

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte NOUBAR B. AFEYAN and NEAL F. GORDON

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Appeal No. 1997-2373  
Application 08/333,880

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH 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 1, 2, 4, 5, 19, 20, and 22-32. Claims 1 and 29 are representative and read as follows:

1. An apparatus for the separation of proteins in a sample, said apparatus comprising  
  
sample solution input means,  
  
a first liquid chromatography column,

at least one multiport injection valve connecting said sample solution input means to said column,

a second liquid chromatography column in communication with a said multiport injection valve, said second column being operative successively with or alternatively to said first column,

at least one of said first and second columns being packed with a particulate chromatography material comprising perfusive particles which permit convective fluid transport both within and between the particles, or non-porous particles, thereby to confer on said column a chromatographically effective mobile phase transit time therethrough less than five minutes,

pump means for providing variable pressure delivery of solutions to said columns via a said multiport valve,

plural solution reservoirs,

a mixing valve, connecting said solution reservoirs to said columns, operative to mix solutions from said reservoirs, and

program means for specifying a sequence of system control programs, the mixing of solution by said mixing valve, and the delivery of said mixed solution to said columns via a said multiport injective valve.

29. An apparatus for the quantitative detection of proteins in a sample, comprising

first and second multiport valves, each said valve comprising a sample loop which holds a defined volume of sample and connects two ports of said valve;

a liquid chromatography column in communication with a said valve, said column being packed with a particulate chromatography material comprising perfusive particles which permit convective fluid transport both within and between the particles, or non-porous particles, thereby to confer on said column a chromatographically effective mobile phase transit time therethrough less than five minutes;

a sample feed line in communication with each said valve;

detector means in communication with said column for detecting output; and

control means for operating said multiport valves to switch between

a collection line comprising said sample feed line, wherein plural sample volumes are introduced into said sample loops and

a detection line comprising said chromatography column, wherein one sample volume is passed directly through said detector means and another is passed through said column and said detector means.

The examiner relies on the following references:

Mowery Jr.	4,271,697	Jun. 09, 1981
Cazer et al. (Cazer)	5,071,547	Dec. 10, 1991

Afeyan et al. (Afeyan), "Perfusion Chromatography, An Approach to Purifying Biomolecules," Bio/Technology, Vol. 8, pp. 203-206 (1990)

Claims 1, 2, 4, 5, 19, 20, and 22-28 stand rejected under 35 U.S.C. § 103 as obvious over the combined disclosures of Cazer and Afeyan.

Claims 29-32 stand rejected under 35 U.S.C. § 103 as obvious over the combined disclosures of Mowery and Afeyan.

We reverse.

#### Discussion

The claims are directed to a chromatographic apparatus having, inter alia, a chromatography column comprising "a particulate chromatography material comprising perfusive particles," together with the other features set out in representative claims 1 and 29. The examiner rejected claims 1, 2, 4, 5, 19, 20, and 22-28 as obvious over Cazer and Afeyan, and rejected claims 29-32 as

obvious over Mowery and Afeyan. The examiner's rationale in both rejections was similar: Cazer and Mowery teach chromatography systems and Afeyan teaches a perfusive chromatography medium. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art to combine the perfusive particles disclosed by Afeyan with the chromatography system of either Cazer or Mowery, because Afeyan teaches that the perfusive matrix enhances productivity without compromising resolution. Examiner's Answer, pages 4 and 6.

The examiner appears to concede that Cazer "does not teach the valve arrangement as claimed [in claim 1], i.e., mixing valve connecting the solution reservoirs to the columns." Examiner's Answer, pages 3-4. The examiner nonetheless concluded that the claimed apparatus would have been obvious because "it would have been obvious to the ordinarily skilled artisan at the time the invention was made to have provided a mixing valve in the embodiment of Cazer et al. in which multiple solutions are mixed together prior to mixing with the sample for injection into the columns." Id., page 5. The examiner argues that

[t]he arrangement of the valves are [sic] not patentably distinctive features since Cazer et al. teaches that the multi-port and multi-modal valves are arranged in a way to . . . convey pumped fluid, sample mixed with a mobile phase or mobile phase alone, to the columns and the detector, which function is that required by the instant invention, and since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70 [(CCPA 1950)].

Examiner's Answer, page 5.

The examiner also rejected claims 29-32 as obvious over Mowery and Afeyan. Claims 29-32 require that part of the sample volume be passed directly through a detector means and that another part of the sample be passed through a chromatography column and the detector means. The examiner argues that the language of the claims “reads on the device of Mowery wherein when the multiport valve is switched[,] a sample is forced out to the detector and a second sample which was held in the sample loop goes to the chromatography column and subsequently to the detector.” Examiner’s Answer, page 14.

“In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.” In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). “Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.’ Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious ‘modification’ of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” Id. at 1266, 23 USPQ2d at 1783 (citations omitted, emphasis in original).

Here, the examiner has acknowledged that both the Cazer apparatus and the Mowery apparatus must be modified in order to meet the limitations of the

instant claims. Cazer's apparatus does not include the mixing valve required by claim 1, although it does contain a "solvent selection zone **37** for selection, mixing, or combining of the solvent mobile phases." See column 12, lines 42-44. The examiner argues that the skilled artisan would have found it obvious to include a mixing valve in the disclosed apparatus, and that a mixing valve is not a patentably distinctive feature, but she cites nothing in the references that would have suggested a mixing valve to those skilled in the art.

Similarly, Mowery's apparatus does not contain "a detection line . . . , wherein one sample volume is passed directly through said detector means and another is passed through [the] column and said detector means," as required by claim 29. The examiner argues that Mowery's device could be modified to operate in such a way but again cites nothing in the prior art that would have led a person skilled in the art to so modify the device.

The rationale relied on by the examiner does not support a prima facie case of obviousness. Even though Cazer's apparatus could be modified to include a mixing valve in the solvent selection zone, and Mowery's apparatus could be modified to send part of the sample volume directly to the detector, it would not have been obvious to so modify the prior art devices, unless there was motivation to do so. The examiner has pointed out nothing in the prior art that would have led a person of ordinary skill to make the necessary modifications. The cited references therefore do not establish prima facie obviousness.

One final note: the examiner has cited the case of In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950), for the supposed rule that "rearranging parts of

an invention involves only routine skill in the art.” Examiner’s Answer, page 5. She has also cited In re Venner, 262 F.2d 91, 120 USPQ 192 (CCPA 1958), for the supposed rule that it is obvious to automate a formerly manual process. Examiner’s Answer, page 11. We take this opportunity to point out that there are no per se rules of unpatentability. See In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) (“The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention—including all its limitations—with the teachings of the prior art, flouts section 103 and the fundamental case law applying it.”); In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966) (“[I]t is facts appearing in the record, rather than prior decisions in and of themselves, which must support the legal conclusion of obviousness under 35 U.S.C. § 103.”). Each claimed invention must be considered on its own merits and in every instance, the test for patentability under § 103 is the same: “whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention.” In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

Summary

We reverse the rejection of the claims under 35 U.S.C. § 103 because the prior art does not provide the required “reason, suggestion, or motivation” to modify the prior art chromatography systems as required by the instant claims.

REVERSED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
William F. Smith	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Eric Grimes	)	
Administrative Patent Judge	)	

EG/dm

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Application No. 08/333,880

Testa, Hurwitz & Thibeault  
Patent Administrator  
High Street Tower  
125 High Street  
Boston, MA 02100