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for publication and is not binding precedent of the Board.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. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER WILDING, and LARRY J. KRICKA

Appeal No. 2003-1103
Application No. 09/212,029

ON BRIEF

Before SCHEINER, MILLS, 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 12-15, 23, 39, 40, and 44-47.[1] Claim 44 is representative and reads as follows:

44. A device for amplifying a preselected polynucleotide in a sample by conducting a polynucleotide polymerization reaction, the device comprising:

a solid substrate microfabricated to define:

a sample inlet port; and

a mesoscale flow system comprising:

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[1] Claims 24 and 41 are also pending. The examiner has indicated that these claims would be allowable if rewritten to eliminate their dependence on rejected claims. See Paper No. 11, mailed Sept. 26, 2000, page 5.

a sample flow channel having a cross-section and extending from said inlet port; and

a polynucleotide polymerization reaction chamber having a cross-section and being in fluid communication with said flow channel, said chamber containing reagents for the polymerization reaction, said flow channel and said reaction chamber having at least one cross-sectional dimension of width or depth which is between about 0.1 to 500 µm said reaction chamber cross-section and said flow channel cross-section being dissimilar;

means for thermally regulating the contents of said chamber whereby the temperature is controlled to amplify said preselected polynucleotide; and

means for detecting said amplified polynucleotide.

The examiner relies on the following references:

Schnipelsky et al. (Schnipelsky)	5,229,297	Jul. 20, 1993
Wilding et al. (Wilding)	5,498,392	Mar. 12, 1996

Claims 12-15, 23, 39, 40, and 44-47 stand rejected under 35 U.S.C. § 102(e) as anticipated by Schnipelsky.

Claims 44 and 46 stand rejected for obviousness-type double patenting over claim 15 of Wilding.

We reverse.

Background

The specification discloses devices for amplifying a preselected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. Specification, page 50. In this field, methodologies for using polymerase chain reaction ("PCR") to amplify a segment of DNA are well

established. Id., page 3. "PCR amplification has been applied to the diagnosis of genetic disorders . . ., the detection of nucleic acid sequences of pathogenic organisms in clinical samples . . ., the genetic identification of forensic samples, e.g. sperm . . ., the analysis of mutations in activated oncogenes . . . and in many aspects of molecular cloning." Id., page 4. The invention:

> provide[s] analytical systems with optimal reaction environments that can analyze microvolumes of sample, detect very low concentrations of a polynucleotide, and produce analytical results rapidly[,] . . . provide[s] easily mass produced, disposable, small (e.g., less than 1 cc in volume) devices having mesoscale functional elements capable of rapid, automated PCR analyses of a preselected cell or cell-free sample, in a range of applications[, and] . . . provide[s] a family of such devices that individually can be used to implement a range of rapid clinical tests, e.g., tests for viral or bacterial infection, tests for cell culture contaminants, or tests for the presence of recombinant DNA or a gene in a cell, and the like.

Id., page 5.

Discussion

The claims stand or fall together because appellants have not argued to the contrary in either the Appeal Brief or the Reply Brief. Also, because multiple claims have been rejected on the same basis, we have chosen claim 44 as representative of the rejected claims. See 37 CFR § 1.192(c)(7).

1. The rejection under 35 U.S.C. § 102(e).

The examiner rejected claims 12-15, 23, 39, 40, and 44-47 as anticipated by Schnipelsky. Examiner's Answer, page 3. The examiner characterized Schnipelsky as disclosing a device meeting the limitations of the instant claims

and a method of using the device to amplify a preselected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. See id., pages 3-4.

Specifically, the examiner found that Schnipelsky discloses a device that includes:

> an inlet port, flow channel, amplification reaction chamber, and detection chamber, particularly depicted in Figure 1 and discussed in detail in column 1, line 20, through column 20, line 31. The inlet port and flow channel is [sic] described in column 10, lines 8-12. Detection chamber practice with induced flow is specifically cited in column 10, line 62, through column 11, line 47.

Examiner's Answer, pages 3-4. Further, the examiner found that Schnipelsky discloses at least one mesoscale dimension in column 11, lines 20-30. This paragraph refers to the reaction compartment (number 26 in Figure 5) and states that: "Even with layer 66 present, the thermal path length of compartment 26 is no more than about 0.3 mm." Schnipelsky, column 11, lines 20-30. A thermal path length of "no more than 0.3 mm" is the same dimension as "no more than 300 µm." Examiner's Answer, page 5. The examiner specifically noted that compartment 26 in Figure 5 is the "interior liquid reaction chamber compartment and not the layers of material which surround the compartment." Id. Therefore, the examiner concluded that "the reference does disclose mesoscale dimensions which fall within the sizes of the instant claims." Id., page 6.

Appellants do not dispute that Schnipelsky discloses most of the claim limitations as recited by the examiner. Instead, Appellants' argument focuses on the specific size limitation of the flow channel and reaction chamber:

"Schnipelsky et al. provides no disclosure which satisfies the claim recitation 'said flow channel and said reaction chamber having at least one cross-sectional dimension of width or depth which is between about 0.1 to 500 µm.'" Appeal Brief, page 11. Appellants contend that Schnipelsky is silent regarding these dimensions. Id. Appellants argue that the dimensions, listed in column 11, lines 20-30 of Schnipelsky and noted by the examiner in the final rejection on page 4, are the dimensions of the "materials of construction," and are "not the dimensions of the flow channel and reaction chamber required in appellants' claims." Appeal Brief, page 12 (emphasis in original). The focal point of appellants' argument is that the examiner has "misinterpreted the meaning of 'thermal path length'" as used by Schnipelsky. Reply Brief, page 3. Appellants refer to column 8, lines 26-61, where thermal path length is first discussed:

> Considering first the preferred thermal transfer mechanism, namely the passive transfer wall of the compartment, the material of such wall is selected to provide a predetermined thermal path length and thermal resistance that will provide a high rate of thermal energy transfer. Most preferably, such path length is no greater than about 0.3 mm . . . . These properties are readily achieved by constructing the thermal transfer wall out of a plastic, or a laminate of plastic and metal such as aluminum that is about 0.05 mm thick.

Reply Brief, page 4 (quoting Schnipelsky, column 8, lines 26-37) (emphasis added in Reply Brief). Based on this disclosure, appellants contend that the term "thermal path length" refers to the "material of construction used for the thermal transfer wall . . . not . . . the internal dimensions of the reaction compartment, or a flow channel or any other void space within the device." Reply Brief, page 5.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). We conclude that appellants' interpretation of the disputed claim limitation is more reasonable and therefore reverse the examiner's rejection. We agree with appellants' argument that the term "thermal path length" as used in Schnipelsky refers to the thickness of the wall of the reaction chamber and not the internal dimensions of such chamber or the flow channel. We reach this conclusion based on three disclosures in the reference.

First, as noted by appellants, Schnipelsky refers to the thermal path length as a characteristic of the material of construction used for the thermal transfer wall that separates the reaction compartment from the heat source. See column 8, lines 26-29: "Considering first the preferred thermal transfer mechanism, namely the passive transfer wall of the compartment, the material of such wall is selected to provide a predetermined thermal path length." (Emphasis added).

Second, Schnipelsky discusses the layers that may make up the wall of the reaction chamber (compartment 26). It states:

> At least for compartment 26, sheet 14 [,which represents one of the walls,] can comprise a laminate of an aluminum foil 64 on the outside, FIG. 5, and a polymer layer 66 on the inside, preferably a layer of polyester, like sheet 12. The aluminum foil preferably has a thickness of between about 0.0013 cm and about 0.026 cm, and most preferably about 0.005 cm. Layer 66 has a thickness of between about 0.0013 and about 0.03, and most preferably about 0.005 cm. Even with layer 66 present, the thermal path length of compartment 26 is no more than about 0.3 mm.

Column 11, lines 20-29. We agree with appellants that "the clear implication of the disclosure at column 11, line 28 of Schnipelsky et al., when properly considered in context and taking into account all of the relevant disclosure . . . [as discussed above], is that even when the thermal transfer wall is laminated, its thermal path length (or wall thickness) is no more than about 0.3 mm, which is entirely consistent with the earlier disclosure in column 8." Reply Brief, page 5. Specifically, the disclosure in column 8, line 35-36, refers to "constructing the thermal transfer wall out of a plastic, <u>or</u> a laminate of plastic and metal." Schnipelsky, column 8, lines 35-36 (emphasis added). This means that the thermal transfer wall may be constructed out of plastic alone. As the reference discloses, the plastic layer can range in thickness up to 0.03 cm. See Schnipelsky, column 11, lines 25-26. Even at its maximum thickness of 0.03 cm, the thermal transfer wall constructed out of plastic alone is still "no more than about 0.3 mm," which is equivalent to 0.03 cm. <u>Id.</u>, column 11, line 29. Therefore, we agree with appellants that this disclosure "does not indicate any contrary meaning" to that of the first disclosure discussed above. Reply Brief, page 5.

Finally, claim 4 of Schnipelsky in column 22, lines 19-22, specifically refers to the method of claim 3, "wherein said <u>wall</u> has a <u>thermal path length</u> of no more than about 0.3 mm." Schnipelsky, column 22, lines 19-20 (emphasis added). This third disclosure, specifically referring to the "wall" and a "thermal path length of no more than about 0.3 mm" is quite telling. Schnipelsky's claim 4 provides further evidence that the term "thermal path length" as used by Schnipelsky,

columns 8 and 11, refers to the thickness of the thermal transfer wall, and "not the dimensions of the flow channel and reaction chamber required in appellants' claims 12-15, 23, 39, 40 and 44-47." Appeal Brief, page 12.

Therefore, because Schnipelsky does not contain all of the limitations of appellants' claims, it cannot anticipate. For the reasons discussed above, the rejection under 35 U.S.C. § 102(e) is reversed.

2. Obviousness-type double patenting

The examiner rejected claims 44 and 46 under the judicially-created doctrine of obviousness-type double patenting, on the basis that these claims were not patentably distinct from claim 15 of U.S. Patent No. 5,498,392. See Examiner's Answer, page 6.

The examiner reasoned that "a detection chamber [as in the '392 patent's claim 15] is reasonably a 'means' for detecting . . . amplified polynucleotide as utilized in both the instant application as well as in said Patent reference." Examiner's Answer, pages 6-7. The examiner also argues that the instant claims and claim 15 of the '392 patent are directed to devices and are "therefore . . . contained within the same restriction group and not restricted as distinct." Paper No. 11, mailed Sept. 26, 2000, page 5.

We disagree. A restriction requirement was made during the prosecution of U.S. Patent Application No. 08/308,199, the application that issued as the '392 patent. Claim 26, which became claim 15 in the '392 patent, and claim 10 were placed into two different restriction groups. Claim 10 of the '199 application was

withdrawn because of this restriction requirement. Claim 10 contained the limitation "means for detecting said amplified polynucleotide." Reply Brief, Appendix. Claims 44 and 46 in the present application contain this same limitation, "means for detecting said amplified polynucleotide." Therefore, claims 44 and 46, at least in regards to this limitation, correspond to claim 10 of the '199 application, which was withdrawn pursuant to the restriction requirement.

In this regard, the third sentence of 35 U.S.C. § 121 provides that:

> [A] patent issuing on an application with respect to which a requirement for restriction . . . has been made . . . shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application . . . if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121; see Reply Brief, page 11 (citing 35 U.S.C. § 121). The instant application satisfies these requirements because it is a continuation of the divisional application "which divisional (08/614,242) was filed before the issue date of the '392 patent." Reply Brief, page 11. Appellants also cite In re Berg, 130 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998) for the proposition that "[w]hen such a divisional application is filed, the PTO is prohibited from using the claims of the patent issuing on the application that prompted the restriction requirement as a reference against the claims of any divisional application." Id. at 1436, 46 USPQ2d at 1232. This rule applies where the claims in the two applications are maintained consonant with the restriction requirement.

> Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.

Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1440 (Fed. Cir. 1990). As stated above, withdrawn claim 10 and instant claims 44 and 46 contain the same limitation, "means for detecting said amplified polynucleotide." Reply Brief, Appendix. Because instant claims 44 and 46 are consonant with the restricted and subsequently withdrawn claim 10 of the '199 application, the '392 patent is not available as a reference for rejecting the instant claims under the judicially-created doctrine of obviousness-type double patenting. The examiner's rejection is reversed.

Summary

We reverse the rejection under 35 U.S.C. § 102(e) because Schnipelsky does not reasonably appear to disclose a device for amplifying a preselected polynucleotide in a sample by conducting a polynucleotide polymerization reaction that satisfies all of the limitations of appellants' claims. Further, we

reverse the rejection under the judicially-created doctrine of obviousness-type double patenting because the ‘392 patent was not available as a reference based on the restriction requirement made in the ‘199 application.

REVERSED

Toni R. Scheiner	)
Administrative Patent Judge	)
	)
	) BOARD OF PATENT
Demetra J. Mills	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
Eric Grimes	)
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