9, line 46.

In response to the examiner's reliance on Latter, Appellant filed a declaration under 37 CFR § 1.132. See Paper No. 10, filed Nov. 8, 2000. In his declaration, Appellant stated that

- "Micronisation is a typical milling procedure used to pulverise [a] drug substance. However, in this form atovaquone was limited in its efficacy by poor bioavailability." ¶ 5.
- "[C]onventional milling techniques, used to reduce the particle size of crystalline chemical compounds, had all failed to provide small particles of atovaquone which demonstrated improved bioavailability." ¶ 9.
- "[M]icrofluidisation can be used to prepare consistently smaller particles of atovaquone than those achievable by conventional techniques and . . . said particles do indeed display improved bioavailability compared with non-microfluidised atovaquone." ¶ 10.

Appellant attached to the declaration the results of an experiment in which atovaquone was micronized in order to reduce its particle size; micronization did not result in particles having the size range recited in the instant claims. See Annex 1 attached to Paper No. 10.

"It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998). "It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art." Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985). In addition, "when 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).

In this case, we agree with the examiner that Latter’s disclosure was sufficient to support a prima facie case of anticipation and to shift the burden to Appellant to show a difference between the known and claimed products. We disagree, however, with the weight the examiner gave to Appellant’s evidence.

The examiner argued that “[t]he cited prior art is a US patent and, thus, is considered enabled for the particle size taught by said patent. Thus, applicant’s argument of conventional methods can not [sic] be addressed by the examiner.” Examiner’s Answer, page 4. The examiner was half-right, in that “a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled.” Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). But that presumption is rebuttable. See id.: “The applicant, however, can then overcome th[e] rejection by proving that the relevant disclosures of the prior art patent are not enabled.”

In this case, Appellant submitted evidence showing that Latter was not enabling for the atovaquone preparations that are presently claimed. In such a case, just as with a rejection for obviousness, the examiner must start over and re-weigh the evidence on both sides of the issue. Cf. In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976):

When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. . . . An earlier decision should not . . . be considered as set in concrete,

and applicant's rebuttal evidence then be evaluated only on its knockdown ability. . . . Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.

Appellant has provided evidence showing that the prior art would not have enabled those skilled in the art to make the compositions defined by the claims on appeal. The examiner has provided no evidence to the contrary. Therefore, the weight of the evidence in the record tends to show that the prior art disclosure was not enabling for the claimed product.

"No doctrine of patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated." Dewey & Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 989, 52 USPQ 138, 142 (2d Cir. 1942) (Learned Hand, J.). What was well-settled sixty years ago is still the law today. See Amgen, 314 F.3d at 1354, 65 USPQ2d at 1416 ("A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."). The rejection under 35 U.S.C. § 102(b) is reversed.

The examiner also rejected claims 28 and 29 as obvious in view of Latter, on the basis that it would have been obvious to modify Latter's atovaquone composition by adding xanthan gum. See the Examiner's Answer, pages 3-4. We have concluded that Latter does not disclose the atovaquone particles

required by the pharmaceutical composition of claim 23. Therefore, Latter does not render obvious the pharmaceutical compositions of claims 28 and 29, which depend on claim 23. The rejection under 35 U.S.C. § 103 is reversed.

Summary

Appellant has provided evidence that the prior art disclosures would not have enabled those skilled in the art to make the claimed compositions. The rejections on appeal are reversed because they are not supported by a preponderance of the evidence in the record.

REVERSED

Toni R. Scheiner	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Donald E. Adams	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Eric Grimes	)	
Administrative Patent Judge	)	

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