

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; or Andrea S. Grossman, Legal Advisor at (571) 270-3314 or email 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, 2024.¹ 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.

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

II. Rescission 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*² factors to AI-assisted inventions, is withdrawn. The *Pannu* factors only apply when determining whether multiple natural persons qualify as joint inventors.³ *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.⁴

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.⁵ 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.⁶ 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.⁷

The Federal Circuit has centered its inventorship inquiry around "conception," characterizing conception as "the touchstone of inventorship."⁸ 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."⁹ 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."¹⁰

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

³ *Id.*

⁴ 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)).

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

⁶ *Thaler*, 43 F.4th at 1212.

⁷ See *id.*

⁸ *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)).

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

¹⁰ *Id.*

Determining inventorship is highly fact intensive.¹¹ The question is whether the natural person possessed knowledge of all the limitations of the claimed invention such that it is so “clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”¹² Analysis of conception turns on the ability of an inventor to describe an invention with particularity.¹³ Absent such a description, an inventor cannot objectively prove possession of a complete mental picture of the invention at a later time.¹⁴

IV. Inventorship Guidance for AI-Assisted Inventions

Generally, the USPTO presumes those inventors named on the application data sheet or oath/declaration are the actual inventor or joint inventors of the application.¹⁵ A rejection under 35 U.S.C. 101 and 115, or other appropriate action, should be made for all claims in any application that lists an AI system or other non-natural person as an inventor or joint inventor.

AI systems, including generative AI and other computational models, are instruments used by human inventors. They are analogous to laboratory equipment, computer software, research databases, or any other tool that assists in the inventive process. As the case law establishes, inventors may “use the services, ideas, and aid of others” without those sources becoming co-inventors.¹⁶ The same principle applies to AI systems: they may provide services and generate ideas, but they remain tools used by the human inventor who conceived the claimed invention. When one natural person is

involved in creating an invention with the assistance of AI, the inquiry is whether that person conceived the invention under the traditional conception standard set forth above in Section III.

When multiple natural persons are involved in creating an invention with AI assistance, the traditional joint inventorship principles apply, including the *Pannu* factors to determine whether each person qualifies as a joint inventor.¹⁷ Each purported inventor must “(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.”¹⁸ The fact that AI tools were used in the development process does not change the joint inventorship analysis among the human contributors.

V. Applicability of This Guidance to Design and Plant Patent Applications and Patents

35 U.S.C. 171 provides that a patent for a design may be obtained by “[w]hoever invents any new, original, and ornamental design for an article of manufacture” and that the provisions related to utility patents are applicable to design patents, except as otherwise provided (e.g., in 35 U.S.C. 172–173).¹⁹ The Federal Circuit has interpreted 35 U.S.C. 171 such that the inventorship inquiry is the same for a design patent and a utility patent.²⁰

35 U.S.C. 161 provides that a plant patent may be obtained by “[w]hoever invents or discovers and asexually reproduces” a distinct and new variety of plant.²¹ 35 U.S.C. 161 limits patent protection to plants “that were created as a result of plant breeding or other agricultural and horticultural efforts and that were created by the inventor” (emphasis in original).²² That is, to be entitled to patent protection, the inventor of a plant must have contributed to the creation of the plant in addition to having appreciated its

uniqueness and asexually reproduced it.²³ This is true for new and distinct plant varieties invented with the assistance of AI.

Therefore, this guidance regarding AI-assisted inventions applies not only to utility patents and patent applications but also to design and plant patents and patent applications.

VI. Benefit/Priority Claims to Prior-Filed Applications

Applications and patents claiming the benefit of, or priority to, a prior application filed in the United States or a foreign country under 35 U.S.C. 119, 120, 121, 365, or 386 must name the same inventor or have at least one joint inventor in common with the prior-filed application.²⁴ For all applications and patents, including those that cover AI-assisted inventions, the prior-filed application and the United States application or patent claiming the benefit of, or priority to, the prior-filed application must name the same natural person as the inventor, or have at least one joint inventor who is a natural person in common. Therefore, a priority claim to a foreign application that names an AI tool as the sole inventor will not be accepted. This policy also applies to U.S. patent applications and patents claiming priority to foreign applications that allow the naming of non-natural persons as joint inventors. For a U.S. application claiming priority to a foreign application that names both a natural person(s) and a non-natural person as a joint inventor, the application data sheet accompanying the application filed in the United States must list only the natural person(s) identified as the inventor(s), including one in common with the foreign application. Similarly, for an application entering the national stage under 35 U.S.C. 371 where the international application indicates a joint inventor that is not a natural person, applicants can comply with the U.S. inventorship requirement by naming the natural person(s) identified as the inventor(s) in an application data sheet accompanying the initial submission under 35 U.S.C. 371.²⁵

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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²³ *Id.* at 1348.

²⁴ See MPEP 213.02 (subsection II), 211.01, 1895, 2920.05(e).

²⁵ See 37 CFR 1.76; MPEP 1893.01(e).

¹¹ *In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002).

¹² *Burroughs Wellcome Co.*, 40 F.3d at 1228 (citing *Sewall*, 21 F.3d at 415).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See MPEP 2157; see also MPEP 602.01 (“The inventorship of a nonprovisional application under 35 U.S.C. 111(a) is the inventor or joint inventors set forth in the application data sheet in accordance with [37 CFR] § 1.76 filed before or concurrently with the inventor’s oath or declaration.”).

¹⁶ *Shatterproof Glass Corp. v. Libby-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985) (quoting *Hobbs v. United States Atomic Energy Commission*, 451 F.2d 849, 864 (5th Cir. 1971)); see also *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 981 (Fed. Cir. 1997) (quoting *O’Reilly v. Morse*, 56 U.S. 62, 111 (1853) (“it can make no difference [. . .] whether [the inventor] derives his information from books, or from conversation with men skilled in the science.” [. . .] “the fact that Morse sought and obtained the necessary information and counsel from the best sources, and acted upon it, neither impairs his rights as an inventor, nor detracts from his merits.”)).

¹⁷ *Pannu*, 155 F.3d at 1351.

¹⁸ *Id.*

¹⁹ 35 U.S.C. 171 (2024).

²⁰ *Hoop v. Hoop*, 279 F.3d 1004, 1007 (Fed. Cir. 2002) (“We apply the same standard of inventorship to design patents that we require for utility patents.”) (citing *In re Rouso*, 222 F.2d 729, 731 (CCPA 1955)).

²¹ 35 U.S.C. 161 (2024).

²² *In re Beineke*, 690 F.3d 1344, 1352 (Fed. Cir. 2012).