

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte SAGHIR AKHTAR, PATRICIA FELL, and JAMES A. MCSWIGGEN

Appeal No. 2002-1815
Application No. 09/401,063

ON BRIEF¹

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 27-34, 40, 42-46 and 48-53, which are all the claims pending in the application.

Claim 27 is illustrative of the subject matter on appeal and is reproduced below:

27. An enzymatic nucleic acid molecule which specifically cleaves RNA of epidermal growth factor receptor (EGFR) gene, wherein said enzymatic nucleic acid molecule comprises a chemical modification, a substrate binding sequence and a nucleotide sequence within or surrounding said substrate binding sequence wherein said nucleotide sequence imparts to said enzymatic nucleic acid molecule activity for the cleavage of said RNA of the EGFR gene.

¹ Appellants waived their request for oral hearing. Accordingly, we considered this appeal on Brief.

The references relied upon by the examiner are:

Joyce et al. (Joyce) 5,807,718 Sep. 15, 1998

Yamazaki et al. (Yamazaki), "Cleavage of glioma-Specific Aberrant mRNA of Epidermal growth factor receptor (EGFR) by Ribozyme in Vitro," Proceedings of the American Association for Cancer Research Annual Meeting, Vol. 36, pp. 429, Abstract No. 2556 (1995)

Rossi, "Controlled Targeted, Intracellular Expression of Ribozymes: Progress and Problems," Tibtech, Vol. 13, pp. 301-06 (1995)

Usman et al. (Usman), "Design, Synthesis, and Function of Therapeutic Hammerhead Ribozymes," Nucleic Acids and Molecular Biology, Vol. 19, pp. 243-64 (1996)

Ortigão, et al. (Ortigão), "Antisense Effect of Oligonucleotides with Inverted Terminal Internucleotidic Linkages: A Minimal Modification Protecting Against Nucleolytic Degradation," Antisense Research and Development, Vol. 2, pp. 129-46 (1992)

GROUND OF REJECTION

Claims 27-34, 40, 42-46 and 48-53 stand rejected under 35 U.S.C. § 103 as obvious over Yamazaki in view of Rossi, Usman, Joyce and Ortigão.

We reverse.

DISCUSSION

Obviousness is a question of law supported by underlying facts.

In re Gartside, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000).

What the prior art teaches and whether it teaches away from the claimed invention are questions of fact. In re Bell, 991 F.2d 781, 784, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).

According to the examiner, Yamazaki teach a hammerhead ribozyme that cleaves mutant EGFR mRNA found in malignant gliomas. Answer, page 4. The

examiner, however, finds that Yamazaki do not teach a ribozyme which has a chemical modification as required by the claimed invention. Id. To make up for this deficiency, the examiner relies on Rossi, to teach vector delivery systems for ribozymes; Usman, to teach modified ribozymes; Joyce, to teach DNAzymes; and Ortigão, to teach antisense oligodeoxynucleotides with inverted terminal internucleotidic linkages. Answer, pages 4-5.

However, as appellants point out (Brief, page 15), The Yamazaki abstract merely teaches that a specific ribozyme can be used to cleave a specific mutant EGFR sequence. According to appellants, Yamazaki “does not provide an enabling disclosure by which one skilled in the art could reasonably expect to successfully cleave an EGFR RNA using a chemically modified enzymatic nucleic acid. First, Yamazaki does not provide any EGFR sequences, nor does it teach any binding/target sites in the EGFR gene.” Id. In addition, appellants argue (Brief, page 16), “none of the other cited references even mentions the EGFR gene, none of them provide a disclosure by which one skilled in the art could reasonably expect to successfully cleave an EGFR RNA using a chemically modified enzymatic nucleic acid.”

The examiner recognizes appellants’ arguments (see, e.g., Answer, page 9). Nevertheless, the examiner argues (Answer, page 10):

Yamazaki clearly teaches an enzymatic nucleic acid which specifically cleaves EGFR. Applicant’s claimed invention is distinguished from the ribozyme taught by Yamazaki only in that the claimed enzymatic nucleic acid molecule further comprises a chemical modification; however, chemically modified ribozymes were not novel at the time the instant invention was made. The prior art taught chemical modifications for incorporation into ribozymes and provided clear motivation to modify the ribozyme

taught by Yamazaki, for example, to impart greater stability to the ribozyme taught by Yamazaki.

Therefore, the examiner finds (Answer, page 11), “[t]he explicit teaching by Yamazaki to target EGFR for therapy purposes would have led one of ordinary skill in the art to modify the enzymatic nucleic acid taught by Yamazaki so as to become a more viable means for targeting the aberrant EGFR RNA.” The question remains, however, that if Yamazaki is not an enabling reference, would persons of ordinary skill in the art at the time the invention was made have possession of the Yamazaki ribozyme to modify? In our opinion, they would not.

As set forth in In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968), “if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public.” As discussed, supra, Yamazaki does not disclose or render obvious a method of making their ribozyme. In addition, there is no evidence on this record that the Yamazaki ribozyme was deposited, on sale, or otherwise made publicly available at the time the invention was made. Accordingly, we are compelled to agree with appellants (Brief, page 15), Yamazaki “does not provide an enabling disclosure by which one skilled in the art could reasonably expect to successfully cleave an EGFR RNA using a chemically modified enzymatic nucleic acid.”

We recognize that a non-enabling reference may qualify as prior art for the purpose of determining obviousness under §103. Reading & Bates Constr. Co. v. Baker Energy Resources Corp., 748 F.2d 645, 652, 223 USPQ 1168, 1173 (Fed. Cir. 1985) (reference that lacks enabling disclosure is not

anticipating, but “itself may qualify as a prior art reference under §103, but only for what is disclosed in it”). In this regard, the examiner finds that the teaching of Yamazaki would have motivated a person of ordinary skill in the art to modify the enzymatic nucleic acid taught by Yamazaki. Answer, page 11. While this may be true, what is missing is a disclosure in Yamazaki that placed the ribozyme in the possession of a person of ordinary skill in the art. There is no evidence on this record that the other references relied upon to teach DNAzymes and various modifications of ribozymes would have made up for the deficiencies in Yamazaki.

For the foregoing reasons, we reverse the rejection of claims 27-34, 40, 42-46 and 48-53 stand rejected under 35 U.S.C. § 103 as obvious over Yamazaki in view of Rossi, Usman, Joyce and Ortigão.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Donald E. Adams)	
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