

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INFOPIA CO., LTD.,
Petitioner,

v.

POLYMER TECHNOLOGY SYSTEMS, INC.,
Patent Owner.

Case IPR2015-01109
Patent 7,087,397 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Infopia Co., Ltd. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 7,087,397 B2 (Ex. 1001, “the ’397 patent”). Paper 1 (“Pet.”). Polymer Technology Systems, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims of the ’397 patent. Accordingly, we deny institution of *inter partes* review in this proceeding.

A. *Related Proceeding*

The parties identify a related district court litigation pending in the Central District of California, in which Petitioner is a party, involving the ’397 patent: *Polymer Technology Systems, Inc. v. Jant Pharmacal Corp.*, Case No. 2:15-CV-02585-JAK-E (C.D. Cal.). Pet. 2; Paper 6, 1.

Additionally, Petitioner has also filed a separate petition for *inter partes* review in Case IPR2015-01192, challenging claims 19 and 20 of the ’397 patent. We issue our decision denying institution in that proceeding concurrently with our decision here.

B. *The ’397 Patent (Ex. 1001)*

The ’397 patent relates to a blood separation mechanism for a blood test strip to determine component analyte amounts, more particularly, to determine the level of HDL cholesterol in whole blood. Ex. 1001, 4:41–43.

As noted in the Background section of the '397 patent, “[t]he level of cholesterol in blood is a significant indicator of risk of coronary heart disease.” *Id.* at 1:21–22. However,

[t]he level of total cholesterol in blood, which is a measure of the sum total of HDL, LDL, VLDL and chylomicrons, is not generally regarded as an adequate indicator of the risk of coronary heart disease because the overall level of total cholesterol does not reveal the relative proportions of HDL, LDL and VLDL. To better assess the risk of heart disease, it is desirable to determine the amount of HDL cholesterol in addition to total cholesterol.

Id. at 1:30–37.

The '397 patent explains that, when measuring HDL cholesterol, “two significant treatment steps to a whole blood sample are usually necessary.” *Id.* at 1:38–40. First, erythrocytes (i.e. red blood cells) must be separated from the whole blood sample to produce plasma. *Id.* at 1:40–43. “Second, non-HDLs (i.e., LDL, VLDL and chylomicrons) must be removed from the plasma to be tested because reagents used to determine the level of HDL will also react with LDL and VLDL.” *Id.* at 1:43–46. The invention described in the '397 patent achieves this using a “multilayer vertical flow test strip” with a first glass fiber matrix layer that separates the blood cells and a second layer that “precipitates and retains non-HDL cholesterol.” *Id.* at 4:41–52.

In contrast to the prior art teaching “that two layers and two associated process steps are necessary to precipitate and separate non-HDLs from plasma,” the inventors of the '397 patent found that “a single, substantially uniform layer” can be used for the separation of non-HDLs from HDLs. *Id.* at 10:49–65; *see also id.* at 5:56–61. Figure 1 of the '397 patent is

reproduced below:

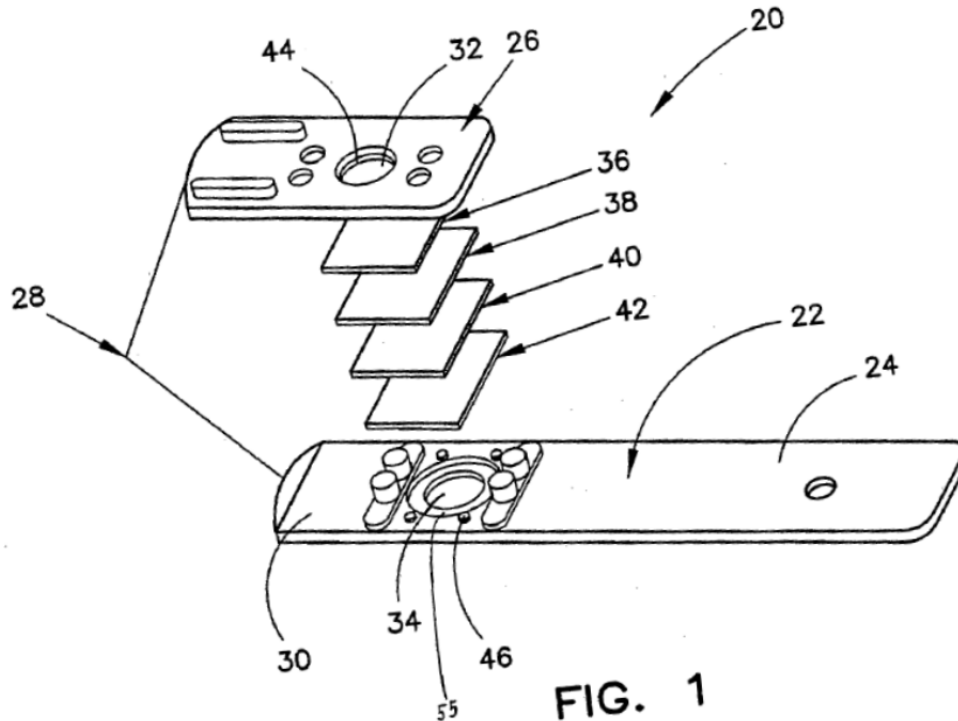


Fig. 1 is an exploded perspective view of a test strip in accordance with the invention described in the '397 patent, showing 1) disbursement or spreader layer 36 that provides a more uniform distribution of blood to the subjacent layer, 2) red blood separation layer 38, which is generally a glass fiber matrix, 3) non-HDL separation layer 40, and 4) reaction layer 42 that generates a visible color change when cholesterol is present. *Id.* at 6:9–12, 8:41–66.

C. Illustrative Claim

Petitioner challenges claims 1–18 of the '397 patent in this proceeding. Independent claim 1 is illustrative and is reproduced below:

1. A method of determining concentration of HDL cholesterol in a whole blood sample containing non-HDL cholesterol, said method comprising:
 - a) providing a test strip holder and a test strip; said test strip holder including an application window and a rest reading

window, said windows comprising vertically aligned openings in said holder; said test strip comprising a layered stack comprising a red blood cell separation layer, a non-HDL separation chemistry layer, and an HDL reaction layer; said non-HDL cholesterol separation chemistry layer containing non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in the reaction in said HDL reaction layer; said HDL reaction layer containing chemicals for reacting with said HDL, said layers arranged in a vertical stack with said HDL reaction layer at the bottom of said stack; said test strip located in said test strip holder between said windows, with said reaction layer adjacent said test reading window;

- b) applying blood to the top of said stack through said application window and permitting fluid from said blood to flow vertically downward in said stack to said HDL reaction layer without substantial lateral migration of fluid below said red blood cell separation layer;
- c) separating said red blood cells from a fluid portion of said blood;
- d) separating said non-HDL cholesterol from said HDL cholesterol with said non-HDL cholesterol separation chemicals;
- e) reacting said HDL with said chemicals in said HDL reaction layer; and
- f) reading a property of said reaction layer through said reading window to determine said concentration of HDL cholesterol.

Id. at 24:9–44.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–18 of the '397 patent for obviousness based on the following combination of references (Pet. 31–60):

References	Basis	Claims challenged
Connolly, ¹ Patel, ² and Kozak ³	§ 103	1, 3, 4, 5, and 10–18
Connolly, Patel, Kozak, Kitajima, ⁴ and Kawaguri ⁵	§ 103	2, 6
Connolly, Patel, Kozak and Jeng ⁶	§ 103	7
Connolly, Patel, Kozak, Jeng and Grage ⁷	§ 103	8
Connolly, Patel, Kozak, Jeng, Grage and Neyer ⁸	§ 103	9
Carroll, ⁹ Patel, and Kozak	§ 103	1, 3, 4, and 10–18
Carroll, Patel, Kozak, Kitajima, and Kawaguri	§ 103	2, 5, and 6

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). The Board, however, may not “construe claims during IPR so broadly that its constructions are *unreasonable* under general claim

¹ U.S. Patent No. 5,597,532, issued Jan. 28, 1997 (Ex. 1015, “Connolly”).

² U.S. Patent No. 5,215,886, issued June 1, 1993 (Ex. 1014, “Patel”).

³ U.S. Patent No. 5,460,974, issued Oct. 24, 1995 (Ex. 1007, “Kozak”).

⁴ U.S. Patent No. 5,876,605, issued Mar. 2, 1999 (Ex. 1016, “Kitajima”).

⁵ U.S. Patent No. 5,171,689, issued Dec. 15, 1992 (Ex. 1017, “Kawaguri”).

⁶ U.S. Patent No. 5,064,541, issued Nov. 12, 1991 (Ex. 1018, “Jeng”).

⁷ U.S. Patent No. 5,968,765, issued Oct. 19, 1999 (Ex. 1019, “Grage”).

⁸ U.S. Patent No. 5,762,871, issued June 9, 1998 (Ex. 1020, “Neyer”).

⁹ U.S. Patent No. 6,040,195, issued Mar. 21, 2000 (Ex. 1008, “Carroll”).

construction principles. . . . [T]he protocol of giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citation omitted). Rather, “claims should always be read in light of the specification and teachings in the underlying patent.” *Id.* (citations omitted). The broadest reasonable interpretation must “take[] into account any definitions presented in the specification.” *In re Bass*, 314 F.3d 575, 577 (Fed. Cir. 2002)(citation omitted).

1. “non-HDL” (claim 1)

The claims require a “non-HDL separation chemistry layer” that “contain[s] non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in said HDL reaction layer.” Ex. 1001, 24:17–23. The Specification defines “[n]on-HDL” as “LDL, VLDL and chylomicrons, i.e., lipoproteins other than HDL that will react with a conventional cholesterol reaction membrane.” *Id.* at 7:38–40. The Specification further states in the Background Section that “non-HDLs (i.e., LDL, VLDL and chylomicrons) must be removed from the plasma to be tested because reagents used to determine the level of HDL will also react with LDL and VLDL.” *Id.* at 1:43–46. In view of these statements in the Specification, Patent Owner asserts that the patentee acted as its own lexicographer in defining the term. Prelim Resp. 13–14.

Consistent with the express definition provided in the Specification, we construe “non-HDL” as “LDL, VLDL and chylomicrons.”

2. Other Claim Terms

We determine that, for purposes of this Decision, none of the other terms in the challenged claims requires express construction.

B. Analysis

Petitioner asserts that independent claim 1 is rendered obvious by the combination of Connolly or Carroll with Patel and Kozak. Pet. 31, 49. In order to satisfy the claim requirement of a non-HDL separation chemistry layer, Petitioner relies upon the teachings of Patel and Kozak. *Id.* at 33, 50. Despite the express definition of “non-HDL” provided in the Specification, as discussed above, Petitioner does not address chylomicrons at all in the Petition. Rather, Petitioner only points to the teachings of Patel and Kozak of removing VLDL and LDL fractions using a filter. *Id.* (citing Ex. 1014, 3:3–9, 6:48–55; Ex. 1007, 24:11–21, Fig. 4). Petitioner does not identify any other prior art teaching regarding the separation of chylomicrons, nor has Petitioner alleged that chylomicrons would inherently be removed by using any of the prior art devices. Moreover, Petitioner has not alleged that the separation of chylomicrons, in addition to LDL and VLDL, would otherwise have been obvious.¹⁰ Because we construe the claims to require the separation of all three types of lipoproteins defined as “non-HDL” (i.e., LDL, VLDL, and chylomicrons) by the non-HDL separation chemistry layer, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on any of the grounds presented.

III. CONCLUSION

We conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that any of claims 1–18 of the ’397 patent are unpatentable for obviousness.

¹⁰ The ’397 patent Specification describes that “reagents used to determine the level of HDL will also react with LDL and VLDL.” Ex. 1001, 1:43–46. Petitioner, however, does not argue that the reagents would not react with chylomicrons or that the removal of chylomicrons is unnecessary to satisfy the claim requirements.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is DENIED, and no trial is instituted.

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