

**UNITED STATES PATENT AND TRADEMARK OFFICE**

---

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

---

*Ex parte* TIMOTHY HUNKAPILLER, CHERYL L. HEINER,  
CURTIS GEHMAN, JAMES LABRENZ, and SHIAW-MIN CHEN

---

Appeal 2008-3529  
Application 10/193,776  
Technology Center 1600

---

Decided: August 22, 2008

---

Before TONI R. SCHEINER, HOWARD B. BLANKENSHIP, and  
ERIC B. GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to a program storage device for use in automated DNA sequencing. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

## BACKGROUND

“Base-calling is the data analysis part of automated DNA sequencing, which takes the time-varying signal of four fluorescence intensities and produces an estimate of the underlying DNA sequence” (Spec. 1: 31-33). The Specification discloses that problems in base-calling accuracy can be addressed “by way of the addition of a calibration standard to a polynucleotide analysis (e.g., sequencing or sizing) reaction. For example, one or both of peak shape and spacing information can be usefully extracted from the standard, providing a better model of fragment migration behavior.” (*Id.* at 3: 3-6.)

The Specification states that modern DNA sequencers “are no longer limited to the four-color detection scheme typically used in DNA sequencing and fragment analysis. Therefore, standards labeled with different or ‘5th’ dyes can be added to the same separation lane as samples.” (*Id.* at 5: 23-25.) The Specification discloses that such internal standards (for example, a set of labeled polynucleotide fragments of known size) “can be used to estimate the number of bases to be found within a given separation time interval as well as a more accurate peak shape model for that region (lane and migration time) of the gel” (*id.* at 5: 29-31).

## DISCUSSION

### 1. CLAIMS

Claim 46, the only claim on appeal,<sup>1</sup> reads as follows:

---

<sup>1</sup> Claims 47 and 48 are also pending but have been withdrawn from consideration by the Examiner (Appeal Br. 5).

46. A program storage device readable by a machine, embodying a program of instructions executable by the machine to perform method steps for calibration of polynucleotide sequence data, said method steps comprising:

- (i) receiving a set of fluorescent emission intensity signals where each of said fluorescent emission intensity signals of said set is comprised of a plurality of component signals, with each of said component signals representing a respective nucleotide base or an internal standard in a multicomponent mixture including a plurality of analyte polynucleotide fragments of unknown nucleotide sequence;
- (ii) determining a first component signal corresponding to the internal standard;
- (iii) determining a second, third, fourth and fifth component signal representing the respective nucleotide bases;
- (iv) identifying features from said first component signal and determining at least one peak shape characteristic thereof,; and
- (v) generating a calibration model based at least in part on said at least one characteristic, and applying said calibration model to said second, third, fourth and fifth component signals.

## 2. ANTICIPATION

Claim 46 stands rejected under 35 U.S.C. § 102(e) anticipated by Izmailov.<sup>2</sup> The Examiner finds that “Izmailov teaches . . . a method and apparatus for sequencing of DNA using an internal calibrant” that meets all the limitations of claim 46 (Answer 3-4).

Appellants argue that Izmailov does not teach “identifying features from said first component signal and determining at least one peak shape

---

<sup>2</sup> Izmailov, U.S. Patent 6,397,150, issued May 28, 2002.

characteristic thereof,” as recited in claim 46’s step (iv) (Appeal Br. 10-11). The Examiner’s position is that “[a]lthough the reference of Izmailov teaches peak spacing, the broad definition of ‘peak-shape characteristic’ encompasses peak spacing, which has a height and a width” (Answer 5).

We agree with Appellants that the Examiner has not shown that Izmailov identically discloses the invention of claim 46. “During examination proceedings, claims are given their broadest *reasonable* interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (emphasis added).

In this case, the Specification distinguishes between peak spacing and peak shape. The Specification states, for example, that “one or both of peak shape and spacing information can be usefully extracted from the standard” (Spec. 3: 5-6), indicating that “peak shape” and “peak . . . spacing” are different characteristics. The Specification also states that in “various embodiments,” the disclosed method can comprise “(iv) locating peaks of the trace corresponding to said 5th label and determining at least one characteristic thereof, including at least one of peak shape and peak-to-peak spacing” (*id.* at 3: 29-31). Finally, the Specification states that

inclusion in the sequencing lane . . . of an internal standard . . . can provide, for example, one or more of the following:

- A spacing curve for determining how many bases should be in a given separation interval; [and]
- A lane/capillary/track and experiment-specific peak shape model (e.g. for deconvolution of the sample data).

(*Id.* at 6: 10-18.)

Prosecution history can also be relevant to claim interpretation. *See Renishaw plc v. Marposs Societa per Azioni*, 158 F.3d 1243, 1249 n.3 (Fed. Cir. 1998)(“[A]ny interpretation that is provided or disavowed in the prosecution history also shapes the claim scope.”). *See also Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002)(“[P]rosecution history . . . cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter.”).

In this case, claim 46 originally recited “identifying features from said first component signal and determining at least one characteristic thereof, including at least one of peak shape and peak-to-peak spacing” (Amendment filed Dec. 2, 2003, page 2). The Examiner rejected the claim as anticipated by Izmailov (Office action mailed Jan. 12, 2005, page 2).

Appellants amended claim 46 to recite “identifying features from said first component signal and determining at least one peak shape characteristic thereof” (Amendment filed Feb. 24, 2006, page 2) and argued that “[w]hile calibration by linearization and fitting of component signals using peak-number and -spacing data from an internal standard may be discussed in Izmailov, Izmailov does not teach calibration using the peak-shape characteristics of an internal standard.” (*Id.* at 3.) Appellants argue that the prosecution history **“clearly distinguishes peak shape from peak-spacing”** (Appeal Br. 17).

We agree with Appellants that a person of ordinary skill in the art would not interpret “at least one peak shape characteristic” to include peak

Appeal 2008-3529  
Application 10/193,776

spacing. Such an interpretation would not be consistent with the description of peak shape in the Specification or with the prosecution history of the instant application. The rejection of claim 46 as anticipated by Izmailov is reversed.

REVERSED

clj

MILA KASAN, PATENT DEPT.  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY, CA 94404