

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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*Ex parte* STEPHEN R. HANN

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Appeal 2009-002068  
Application 10/997,763  
Technology Center 1600

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Decided:<sup>1</sup> June 30, 2009

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Before TONI R. SCHEINER, DONALD E. ADAMS, and STEPHEN  
WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to a substance screening assay. The Patent Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

## STATEMENT OF THE CASE

Claims 1-15, which are all the pending claims, are on appeal. Claim 1 is representative and reads as follows:

1. A method of screening a candidate substance comprising:
  - (a) providing an isolated c-Myc polypeptide;
  - (b) mixing said c-Myc polypeptide with a candidate substance;
  - (c) mixing the mixture of step (b) with p19Arf polypeptide; and
  - (d) measuring the binding of p19Arf and c-Myc polypeptides,

wherein a decrease in p19Arf polypeptide binding to c-Myc polypeptide, as compared to the binding of p19Arf polypeptide to c-Myc polypeptide in the absence of said candidate substance, identifies said candidate substance as a p19Arf mimic.

The Examiner rejected the claims under 35 U.S.C. § 103(a) as obvious over the combined teachings of Sherr,<sup>2</sup> Matsumura<sup>3</sup> and Eischen.<sup>4</sup>

## OBVIOUSNESS

### *The Issue*

The Examiner's position is that Sherr disclosed the Arf polypeptide, screening assays for mimics of Arf, and that Myc and Arf interact. (Ans. 4.) The Examiner concluded "it would have been obvious to combine the 'drug screening' method disclosed in Sherr et al. to identify candidate substances

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<sup>2</sup> U.S. Patent No. 6,586,203 B1, issued to Sherr et al., Jul. 1, 2003.

<sup>3</sup> Itaru Matsumura et al., *E2F1 and c-Myc in Cell Growth and Death*, 2 CELL CYCLE 333-38 (2003).

<sup>4</sup> Christine M. Eischen et al., *Disruption of the ARF-Mdm2-p53 tumor suppressor pathway in Myc-induced lymphomagenesis*, 13 GENES & DEVELOPMENT 2658-69 (1999).

that mimic p19Arf by measuring the interaction of p19Arf and c-Myc in the presence/absence of candidate substances based on the teachings of Matsumura et al. and Eischen et al.” (*Id.* at 5.)

Appellant disputes the Examiner’s finding that p19Arf and c-Myc were known to “physically interact.” (App. Br. 4.) Appellant contends that Sherr’s Fig. 25, on which the Examiner relied, “merely shows that MYC has an *effect* on ARF-p19, not that there is any binding between these two molecules.” (*Id.*) “If anything, Sherr suggests that MYC interacts with the p19-ARF *promoter*, not p19-ARF itself.” (*Id.*) Further, according to Appellant, neither Matsumura nor Eischen provides “the teaching clearly missing from Sherr, namely, that p19-ARF and Myc physically interact.” (*Id.*)

The issue with respect to this rejection is whether the evidence supports the Examiner’s finding that Sherr taught interaction between p19Arf polypeptide and c-Myc polypeptide.

### *Findings of Fact*

#### Sherr

1. Sherr disclosed that “ARF is activated via MYC and E2F-1 and acts in turn to trigger p53-dependent cell cycle arrest or apoptosis.” (Col. 16, ll. 22-24.)
2. Sherr explained that “[a]ctivation of ARF by MYC and E2F-1 need not be direct, although both transcription factors have been demonstrated to increase ARF mRNA levels.” (Col. 16, ll. 28-32.)

3. Sherr further disclosed that “[o]verexpression of MYC induces the accumulation of p19<sup>ARF</sup>, at least in part by increasing ARF gene expression.” (Col. 81, ll. 49-51.)
4. Sherr stated that ARF protein binds mdm and p53 proteins. (Col. 68, ll. 32-38.)

#### Matsumura

4. According Matsumura’s diagram on page 335, Myc has an effect on ARF via transcriptional regulation.
5. Matsumura disclosed that c-Myc and E2F1 “induce p14/p19<sup>ARF</sup> that inhibits MDM2-mediated degradation of p53.” (p. 335, right col.)
6. Matsumura further described the induction process: “[i]n this process, c-Myc and E2F1 upregulate the protein expression level of DAP kinase, a calcium-regulated serine/threonine kinase, which in turn induces the expression of p14/p19<sup>ARF</sup>.” (p. 335, right col.)

#### Eischen

7. Eischen disclosed that “Myc rapidly induces p19<sup>ARF</sup> expression, but without evidence that Myc transactivates the ARF promoter, its action may be indirect.” (p. 2659, Fig. 1 legend.)
8. Eischen further disclosed that “p19<sup>ARF</sup> binds directly with Mdm2 to neutralize its function.” (p. 2659, Fig. 1 legend.)

*Principles of Law*

Obviousness is a question of law based on fact findings. The scope and content of the prior art are determined; differences between the prior art and the claims at issue are ascertained; the level of skill in the art is resolved; and objective record evidence of nonobviousness is considered. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). A rejection for obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

*Analysis*

The claimed method of screening candidate substances includes a step “measuring the binding of p19Arf and c-Myc polypeptides.” When a candidate substance is being tested, a decrease from the standard amount of binding between the p19Arf and c-Myc polypeptides will indicate that the candidate substance is a p19Arf mimic.

In order for the claimed screening method to have been obvious to a person having ordinary skill in the art at the time Appellant invented the method, that person must have known that p19Arf polypeptide binds to c-Myc polypeptide. The Examiner found the binding information disclosed in Sherr. Appellant disputes the finding. We agree with Appellant.

The Examiner cited Sherr’s Fig. 25 as evidence that p19Arf and c-Myc polypeptides interact, but Sherr’s explanation of Fig. 25 does not support the Examiner’s inference that Sherr meant the polypeptides interact by binding to each other. Instead, Sherr explained that Myc is a

transcription factor that induces Arf gene expression. (FF2, FF3.) In a separate section on protein interactions, Sherr disclosed that p19Arf polypeptide binds to the mdm and p53 proteins, but did not disclose that p19Arf protein binds to the Myc protein. (FF4.) Matsumura and Eischen repeated Sherr's description of Myc as a transcription factor, but neither disclosed that Myc polypeptide binds to p19Arf polypeptide. (FF4, FF7.) Eischen repeated Sherr's disclosure that p19Arf protein binds to Mdm protein. (FF8.)

The portions of Sherr's disclosure that the Examiner cited do not support a finding that Sherr taught binding between p19Arf polypeptide and c-Myc polypeptide. We agree with Appellant that the claimed method could not have been obvious without the knowledge that p19Arf polypeptide and c-Myc polypeptide bound to each other. (Reply Br. 3.) We conclude that the evidence developed on this record under the first *Graham* factor is insufficient to support a conclusion of obviousness.

#### CONCLUSIONS OF LAW

Appellant established that the evidence of record does not support the Examiner's finding that Sherr taught a binding interaction between p19Arf polypeptide and c-Myc polypeptide.

#### SUMMARY

We reverse the rejection of claims 1-15 under 35 U.S.C. § 103(a) as obvious over the combined teachings of Sherr, Matsumura and Eischen.

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REVERSED

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