

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRITTAN L. PASLOSKE

Appeal 2008-2246
Application 10/352,806
Technology Center 1600

Decided: August 27, 2008

Before, DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation. We have jurisdiction under 35 U.S.C. § 6(b).

The following claims are representative.

41. A method for producing cDNA from one or more biological units comprising:
obtaining at least one biological unit;
obtaining at least one catabolic enzyme;
obtaining at least one reverse transcriptase;

preparing an admixture comprising: (i) all or part of an extract produced by lysing the biological unit, and (ii) the catabolic enzyme; incubating the admixture at a temperature where the catabolic enzyme is active; adding the reverse transcriptase to all or a part of the admixture comprising the extract of the biological unit and the catabolic enzyme; and incubating the admixture under conditions where the reverse transcriptase is active; wherein cDNA is produced, and wherein the method does not involve the isolation of RNA from the extract prior to the production of the cDNA.

Cited References

Reardon	US 4,997,932	Mar. 5, 1991
Laugharn	US 6,111,096	Aug. 29, 2000
Kudlicki	US 6,664,379 B1	Dec. 16, 2003

New England Biolabs Catalog, 96 (1993-1994).

Lawrence O. Baum et al., “Regulation of expression of cytochrome P-450 ZD mRNA in rat brain with steroid hormones,” 765 *Brain Research* 67-73 (1997).

Gary Kobs, “Isolation of RNA from Plant, Yeast and Bacteria,” 68 *Promega Notes* 28-31 (1998).

Qiagen, “RNeasy Mini Protocols for Isolation of Total RNA from Animal Cells,” Third Edition, *RNeasy Mini Handbook* 30-41 (2001).

Grounds of Rejection

1. Claims 11, 13, 16, 27, 30, 31, 39-41, 42, 45, 46, 52, 54, and 55-57 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Baum and Stroebel.

2. Claims 6, 7, 9, 14, 15, 19, 26, 28, 38, 43, 44, 48, 49, 71-75, and 78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Stroebel in view of Reardon.

3. Claims 8, 10, 24, 47, 51, and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Stroebel in view of Reardon and Laugharn.

4. Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Stroebel in view of Reardon and Quiagen.

5. Claim 22, 50, and 76 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Stroebel in view of Reardon and Kobs.

6. Claims 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Strobel in view of Reardon and New England Biolabs.

7. Claim 31 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Strobel in view of Reardon and Kudlicki.

DISCUSSION

Background

“The present invention relates generally to the field of RNA analysis, more specifically it teaches a more direct method for the detection of a specific sequence of RNA in a biological unit, for example a virus, cell or tissue sample. More generally, the invention may be used to enzymatically

manipulate and protect the RNA in a crude cell lysate for a number of applications.” (Spec. 2.)

Claim Interpretation

During patent examination, the PTO is permitted to adopt “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *In re Crish*, 393 F.3d 1253, 1256 (Fed. Cir. 2004).

Claim 41 recites, the limitation, “wherein cDNA is produced, and wherein the method does not involve the isolation of RNA from the extract prior to the production of the cDNA.” The Specification indicates that the method of cDNA production involves “direct use of a cell lysate.” (Spec. 6: 1-11.) Furthermore, the examples in the Specification describe processes for making cDNA where RNA is not removed from the cell extract prior to reverse transcription. (Spec. 12-17.) Therefore, we interpret the phrase “wherein cDNA is produced, and wherein the method does not involve the isolation of RNA from the extract prior to the production of the cDNA” to mean that RNA has never been isolated or purified or removed from the cell extract.

1. Claims 11, 13, 16, 27, 30, 31, 39-41, 42, 45, 46, 52, 54, and 55-57 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Baum and Stroebel.

The Examiner finds that:

Baum and Strobel teach (claim 41) producing cDNA from one or more biological units comprising:
obtaining at least one biological unit (see p. 68 preparation of RNA);
obtaining at least one catabolic enzyme (see p. 68 cDNA synthesis, where DNase I is the catabolic enzyme);
obtaining at least one reverse transcriptase (see p. 68 cDNA synthesis)
preparing an admixture comprising all or part of an extract produced by lysing the biological unit (see p. 68 preparation of RNA) and the catabolic enzyme (see p. 68 cDNA synthesis);
incubating the admixture at a temperature where the catabolic enzyme is active and adding the reverse transcriptase to all or part of the admixture comprising the extract of the biological unit and the catabolic enzyme and incubating the admixture under conditions where the reverse transcriptase is active wherein the cDNA is produced and wherein the method does not involve the isolation of RNA prior to the production of DNA (see p. 68 cDNA synthesis, where the phrase “wherein the method does not involve the isolation of RNA prior to the production of the cDNA” is interpreted as mechanically separating the RNA, with for example a filter, from any contaminating substances such as DNA prior to the start of reverse transcription. Here Baum and Strobel teach lysing brain cells (a biological unit) to form an extract. Baum and Strobel phenol extract the RNA from the cell lysate. The phenol extraction, however meets the limitation *of part* of an extract from a biological unit. The phenol extracted RNA is part of an extract and contains some DNA and the DNA is digested with a DNase (a catabolic enzyme) and RT-PCR (requiring a reverse transcriptase) is performed to produce cDNA. The RNA has

never been mechanically separated prior to the production of cDNA).

(Ans. 3-4.)

In response, Appellant contends that Baum removes RNA from brain tissue prior to cDNA production by precipitation. (App. Br. 6.) Appellant argues that the claimed method does not involve the isolation of RNA from the extract prior to the production of cDNA. (Br. 6.) In support of Appellant's position, Appellant puts forth the Declaration of Ellington which evidences that the RNA Stat-60 procedure described in Baum and Strobel provides for isolation of the RNA from biological samples before making cDNA. (Ellington Declaration ¶ 11.) In particular, the aqueous phase of the phenol extraction using RNA Stat-60 precipitates RNA which is transferred to a fresh tube. (App. Br. 10-11.)

Thus, Appellant has provided evidence that Baum and Strobel teach isolation or mechanical separation of RNA, i.e., removing RNA from the extract prior to the production of the cDNA.

The Examiner does not contest the teachings of Baum and Strobel, but rather finds that the issue revolves around the interpretation of the claimed embodiments. (Ans. 13.) The limitation "wherein the method does not involve the isolation of RNA prior to the production of the cDNA" is interpreted by the Examiner to mean "mechanically separating the RNA, with for example a filter, from any contaminating substances such as DNA prior to the start of reverse transcription." (Ans. 13.)

Even if we were to accept the Examiner's claim interpretation, we find that Baum and Strobel teaches mechanical separation of RNA using the

RNA-Stat-60 product which precipitates RNA and transfers it to a fresh tube. (Baum and Strobel, p. 68, col. 2.)

Thus, based on the evidence before us, we do not find the examiner has provided sufficient evidence to support a *prima facie* case of anticipation of the claimed subject matter as the prior art fails to disclose the limitation “wherein the method does not involve the isolation of RNA prior to the production of the cDNA”. The anticipation rejection is reversed.

2. Claims 6, 7, 9, 14, 15, 19, 26, 28, 38, 43, 44, 48, 49, 71-75, and 78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Stroebel in view of Reardon.

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6. Claims 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Strobel in view of Reardon and New England Biolabs.

7. Claim 31 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Baum and Strobel in view of Reardon and Kudlicki.

Each of the above rejections (2)-(7) rely on the primary reference Baum and Strobel. For the reasons indicated herein we do not find that

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Baum and Strobel discloses the limitation “wherein the method does not involve the isolation of RNA prior to the production of the cDNA”. We do not find that the cited secondary references overcome this deficiency of Baum and Strobel. In view of the above, the obviousness rejections (2)-(7) are reversed.

SUMMARY

The anticipation and obviousness rejections are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REVERSED

Ssc:

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