

**UNITED STATES
PATENT AND TRADEMARK OFFICE**



Requirements for Information under 37 CFR 1.105 and the Submission of Said Information under MPEP 724 (e.g. Trade Secrets).

TC1600 Biotech/Pharma/Chem Customer Partnership Meeting

UNITED STATES
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37 CFR 1.105 (Rule 105) - Requirements for Information

- An Examiner or other Office employee may require the submission of such information as may be reasonably necessary to properly examine or treat a matter in an application or a patent.
- *See MPEP 704.10 for more information.*

Who can be required to submit?

- **Individuals identified under 37 CFR 1.56(c)**
 - Each inventor named in the application
 - Each attorney or agent who prepares or prosecutes the application, and
 - Every other person who is substantially involved in the preparation or prosecution of the application and who is associated with the inventor or the assignee
- **Assignees or anyone to whom there is an obligation to assign**
- *See MPEP 704.10 for more information.*

What information may be required?

- Information reasonably necessary to properly examine or treat a matter in a pending or abandoned application or in a patent
 - Information used to draft a patent application
 - Information reasonable necessary for finding prior art
 - Information used in invention process
 - See 37 CFR 1.105 (a)(1) for more examples
 - *See MPEP 704.11 for more information.*

More specific examples of information that may be required

- The name and citation of any particularly relevant indexed journal, or treatise.
- The trade name of any goods or services in which the claimed subject matter is embodied.
- The citation for, the dates initially published, and copies of any advertising and promotional literature prepared for any goods or services in which the claimed subject matter has been embodied.
- The trade names, providers, as well as any written descriptions or analyses prepared by any of the inventors or assignees, of any goods or services in competition with the goods or services in which the claimed subject matter has been embodied.
- *See MPEP 704.11 for more examples*



How is the criteria of “reasonably necessary” met?

- The examiner’s search and preliminary analysis demonstrate that the claimed subject matter cannot be adequately searched by class or keywords among patents and typical sources of non-patent literature, or
- Either the application file or the lack of relevant prior art found in the examiner’s search justifies asking the applicant if he or she has information that would be relevant to the patentability determination.
- *See MPEP 704.11 for more information.*

When may a requirement for information be made?

- At any time once the necessity for the information is recognized and should be made at the earliest opportunity after the necessity is recognized.
- The optimum time for making a requirement is prior to or with a first action on the merits.
- Ordinarily, a requirement for information should not be made with or after a final rejection.
- *See MPEP 704.11(b) for more information.*

Requirement for information under 37 CFR 1.105 versus duty of disclosure under 37 CFR 1.56

- [37 CFR 1.56](#) requires disclosure of information material to the patentability of the claimed subject matter.
- [37 CFR 1.105](#) requires information reasonably necessary to the examination of the application or treatment of a matter.
- Similar to 37 CFR 1.56, applicant is required by 37 CFR 1.105 to submit information already known, but no requirement to search for info that is unknown.
- Unlike 37 CFR 1.56, applicant is required by 37 CFR 1.105 to submit information that may not be material to patentability in itself, but that is necessary to obtain a complete record from which patentability may be determined.
- *See MPEP 704.12(a) for more information.*

What constitutes a complete reply to a requirement for information?

- Providing the information required, or
- A statement that the information required is unknown and/or is not readily available to the party or parties from which it was requested.
- There is NO requirement to show the required information was not in fact readily attainable.
- Applicant is required to make a good faith attempt to obtain the information and to make a reasonable inquiry once the information is requested.
- *See MPEP 704.12(b) for more information.*

When is an information “Not readily available?”

- Not readily obtained after reasonable inquiry.
- Applicant is expected to make a reasonable inquiry under the circumstances to find the factual information requested.
- Applicant need not, however, derive or independently discover a fact, such as by experimentation, in response to a requirement for information.
- *See MPEP 704.11 and 704.12(b) for more information.*

Time periods for reply to a requirement for information?

- Independent: Requirements made without an action on the merits should set a shortened statutory period (SSP) of 2 months for reply.
 - May petition to extend the time period for reply up to 6 months under [37 CFR 1.136\(a\)](#).
- Dependent: Requirements sent with an Office action on the merits, and not as a separate Office action, will be given the same period for reply as the action on the merits.
- *MPEP 704.13*

Rule 105 requirements in plant patent application under 35 U.S.C. 161

- **If an examiner finds a printed publication describing the instantly claimed plant variety in a plant application, typically the information to require is when, if ever, the plant variety was placed in the public domain by offer for sale or other public use**
- **This information is germane because...**

Printed publication alone in plant patent application may not be enabling.

- Printed publications may not be enabling prior art, if the disclosed plant variety was not available to one skilled in the art.
- “When the claims are drawn to plants, the reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant.”
 - See MPEP 2121.03 citing *In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA 1962).

Printed publication in plant patent application

- “A printed publication anticipates a claim if it discloses the claimed invention “such that a skilled artisan could take its teachings *in combination with his own knowledge of the particular art and be in possession of the invention.*”
 - *In re LeGrice*, 301 F.2d 929, 936, 133 USPQ 365, 372 (CCPA 1962).

Printed publication in plant patent application

- A printed publication can be an enabling disclosure if the disclosed plant variety is available to one skilled in the art.
 - In *Ex parte Thomson*, the seeds were commercially available more than 1 year prior to applicant's filing date. One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had "enabled disclosures."
 - *Ex parte Thomson*, 24 USPQ2d 1618 (BPAI 1992).
 - See also MPEP 2121.03

Examples of printed publications which could trigger a rule 105 requirement

- Plant Breeder's Right or Plant Variety Protection applications or grants disclosed in the UPOV database
- Catalogs with unclear release dates, e.g. "Fall 1998," "1998/1999"
- "Preview" type articles disclosing an anticipated release date
- When there is evidence suggesting that the claimed plant may have been in the public domain

Trade secrets, proprietary, and protective orders submitted under MPEP 724

- You have submitted information when responding to a request for information under rule 105 and that information is a trade secret, proprietary, or under a protective order.
 - How do you submit?
 - If you submit, will the submission become part of the record?
 - What can you do if you do not want the information submitted in response to a request for information (37CFR 1.105) to become part of the record?

Policy – Why allow information to be submitted under MPEP 724?

- **MPEP 724 governs Trade Secret, Proprietary, and Protective Order Materials**
 - “While one submitting materials to the Office in relation to a pending patent application or reexamination proceeding must generally assume that such materials will be made of record in the file and be made public, the Office is not unmindful of the difficulties this sometimes imposes.”
- **The Office is also cognizant of the sentiment expressed by the court in *In re Sarkar*, 575 F.2d 870, 872, 197 USPQ 788, 791 (CCPA 1978), which stated:**
 - “If a patent applicant is unwilling to pursue his right to a patent at the risk of certain loss of trade secret protection, the two systems will conflict, the public will be deprived of knowledge of the invention in many cases, and inventors will be reluctant to bring unsettled legal questions of significant current interest . . . for resolution.”

How to submit trade secret, proprietary, and/or protective order materials?

- Information which is considered by the party submitting the same to be either trade secret material or proprietary material, and any material subject to a protective order, must be clearly labeled as such and be filed in a sealed, clearly labeled, envelope or container. (*MPEP 724.02*).
- Each document or item must be clearly labeled as a “Trade Secret” document or item, a “Proprietary” document or item, or as an item or document “Subject To Protective Order.” (*MPEP 724.02*).
- It is essential that the terms “Confidential,” “Secret,” and “Restricted” or “Restricted Data” not be used when marking these documents or items in order to avoid confusion with national security information documents which are marked with these terms. (*MPEP 724.02*).
- **Example Language from MPEP 724.02**
 - “TRADE SECRET MATERIAL NOT OPEN TO PUBLIC. TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED U.S. PATENT AND TRADEMARK OFFICE EMPLOYEE.”

How to submit trade secret, proprietary, and/or protective order materials?

- Need more than a clearly labeled envelope or container. (*MPEP 724.02*)
 - Transmittal Letter
 - The envelope or container must be accompanied by a transmittal letter which also contains the same identifying information as the envelope or container. The transmittal letter must also state that the materials in the envelope or container are considered trade secrets or proprietary, or are subject to a protective order, and are being submitted for consideration under **MPEP § 724**.
 - Petition to Expunge
 - A Petition under 37 CFR 1.59 to expunge the information, if found not to be material to patentability, and the required fee under 37 CFR 1.17(g) should accompany the envelope or container.
 - Timing → Needs to be filed prior to the notice of allowance. (*MPEP 724.04*)

Contents of petition to expunge (MPEP 724.05)

- Any such petition to expunge information submitted under MPEP § 724.02 should be submitted at the time of filing the information under MPEP § 724.02 and directed to the Technology Center (TC) to which the application is assigned. Such petition must contain:
 - (A) a clear identification of the information to be expunged without disclosure of the details thereof;
 - (B) a clear statement that the information to be expunged is trade secret material, proprietary material, and/or subject to a protective order, and that the information has not been otherwise made public;
 - (C) a commitment on the part of the petitioner to retain such information for the period of enforceability of any patent with regard to which such information is submitted;
 - (D) a statement that the petition to expunge is being submitted by, or on behalf of, the party in interest who originally submitted the information;
 - (E) the fee as set forth in **37 CFR 1.17(g)** for a petition under **37 CFR 1.59(b)**.

When does the information submitted under MPEP 724 become part of the record?

- **No petition to expunge was filed prior to the notice of allowability.**
- **A petition to expunge was properly filed but denied.**

Petition to expunge - grant/deny

- You have timely submitted a Petition to Expunge. The application has been allowed. What causes the petition to expunge to be granted or denied?
- **Grant**
 - “If the application is being allowed, if the materials submitted under MPEP 724.02 are found **not to be material to patentability**, the petition to expunge will be granted and the materials will be expunged.” (MPEP 724.04).
- **Deny**
 - “If the materials are found to be **material to patentability**, the petition to expunge will be denied and the materials will become part of the application record and will be available to the public upon issuance of the application as a patent.” (MPEP 724.04)

Petition to expunge - abandoned applications

- You have abandoned your application (which has information submitted under 724.02) and there is a petition to expunge.
 - With the mailing of the notice of abandonment, if a petition to expunge has been filed, **irrespective** of whether the materials are found to be **material to patentability**, the petition to expunge will be granted and the materials expunged. (*MPEP 724.04*).

The Big Question – When is information submitted under MPEP 724.02 considered to be material to patentability?

- What is “Material to Patentability” with respect to material submitted under MPEP 724.02?
 - “Materiality” is defined as any information which the examiner considers as being important to a determination of the patentability of the claims. *See FP 7.206 in MPEP 724.06 – Petition under 37 CFR 1.59(b) to Expunge Information Dismissed*.”
- What is “Material to Patentability” with respect to material submitted under 37 CFR 1.56(b).
 - Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
 - (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
 - (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

Example - material to patentability determination for information submitted under MPEP 724.

- **Hypothetical Application**

- Claim 1. A seed of soybean variety XYZ, wherein a representative sample of the seed has been deposited under ATCC Accession No. PTA-123456.
 - Note – Applicant has not submitted the breeding history of Soybean XYZ with the application.
- Specification discloses that soybean variety XYZ has the following traits (Only traits disclosed):
 - Flower Color – Purple
 - Pod Wall Color – Brown
 - Seed Coat Color - Yellow

Example - material to patentability determination for information submitted under MPEP 724.

- **Hypothetical Prior Art**

- Claim 1. A seed of soybean variety ABC, wherein a representative sample of the seed has been deposited under ATCC Accession No. PTA-654321.

- Note – Prior Art discloses that Soybean ABC was made by crossing Plant A with Plant BC .

- Specification discloses that soybean variety ABC has the following traits (Only traits disclosed):

- Flower Color – Purple
 - Pod Wall Color – Brown
 - Seed Coat Color - Yellow

Example - material to patentability determination for information submitted under MPEP 724.

- **Examiner makes a 102 rejection.**
 - Soybean seed XYZ and Soybean seed ABC have identical traits.
 - Phenotypically Identical.
 - Because the breeding history of XYZ is not known, it is not possible for examiner to determine whether soybean seed XYZ was made from plants A and BC.
 - Not possible to determine if the Soybean seed XYZ and Soybean Seed ABC are genetically identical.
- **Examiner when mailing the non-final office action makes the 102 rejection and also submits a requirement for information under 37 CFR 1.105.**
 - The request seeks to identify the breeding history of Soybean seed XYZ.

Example - material to patentability determination for information submitted under MPEP 724.

- **Applicant responds to a non-final office action by submitting proprietary information under MPEP 724:**
 - Responds to the 105 request by providing the breeding history (proprietary) of Soybean Seed XYZ.
 - Soybean Seed XYZ was produced by crossing Plant X with Plant YZ.
 - In remarks accompanying the information submitted in response to the 105 request, applicant argues that the 102 rejection should be withdrawn as Soybean seed XYZ and Soybean seed ABC are genetically different due to different breeding histories.
- **Examiner Action**
 - Compares the breeding histories of Soybean Seed XYZ and Soybean Seed ABC
 - Determines that the seeds are different genetically.
 - Examiner withdraws 102 rejection presented in the non-final office action and allows the application.
 - In the reasons for allowance, the examiner indicates that the 102 rejection was withdrawn due to the information obtained from the rule 105 request.

Example - material to patentability determination for information submitted under MPEP 724.

- Petition To Expunge has been filed to expunge the information submitted under MPEP 724, specifically the breeding history of Soybean Seed XYZ.
- Should the Office grant the petition?
 - Answer → No.
 - “Materiality” is defined as any information which the examiner considers as being important to a determination of the patentability of the claims. *See FP 7.206 in MPEP 724.06 – Petition under 37 CFR 1.59(b) to Expunge Information Dismissed*.
 - In this application → The examiner determined patentability by withdrawing a rejection due solely due to the information submitted under MPEP 724. The patentability was determined based on the information submitted under MPEP 724 and thus it is material to patentability.

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