

Act and the Board's regulations, including section 400.13, and further subject to FTZ 38's 2,000-acre activation limit.

Dated: November 25, 2025.

**Elizabeth Whiteman,**  
*Executive Secretary.*

[FR Doc. 2025-21564 Filed 11-26-25; 8:45 am]

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## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

[Docket No.: PTO-P-2025-0479]

#### Grant of Interim Extension of the Term of U.S. Patent No. 8,785,125; the Aptima® HPV Assay With the Panther® System

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice of interim patent term extension.

**SUMMARY:** The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 8,785,125 ('125 patent).

**FOR FURTHER INFORMATION CONTACT:** Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-0909 or [ali.salimi@uspto.gov](mailto:ali.salimi@uspto.gov); or Andrea S. Grossman, Legal Advisor at (571) 270-3314 or email [andrea.grossman@uspto.gov](mailto:andrea.grossman@uspto.gov).

**SUPPLEMENTARY INFORMATION:** 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On November 20, 2025, Gen-Probe Incorporated, the patent owner of record of the '125 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '125 patent. The '125 patent claims the medical device known by tradename Aptima® HPV Assay with the Panther® System and a method of using this medical device. The application indicates that the approval phase "continues" for the regulatory period, as described in 35 U.S.C. 156(g)(1)(B)(ii),

for Premarket Approval (PMA) 100042/S038 for the Aptima® HPV Assay with the Panther® System and is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the '125 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it appears reasonable to expect the approval phase of the RRP to continue beyond the expiration date of the patent, *i.e.*, December 8, 2025, interim extension of the '125 patent's term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 8,785,125 is granted for a period of one year from the original expiration date of the patent.

**Charles Kim,**

*Deputy Commissioner for Patents, United States Patent and Trademark Office.*

[FR Doc. 2025-21411 Filed 11-26-25; 8:45 am]

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## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

[Docket No. PTO-P-2025-0014]

#### Revised Inventorship Guidance for AI-Assisted Inventions

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Examination guidance.

**SUMMARY:** The United States Patent and Trademark Office (USPTO) had issued inventorship guidance for AI-assisted inventions on February 13, 2024.<sup>1</sup> The USPTO hereby rescinds the previously published Inventorship Guidance for AI-Assisted Inventions and replaces it with the guidance below.

#### FOR FURTHER INFORMATION CONTACT:

Christian Hannon, Senior Patent Attorney, at 571-272-7385; or Courtney Stopp, Patent Attorney, at 571-270-5559, both with the Office of Policy and International Affairs.

#### SUPPLEMENTARY INFORMATION:

##### I. Purpose

This notice provides further guidance on the proper legal standard for determining inventorship in patent applications for AI-assisted inventions.

<sup>1</sup> Inventorship Guidance for AI-Assisted Inventions, 89 FR 10043 (Feb. 13, 2024).

## II. Recission of Prior Guidance

The guidance issued on February 13, 2024, titled "Inventorship Guidance for AI-Assisted Inventions" is rescinded in its entirety. The approach set forth in that guidance, which relied on the application of the *Pannu*<sup>2</sup> factors to AI-assisted inventions, is withdrawn. The *Pannu* factors only apply when determining whether multiple natural persons qualify as joint inventors.<sup>3</sup> *Pannu* is inapplicable when only one natural person is involved in developing an invention with AI assistance because AI systems are not persons and therefore cannot be "joint inventors" so there is no joint inventorship question to analyze.<sup>4</sup>

## III. Governing Legal Standards

The same legal standard for determining inventorship applies to all inventions, regardless of whether AI systems were used in the inventive process.<sup>5</sup> There is no separate or modified standard for AI-assisted inventions.

The Federal Circuit has held that AI cannot be named as an inventor on a patent application (or issued patent) and that only natural persons can be inventors.<sup>6</sup> Artificial intelligence systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons.<sup>7</sup>

The Federal Circuit has centered its inventorship inquiry around "conception," characterizing conception as "the touchstone of inventorship."<sup>8</sup> Conception is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."<sup>9</sup> Conception is complete when "the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan."<sup>10</sup>

<sup>2</sup> *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).

<sup>3</sup> *Id.*

<sup>4</sup> See *Thaler v. Vidal*, 43 F.4th 1207, 1212 (Fed. Cir. 2022) (holding that only a natural person(s) may be listed as an inventor(s)).

<sup>5</sup> See 35 U.S.C. 115(b)(2) (2024) (providing the standard for naming inventorship across all types of utility patent applications).

<sup>6</sup> *Thaler*, 43 F.4th at 1212.

<sup>7</sup> See *id.*

<sup>8</sup> *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (citing *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994)).

<sup>9</sup> *Id.* (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890))).

<sup>10</sup> *Id.*