

# Chapter 2000 Duty of Disclosure

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## **2000 Duty of Disclosure [R-07.2022]**

### **2000.01 Introduction [R-07.2022]**

This Chapter deals with the duties owed toward the U.S. Patent and Trademark Office by each individual who is associated with the preparation or prosecution of the application. Each individual associated with the filing and prosecution of a patent application, supplemental examination, or patent reexamination has a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. These duties, of candor and good faith and disclosure, have been codified in [37 CFR 1.56](#) and [37 CFR 1.555](#), as promulgated pursuant to carrying out the duties of the Director under Sections [2](#), [3](#), [131](#), and [132](#) of Title 35 of the United States Code.

In some instances, the duty to disclose may constitute correcting erroneous material information in the record. Effective September 16, 2012, the America Invents Act (AIA) amended the patent laws to modify notable aspects of the duty of disclosure. Specifically, the AIA eliminated the requirement that applicants disclose that an error in a patent (e.g., change in inventorship) was made without any deceptive intent before correction is permitted. See [35 U.S.C. 116](#), [35 U.S.C. 251](#), and [35 U.S.C. 256](#). This does not negate, however, the continuing obligation to practice candor and good faith in all dealings before the Office.

On October 28, 2016, the Office issued a Notice of Proposed Rulemaking proposing revisions to the materiality standard for the duty to disclose information in patent applications and reexamination proceedings (duty of disclosure) in light of the decision by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288, 99 USPQ2d 1065 (Fed. Cir. 2011)(*en banc*). Specifically, the Office is considering harmonizing the materiality standard for the duty of disclosure to

adopt the “but-for” materiality standard for inequitable conduct as set forth in *Therasense* and adopted in subsequent inequitable conduct cases, which will result in revisions to [37 CFR 1.56](#) and [37 CFR 1.555](#). While these proposed rule changes have not yet been finalized, it is still important for Office stakeholders to recognize the split in how materiality may be considered within the Office and in the courts. Some of the more instructive recent cases on inequitable conduct have been incorporated in the discussion below to provide guidance on compliance with the duty of disclosure regardless of the materiality standard.

On July 29, 2022, the Office issued a Federal Register Notice reinforcing the importance of “duty of disclosure” and “duty of reasonable inquiry”, and clarifying the scope of these duties as they relate to information and statements material to patentability including, but not limited to, those received from or submitted to the Food and Drug Administration (FDA) and other governmental agencies. These duties apply during examination of patent applications, including continuation applications, and after issuance during any post-grant examination or proceeding to review the issued patent. See *Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board*, 87 FR 45764 (July 29, 2022).

## 2001 Duty of Disclosure, Candor, and Good Faith [R-08.2017]

### *37 CFR 1.56 Duty to disclose information material to patentability.*

[Editor Note: Para. (c)(3) below is applicable only to patent applications filed under 35 U.S.C. 111(a) or 363 on or after September 16, 2012.]

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the

patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by [§§ 1.97\(b\)-\(d\)](#) and [1.98](#). However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, 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.

(3) A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability,

as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

***37 CFR 1.56 (pre-AIA) Duty to disclose information material to patentability.***

*[Editor Note: Para. (c)(3) below is not applicable to patent applications filed under 35 U.S.C. 111(a) or 363 on or after Sept. 16, 2012.]*

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(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

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(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

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[37 CFR 1.56](#) defines the duty to disclose information to the Office.

## **2001.01 Who Has Duty To Disclose [R-07.2022]**

***37 CFR 1.56 Duty to disclose information material to patentability.***

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(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

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***37 CFR 1.56 (pre-AIA) Duty to disclose information material to patentability.***

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(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

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The duty to disclose applies to matters pending before the USPTO and extends broadly to “[e]ach individual associated with the filing and prosecution of a patent application” and “[e]ach individual associated with the patent owner in a reexamination proceeding.” [37 CFR 1.56\(c\)](#) and [1.555\(a\)](#). For patent applications, including reissue applications, these individuals include each inventor named in the application, each attorney or agent who prepares or prosecutes the application, and “[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.” This is intended to make clear that the duty does not extend to typists, clerks, and similar personnel who assist with an application. For reexamination proceedings, these individuals include “the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding.” [37 CFR 1.555\(a\)](#).

The duty of disclosure applies only to individuals, not to organizations. For instance, the duty of disclosure would not apply to a corporation or institution as such. However, it would apply to individuals within the corporation or institution who were substantively involved in the preparation or prosecution of the application, and actions by such individuals may affect the rights of the corporation or institution.

## **2001.02 [Reserved]**

## **2001.03 To Whom Duty of Disclosure Is Owed [R-08.2017]**

[37 CFR 1.56\(a\)](#) states that the “duty of candor and good faith” is owed “in dealing with the Office” and that all associated with the filing and prosecution of a patent application have a “duty to disclose to the Office” material information. This duty “in dealing with” and “to” the Office extends, of course, to all dealings which such individuals have with the Office, and is not limited to representations to or dealings with the examiner. For example, the duty would extend to proceedings before the Patent Trial

and Appeal Board and the Office of the Commissioner for Patents.

## 2001.04 Information Under 37 CFR 1.56(a) [R-07.2022]

### *37 CFR 1.56 Duty to disclose information material to patentability.*

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

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The language of [37 CFR 1.56](#) (and [37 CFR 1.555](#)) emphasizes that there is a duty of candor and good faith which is broader than the duty to disclose material information. [37 CFR 1.56](#) further states that “no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.” Specifically, the duty of candor and good faith, and by extension the duty to disclose,

applies to positions taken by applicants or parties involving the claimed subject matter.

If a party to a USPTO proceeding discovers that an earlier position taken in a submission to the USPTO or another Government agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record. See, e.g., *In re Tendler*, Proceeding No. D2013-17 (USPTO Jan. 1, 2014) (suspending a practitioner for four years for failure to correct the written record after learning of inaccuracies in a declaration the practitioner had filed). In the context of prosecution, an applicant must disclose to the USPTO any information that 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. See [37 CFR 1.56\(b\)\(2\)](#). Patent owners may bring information, including prior art and incorrect or inconsistent positions, to the attention of the USPTO through supplemental examination, *ex parte* reexamination, reissue applications, or submissions under [37 CFR 1.501](#). During prosecution, third parties may have an opportunity to disclose information to the USPTO through third party submissions under [37 CFR 1.290](#) and protests under [37 CFR 1.291](#). After issuance, third parties may disclose information directed to issued patents to the USPTO via submissions under [37 CFR 1.501](#), or in *ex parte* reexamination. A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure through bad faith or intentional misconduct with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. See [MPEP § 2016](#).

The Office strives to issue valid patents. The Office has both an obligation not to unjustly issue patents and an obligation not to unjustly deny patents. Innovation and technological advancement are best served when an inventor is issued a patent with the scope of protection that is deserved. The rules serve to remind individuals associated with the preparation and prosecution of patent applications of their duty of candor and good faith in their dealings with the Office, and will aid the Office in receiving, in a timely manner, the information it needs to carry out effective and efficient examination of patent applications. Moreover, an incentive exists to submit



material information to the Office because it may result in enhanced patent quality and may avoid later questions of materiality and intent to deceive.

The definition of materiality in [37 CFR 1.56](#) is intended to provide the Office with the information it needs in order for the examiner to make a proper and independent determination on patentability. The patent examiner should make the patentability determination after considering the relevant facts properly of record in the particular case.

[37 CFR 1.56](#) states that each individual associated with the filing and prosecution of a patent application has a duty to disclose all information known to that individual to be material to patentability as defined in the section. Thus, the duty applies to contemporaneously or presently known information. The fact that information was known years ago does not mean that it was recognized that the information is material to the present application.

The term “information” as used in [37 CFR 1.56](#) means all of the kinds of information required to be disclosed and includes any information which is “material to patentability.” Materiality is defined in [37 CFR 1.56\(b\)](#) and discussed herein at [MPEP § 2001.05](#). In addition to prior art such as patents and publications, [37 CFR 1.56](#) includes, for example, information on enablement, possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, litigation statements, and the like. “Materiality is not limited to prior art but embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent.” *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234, 66 USPQ2d 1481, 1486 (Fed. Cir. 2003) (emphasis in original) (finding article which was not prior art to be material to enablement issue).

Patent examiners also have the ability to require submission of information that may be reasonably necessary to properly examine or treat a matter in a pending or abandoned application, but not necessarily “material to patentability.” [37 CFR 1.105\(a\)\(1\)](#). The information that must be submitted to comply with a requirement for information under

[37 CFR 1.105](#) may not be material to patentability in itself under [37 CFR 1.56](#), but it is necessary to obtain a complete record from which a determination of patentability may be made. See [MPEP § 704.12\(a\)](#). Therefore, when an examiner has a reasonable basis to conclude that an individual identified under [37 CFR 1.56\(c\)](#) or any assignee has information that would aid in the examination of the application or treatment of some matter, the examiner may require submission of information that is not necessarily material to patentability. This requirement could include statements made or information submitted to other Government agencies such as the FDA. See [MPEP § 2015](#). For example, when examining a claim directed to a process of manufacturing a particular drug product that was effectively filed more than one year after FDA approval of the drug product, an examiner may appropriately require an applicant to submit to the USPTO information submitted to the FDA (e.g., in a New Drug Application or Biologics License Application) on how the drug product was manufactured.

The term “information” is intended to be all encompassing, similar to the scope of the term as discussed with respect to [37 CFR 1.291\(a\)](#) (see [MPEP § 1901.02](#)). [37 CFR 1.56\(a\)](#) also states: “The Office encourages applicants to carefully examine: (1) prior art cited in search reports of a foreign patent office in a counterpart application, and (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.”

It should be noted that the rules are *not* intended to require information *favorable* to patentability such as, for example, evidence of commercial success of the invention. Similarly, the rules are not intended to require, for example, disclosure of information concerning the level of skill in the art for purposes of determining obviousness.

[37 CFR 1.56\(a\)](#) states that the duty to disclose information exists until the application becomes abandoned. The duty to disclose information, however, does not end when an application becomes allowed but extends until a patent is granted on that

application. The rules provide for information being considered after a notice of allowance is mailed and before the issue fee is paid ([37 CFR 1.97\(d\)](#)) (see [MPEP § 609.04\(b\), subsection III](#)). The rules also provide for an application to be withdrawn from issue:

(A) because one or more claims are unpatentable ([37 CFR 1.313\(c\)\(1\)](#));

(B) for express abandonment so that information may be considered in a continuing application before a patent issues ([37 CFR 1.313\(c\)\(3\)](#)); or

(C) for consideration of a request for continued examination (RCE) under [37 CFR 1.114](#) ([37 CFR 1.313\(a\)](#) and [\(c\)\(2\)](#)). Note that RCE practice does not apply to utility or plant applications filed before June 8, 1995 or to design applications. See [MPEP § 706.07\(h\)](#).

See [MPEP § 1308](#) for additional information pertaining to withdrawal of an application from issue.

In a continuation-in-part application, individuals covered by [37 CFR 1.56](#) have a duty to disclose to the Office all information known to be material to patentability which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application. See [37 CFR 1.56\(e\)](#).

[37 CFR 1.56](#) provides that the duty of disclosure can be met by submitting information to the Office in the manner prescribed by [37 CFR 1.97](#) and [1.98](#). See [MPEP § 609](#) *et seq.* Applicants are provided certainty as to when information will be considered, and applicants will be informed when information is not considered. Note, however, if even a document was cited to or considered in a prior examination or related Office proceeding, the Office may order reexamination based on the document if it raises a substantial new question of patentability. See [MPEP § 2242](#) and [MPEP § 2258.01](#).

[37 CFR 1.555](#) provides for the duty of disclosure in reexamination proceedings. For a discussion of information material to patentability in a reexamination proceeding, see [MPEP § 2280](#) or [MPEP § 2684](#). For supplemental examination and any *ex parte* reexamination proceeding ordered

under [35 U.S.C. 257](#), information material to patentability is defined by [37 CFR 1.56](#). See [37 CFR 1.625\(d\)\(4\)](#) and [MPEP § 2820](#).

## 2001.05 Materiality Under 37 CFR 1.56(b) [R-07.2022]

*37 CFR 1.56 Duty to disclose information material to patent ability.*

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(b) Under this section, 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.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

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Under the rule, information is not material unless it comes within the definition of [37 CFR 1.56\(b\)\(1\)](#) or [\(2\)](#). Generally, when information is clearly cumulative or not material, there is no duty to disclose the information to the Office. “[I]nformation 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.” [37 CFR 1.56\(b\)](#). In close cases where the materiality or consistency of the information is in question, the applicant should consider submitting this information to the USPTO. The Office believes that most applicants will wish to submit the information even though they may not be required to do so, to strengthen the patent and avoid the risks of an

incorrect judgment on their part on materiality. The USPTO holds those individuals subject to this duty to the highest standards.

### **2001.06 Sources of Information under 37 CFR 1.56 [R-07.2022]**

All individuals covered by [37 CFR 1.56](#) (reproduced in [MPEP § 2001.01](#)) have a duty to disclose to the U.S. Patent and Trademark Office all material information they are *aware* of regardless of the source of or how they become aware of the information. See *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383, 60 USPQ2d 1482, 1490 (Fed. Cir. 2001) (“Once an attorney, or an applicant has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose.”). Materiality controls whether information must be disclosed to the Office, not the circumstances under which or the source from which the information is obtained. If material, the information must be disclosed to the Office. The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof before the application is granted.

Individuals covered by [37 CFR 1.56](#) may be or become aware of material information from various sources such as, for example, co-workers, trade shows, communications from or with competitors, potential infringers, or other third parties, related foreign applications (see [MPEP § 2001.06\(a\)](#)), prior or copending United States patent applications (see [MPEP § 2001.06\(b\)](#)), related litigation and/or post-grant proceedings (see [MPEP § 2001.06\(c\)](#)), preliminary examination searches and supporting information related to regulatory review (see [MPEP § 2001.06\(e\)](#)).

#### **2001.06(a) Prior Art Cited in Related Foreign Applications [R-08.2012]**

Applicants and other individuals, as set forth in [37 CFR 1.56](#), have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any

related foreign application. The inference that such prior art or other information is material is especially strong where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified in some manner as particularly relevant. See *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 216 USPQ 976 (S.D. N.Y. 1982) wherein a patent was held invalid or unenforceable because patentee’s foreign counsel did not disclose to patentee’s United States counsel or to the Office prior art cited by the Dutch Patent Office in connection with the patentee’s corresponding Dutch application. The court stated, 542 F. Supp. at 943, 216 USPQ at 985:

Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

#### **2001.06(b) Information Relating to or From Copending United States Patent Applications [R-08.2017]**

The individuals covered by [37 CFR 1.56](#) have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are “material to patentability” of the application in question. This may include providing the identification of pending or abandoned applications filed by at least one of the inventors or assigned to the same assignee as the current application that disclose similar subject matter that are not otherwise identified in the current application. As set forth by the court in *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972):

[W]e think that it is unfair to the busy examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application . . . [T]he applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent.

See also [MPEP § 2004](#), paragraph 9.

Accordingly, the individuals covered by [37 CFR 1.56](#) cannot assume that the examiner of a particular application is necessarily aware of other applications which are “material to patentability” of the application in question, but must instead bring such other applications to the attention of the examiner. See *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 560 (S.D.N.Y. 2015), and *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003). For example, if a particular inventor has different applications pending which disclose similar subject matter but claim patentably indistinct inventions, the existence of other applications must be disclosed to the examiner of each of the involved applications. Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are “material to patentability” of the subsequent application. See *Dayco Prod.*, 329 F.3d at 1369, 66 USPQ2d at 1808.

If the application under examination is identified as a continuation, divisional, or continuation-in-part of an earlier application, the examiner will consider the prior art properly cited in the earlier application. See [MPEP § 609](#) and [MPEP § 719.05](#), subsection (II)(A), example J. The examiner must indicate in the first Office action whether the prior art in a related earlier application has been reviewed. Accordingly, no separate citation of the same prior art need be made in the later application, unless applicant wants a listing of the prior art printed on the face of the patent.

## **2001.06(c) Information From Related Litigation and/or Trial Proceedings [R-08.2017]**

The America Invents Act (AIA) added trial proceedings to be conducted by the Patent Trial and Appeal Board (PTAB) including *inter partes* review proceedings, post-grant review, covered business method reviews, and derivation. In many instances, these trial proceedings yield information that may be considered material to pending related patent applications. Where the subject matter for which a patent is being sought is or has been involved in litigation and/or a trial proceeding, or the litigation and/or trial proceeding yields information material to currently pending applications, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the examiner or other appropriate official at the U.S. Patent and Trademark Office. In particular, material information that is raised in trial proceedings that is relevant to related applications undergoing examination should be submitted on an Information Disclosure Statement for the examiner’s consideration. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of “fraud,” “inequitable conduct,” and “violation of duty of disclosure.” Another example of such material information is any assertion that is made during litigation and/or trial proceeding which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 USPQ2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation and/or trial proceeding in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents and testimony.

Where a patent for which reissue is being sought is, or has been, involved in litigation and/or trial proceeding which raised a question material to examination of the reissue application, such as the validity of the patent, or any allegation of “fraud,” “inequitable conduct,” or “violation of duty of disclosure,” the existence of such litigation and/or trial proceeding must be brought to the attention of the examiner by the applicant at the time of, or shortly after, filing the application. Such information can be disclosed either in the reissue oath or



declaration, or in a separate paper, preferably accompanying the application, as filed. Litigation and/or trial proceedings that begin after filing of the reissue application should be promptly brought to the attention of the Office. The details and documents from the litigation and/or trial proceedings, insofar as they are “material to patentability” of the reissue application as defined in [37 CFR 1.56](#), should accompany the application as filed, or be submitted as promptly thereafter as possible. See *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258-59, 43 USPQ2d 1666, 1670-71 (Fed. Cir. 1997) (patent held unenforceable due to inequitable conduct based on patentee's failure to disclose a relevant reference and for failing to disclose ongoing litigation).

For example, the defenses raised against validity of the patent, or charges of “fraud” or “inequitable conduct” in the litigation, would normally be “material to the examination” of the reissue application. It would, in most situations, be appropriate to bring such defenses to the attention of the Office by filing in the reissue application a copy of the court papers raising such defenses. At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or “fraud,” or “inequitable conduct” relating to the original patent, and the nature of litigation materials relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation. See [MPEP § 1442.04](#).

If litigation papers of a live litigation relating to a pending reissue application are filed with the Office, the Solicitor’s Office should be notified of the filing of the litigation papers in the application file. If the litigation is not live, the litigation papers are processed by the Technology Center assigned the reissue application.

#### **2001.06(d) Information Relating to Claims Copied From a Patent [R-08.2017]**

Where claims are copied or substantially copied from a patent, [37 CFR 41.202\(a\)](#) requires the applicant, at the time he or she presents the claim(s), to identify

the patent and the numbers of the patent claims. Clearly, the information required by [37 CFR 41.202\(a\)](#) as to the source of copied claims is material information under [37 CFR 1.56](#) and failure to inform the USPTO of such information may violate the duty of disclosure.

#### **2001.06(e) Information Relating to Regulatory Review [R-07.2022]**

Where relevant documentation is submitted to a regulatory review body, such as the U.S. Food & Drug Administration (FDA), and is material to any pending patent application or reexamination proceeding, such documentation should be submitted for Office review. While the considerations made by the FDA for approving clinical trials are different from those made by the USPTO in determining whether a claim is patentable, submissions, particularly any assertion that is made which is contradictory to assertions made to the examiner, may be material to ongoing patent proceedings. *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353-54, 2021 USPQ2d 909 (Fed. Cir. 2021). See also [MPEP § 2164.05](#). Duty of disclosure may require that if the actual filing date of an application is after the date of the applicant’s date of marketing approval by FDA, and the applicant intends to list any resulting patent in the orange book for that product, informing the USPTO during examination of the application of that intent and applicant should consider providing the Paragraph IV “factual and legal basis” notice to USPTO.

Accordingly, each party presenting a paper to the USPTO, whether a practitioner or non-practitioner, has a duty to perform an inquiry that is reasonable under the circumstances. This reasonable inquiry may comprise reviewing documents that are submitted to or received from other Government agencies, including the FDA. If any reviewed document is material to the patentability of a pending matter before the Office, such as a patent application (including a reissue application), or a reexamination proceeding, the party has a duty to submit the information to the USPTO. [37 CFR 1.56](#), [1.555](#), and [11.18\(b\)\(2\)](#). A duty of reasonable inquiry may exist based on circumstances known to the party presenting the paper to the USPTO. Failing to inquire when the circumstances warrant it could result in

sanctions or other action under [37 CFR 11.18\(c\)](#), which may include: (1) striking the offending paper; (2) referring a practitioner's conduct to the Director of Enrollment and Discipline for appropriate action; (3) precluding a party or practitioner from submitting a paper, or presenting or contesting an issue; (4) affecting the weight given to the offending paper; or (5) terminating the proceedings in the Office. See, e.g., *In re Hao*, Proceeding No. D2021-14 (USPTO Apr. 27, 2022) (involving disciplinary sanctions predicated on non-compliance with [37 CFR 11.18](#)). See also [MPEP § 2015](#).

## 2002 Disclosure — By Whom and How Made [R-08.2012]

*37 CFR 1.56 Duty to disclose information material to patentability.*

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(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

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### 2002.01 By Whom Made [R-08.2012]

[37 CFR 1.56\(d\)](#) makes clear that information may be disclosed to the Office through an attorney or agent of record or through a *pro se* inventor, and that other individuals may satisfy their duty of disclosure to the Office by disclosing information to such an attorney, agent, or inventor who then is responsible for disclosing the same to the Office. Information that is not material need not be passed along to the Office.

### 2002.02 Must be in Writing [R-07.2022]

*37 CFR 1.2 Business to be transacted in writing.*

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

*37 CFR 1.4 Nature of correspondence and signature requirements.*

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(b) Since each file must be complete in itself, a separate copy of every paper to be filed in a patent application, patent

file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical. The filing of duplicate copies of correspondence in the file of an application, patent, or other proceeding should be avoided, except in situations in which the Office requires the filing of duplicate copies. The Office may dispose of duplicate copies of correspondence in the file of an application, patent, or other proceeding.

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A disclosure under [37 CFR 1.56](#) must be in writing as prescribed by [37 CFR 1.2](#), and a copy of any such disclosure must be filed in each application or other proceeding to which the disclosure pertains ([37 CFR 1.4\(b\)](#)). “The presentation to the Office (whether by signing, filing, or submitting) of any paper by a party, whether a practitioner or non-practitioner, constitutes a certification under [§ 11.18\(b\)](#).” [37 CFR 1.4\(d\)\(4\)\(i\)](#). [37 CFR 11.18\(b\)](#) includes paragraph (b)(2), which calls for a duty of reasonable inquiry to ensure that the paper is not being presented for any improper purpose, the legal contentions are warranted by law, the allegations and other factual contentions have evidentiary support, and the denials of factual contentions are warranted on the evidence.

## 2003 Disclosure — When Made [R-07.2022]

*37 CFR 1.97 Filing of information disclosure statement.*

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

(3) Before the mailing of a first Office action on the merits;

(4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114; or

(5) Within three months of the date of publication of the international registration under Hague Agreement Article 10(3) in an international design application.

(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under §

1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

(1) The statement specified in paragraph (e) of this section; or

(2) The fee set forth in § 1.17(p).

(d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:

(1) The statement specified in paragraph (e) of this section; and

(2) The fee set forth in § 1.17(p).

(e) A statement under this section must state either:

(1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

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The provisions of [37 CFR 1.97](#) specify when an information disclosure statement will be considered as a matter of right and when a certification must be made and/or fee submitted in order to have the information disclosure statement considered. In any circumstance, information should be submitted promptly.

An applicant, attorney, or agent who is aware of material prior art or other information and its significance should submit the information as early as possible in prosecution, e.g., before the first Office action, and not wait until after allowance. However, potentially material information discovered late in the prosecution should be promptly submitted. That the issue fee has been paid is no reason or excuse for failing to submit information. See [MPEP § 609.04\(b\)](#). Additionally, applicant should be mindful of the incentives of prompt filing of information as set forth in [37 CFR 1.704\(d\)\(1\)](#).

Likewise, material prior art or other information and its significance should be submitted as soon as

possible for reissue applications, and reexamination proceedings.

The presumption of validity is generally strong when prior art was before and considered by the Office and weak when it was not. See *Bolkcom v. Carborundum Co.*, 523 F.2d 492, 498, 186 USPQ 466, 471 (6th Cir. 1975).

## **2003.01 Disclosure After Patent Is Granted [R-07.2022]**

### **I. BY CITATIONS OF PRIOR ART AND WRITTEN STATEMENTS UNDER 37 CFR 1.501**

Where a patentee or any member of the public (including private persons, corporate entities, and government agencies) has certain information which they desire to have made of record in the patent file, they may file a citation of such information with the Office pursuant to [35 U.S.C. 301](#) and [37 CFR 1.501](#). Such citations will be entered in the patent file without comment by the Office. Information which may be filed under [37 CFR 1.501](#) is limited to prior art patents, printed publications or written statements of the patent owner filed by the patent owner in a proceeding before a federal court or the Office in which the patent owner took a position on the scope of any patent claim. Any citations which include items other than those items expressly enumerated in [37 CFR 1.501](#) will not be entered in the patent file. See [MPEP § 2202](#) through [§ 2208](#).

### **II. BY EX PARTE REEXAMINATION**

Where any person, including patentee, has prior art patents and/or printed publications which the person desires to have the U.S. Patent and Trademark Office consider after a patent has issued, such person may file a request for *ex parte* reexamination of the patent (see [37 CFR 1.510](#) and [MPEP § 2209](#) through [§ 2220](#)). Patent owners or third party requesters may bring information, including prior art and incorrect or inconsistent positions, to the attention of the USPTO through *ex parte* reexamination.

### **III. BY SUPPLEMENTAL EXAMINATION**

Where a patent owner desires that the Office consider, reconsider, or correct information,

including prior art and incorrect or inconsistent positions, believed to be relevant to the patent, the patent owner may file a request for supplemental examination. See [37 CFR 1.601-1.625](#) and [MPEP Chapter 2800](#). Supplemental examination became available on September 16, 2012, as a result of section [257](#) of Title 35, United States Code, which was added by Public Law 112-29, enacted on September 16, 2011, known as the Leahy-Smith America Invents Act (AIA). In particular, [35 U.S.C. 257\(c\)\(1\)](#) states that “[a] patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.” Therefore, a patent owner may insulate the patent from being held unenforceable based on information submitted in a properly filed supplemental examination request.

Unlike *ex parte* reexamination practice, the information that the patent owner may request to be considered, reconsidered, or corrected in a supplemental examination proceeding is not limited to patents, printed publications, and patent owner written statements under [35 U.S.C. 301](#). The “information” may include any information that the patent owner believes to be relevant to the patent. For example, the information may include not only a patent or a journal article, but also a sales invoice, or a transcript of an audio or video recording. In addition, the information submitted as part of a request for supplemental examination may involve any ground of patentability, such as, for example, patent eligible subject matter, anticipation, public use or sale, obviousness, written description, enablement, and indefiniteness.

#### IV. REISSUE

Patent owners may bring information, including prior art and incorrect or inconsistent positions, to the attention of the USPTO through reissue applications. If any reviewed document is material to the patentability (i.e., those submitted to another Government entity) of a pending matter before the Office, such as reissue application, there is a duty to submit the information to the USPTO. [37 CFR 1.56](#) and [11.18\(b\)\(2\)](#). See [MPEP § 2015](#).

## 2004 Aids to Compliance With Duty of Disclosure [R-07.2022]

While it is not appropriate to attempt to set forth procedures by which attorneys, agents, and other individuals may ensure compliance with the duty of disclosure, the items listed below are offered as examples of possible procedures which could help avoid problems with the duty of disclosure. Though compliance with these procedures may not be required, they are presented as helpful suggestions or best practices to avoid duty of disclosure problems.

1. Many attorneys, both corporate and private, are using letters and questionnaires for applicants and others involved with the filing and prosecution of the application and checklists for themselves and applicants to ensure compliance with the duty of disclosure. The letter generally explains the duty of disclosure and what it means to the inventor and assignee. The questionnaire asks the inventor and assignee questions about:

- the origin of the invention and its point of departure from what was previously known and in the prior art,
- possible public uses and sales (See *GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 2020 USPQ2d 10092 (Fed. Cir. 2020)),
- prior publication, knowledge, patents, foreign patents, etc.

The checklist is used by the attorney to ensure that the applicant has been informed of the duty of disclosure and that the attorney has inquired of and cited material prior art.

The use of these types of aids would appear to be most helpful, though not required, in identifying prior art and may well help the attorney and the client avoid or more easily explain a potentially embarrassing and harmful “fraud” allegation.

2. It is desirable to ask questions about inventorship. Who is the proper inventor? Are there disputes or



possible disputes about inventorship? If there are questions, call them to the attention of the U.S. Patent and Trademark Office.

3. It is desirable to ask questions of the inventor about the disclosure of the best mode. Make sure that the best mode is described. See [MPEP §§ 2165 - 2165.04](#).

4. It is desirable for an attorney or agent to make certain that the inventor, especially a foreign inventor, recognizes his or her responsibilities in signing the oath or declaration. See [37 CFR 1.69\(a\)](#).

**37 CFR 1.69 Foreign language oaths and declarations.**

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

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Note [MPEP § 602.06](#) for a more detailed discussion.

5. It is desirable for an attorney or agent to carefully evaluate and explain to the applicant and others involved the scope of the claims, particularly the broadest claims. Ask specific questions about possible prior art which might be material in reference to the broadest claim or claims. There is some tendency to mistakenly evaluate prior art in the light of the gist of what is regarded as the invention or narrower interpretations of the claims, rather than measuring the art against the broadest claim with all of its reasonable interpretations. It is desirable to pick out the broadest claim or claims and measure the materiality of prior art against a reasonably broad interpretation of these claims.

6. It may be useful to evaluate the materiality of prior art or other information from the viewpoint of whether it is the closest prior art or other information. This will tend to put the prior art or other information in better perspective. See *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1374, 54 USPQ2d 1001, 1005 (Fed. Cir. 2000) (“A withheld reference may be highly material when it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references.” (citations omitted)). However, [37 CFR](#)

[1.56](#) may still require the submission of prior art or other information which is not as close as that of record.

7. Care should be taken to see that prior art or other information cited in a specification or in an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized. See *Apotex v. UCB, Inc.*, 763 F.3d 1354, 1361-62, 112 USPQ2d 1081, 1087-88 (Fed. Cir. 2014)(finding that the patent specification omitted material information was among the facts that supported a conclusion that the patent is unenforceable due to inequitable conduct). It is particularly important for an attorney or agent to review, before filing, an application which was prepared by someone else, e.g., a foreign applicant or practitioner. It is also important that an attorney or agent make sure that foreign clients, including foreign applicants, attorneys, and agents understand the requirements of the duty of disclosure, and that the U.S. attorney or agent review any information disclosure statements or citations to ensure that compliance with [37 CFR 1.56](#) is present. See *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 54 USPQ2d 1001 (Fed. Cir. 2000). In this case, during prosecution the patentee submitted an untranslated 29-page Japanese reference as well as a concise explanation of its relevance and an existing one-page partial English translation, both of which were directed to less material portions of the reference. The untranslated portions of the Japanese reference “contained a more complete combination of the elements claimed [in the patent] than anything else before the PTO.” 204 F.3d at 1374, 54 USPQ2d at 1005. The patentee, whose native language was Japanese, was held to have understood the materiality of the reference. “The duty of candor does not require that the applicant translate every foreign reference, but only that the applicant refrain from submitting partial translations and concise explanations that it knows will misdirect the examiner’s attention from the reference’s relevant teaching.” 204 F.3d at 1378, 54 USPQ2d at 1008. See also *Gemveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 216 USPQ 976 (S.D.N.Y. 1982) wherein a patent was held invalid or unenforceable because patentee’s foreign counsel did not disclose to patentee’s United States counsel or to the Office prior art cited by the Dutch

Patent Office in connection with the patentee's corresponding Dutch application. The court stated, 542 F. Supp. at 943, 216 USPQ at 985:

Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

8. Care should be taken to see that inaccurate statements, inaccurate evidence or inaccurate experiments are not introduced into the record, either inadvertently or intentionally. For example, stating that an experiment "was run" or "was conducted" when, in fact, the experiment was not run or conducted is a misrepresentation of the facts. See *Apotex v. UCB, Inc.*, 763 F.3d 1359, 112 USPQ2d 1085 (Fed. Cir. 2014). No results should be represented as actual results unless they have actually been achieved. Paper or prophetic examples should not be described using the past tense. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003); see also [MPEP § 608.01\(p\), subsection II](#) and [§ 707.07\(d\)](#). Also, misrepresentations can occur when experiments which were run or conducted are inaccurately reported in the specification, e.g., an experiment is changed by leaving out one or more ingredients. See *Steierman v. Connelly*, 192 USPQ 433 (Bd. Pat. Int. 1975); 192 USPQ 446 (Bd. Pat. Int. 1976). Misrepresentations can also occur in declarations submitted to the Office. See *Intellect Wireless v. HTC Corp.*, 732 F.3d 1339, 1342, 108 USPQ2d 1563, 1565 (Fed. Cir. 2013) wherein applicants submitted a declaration under [37 CFR 1.131](#) containing false statements regarding reduction to practice of the claimed invention.

When drafting a patent application, it is a best practice to take care to ensure the proper tense is employed to describe experiments and test results so readers can readily distinguish between actual

results and predicted results. Any ambiguities should be resolved so a person having ordinary skill in the art reading the disclosure, including those who may not have the level of skill of the inventor, can rely on the disclosure as an accurate description of experiments that support the patent claim coverage. It is a best practice to label examples as prophetic or otherwise separate them from working examples to avoid ambiguities. Such presentation will help a reader easily distinguish prophetic examples from working examples with actual experimental results and will enhance the public's ability to rely on the patent disclosure. See *Properly Presenting Prophetic and Working Examples in a Patent Application*, 86 Fed. Reg. 35074, 5 (July 1, 2021).

9. Do not rely on the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be "material to patentability" of the application the examiner is considering. See *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003) (contrary decision of another examiner reviewing substantially similar claims is 'material'; copending application may be 'material' even though it cannot result in a shorter patent term, when it could affect the rights of the patentee to assign the issued patents). It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. A "lapse on the part of the examiner does not excuse the applicant." *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985); see also [MPEP § 2001.06\(b\)](#).

10. When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant does not consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "[i]n short, the question of relevancy in close cases, should be left to the

examiner and not the applicant.” See also *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

11. It is desirable to submit material information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention. See *TransWeb v. 3M*, 812 F.3d 1295, 1300, 117 USPQ2d 1617, 1619-20 (Fed. Cir. 2016). See also *Hycor Corp. v. The Schlueter Co.*, 740 F.2d 1529, 1534-37, 222 USPQ 553, 557-59 (Fed. Cir. 1984), *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992), and *GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 2020 USPQ2d 10092 (Fed. Cir. 2020).

12. Submit information promptly. An applicant, attorney, or agent who is aware of prior art or other information and its significance should submit the same early in prosecution, e.g., before the first action by the examiner, and not wait until after allowance. Potentially material information discovered late in the prosecution should be immediately submitted. That the issue fee has been paid is no reason or excuse for failing to submit information. See *Elmwood Liquid Products, Inc. v. Singleton Packing Corp.*, 328 F. Supp. 974, 170 USPQ 398 (M.D. Fla. 1971).

13. It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant’s attention and/or are known to be of most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff’d*, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), *cert. denied*, 414 U.S. 874 (1974). But cf. *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

14. Watch out for continuation-in-part (CIP) applications where intervening material information or documents may exist; particularly watch out for foreign patents and publications related to the parent application and dated more than 1 year before the

filing date of the CIP. These and other intervening documents may be material information. See *In re Ruschetta*, 255 F.2d 687, 690-91, 118 USPQ 101, 104 (CCPA 1958); *In re van Langenhoven*, 458 F.2d 132, 173 USPQ 426 (CCPA 1972); *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D. Del. 1972).

15. Watch out for information that might be deemed to be prior art under [pre-AIA 35 U.S.C. 102\(f\)](#) and (g).

Prior art under [pre-AIA 35 U.S.C. 102\(f\)](#) may be available under [pre-AIA 35 U.S.C. 103](#). See *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401, 43 USPQ2d 1641, 1644 (Fed. Cir. 1997)(35 U.S.C. “102(f) is a prior art provision for purposes of § 103”); *Dale Electronics v. R.C.L. Electronics*, 488 F.2d 382, 386, 180 USPQ 225, 227 (1st. Cir. 1973); and *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981).

Note also that evidence of prior invention under [pre-AIA 35 U.S.C. 102\(g\)](#) may be available under [pre-AIA 35 U.S.C. 103](#), such as in *In re Bass*, 474 F.2d 1276, 177 USPQ 178 (CCPA 1973). In addition, the AIA provides that the provisions of [pre-AIA 35 U.S.C. 102\(g\)](#) apply to each claim of an AIA application for patent if the patent application: (1) contains or contained at any time a claim to a claimed invention having an effective filing date as defined in [35 U.S.C. 100\(i\)](#) that occurs before March 16, 2013; or (2) is ever designated as a continuation, divisional, or continuation-in-part of an application that contains or contained at any time a claim to a claimed invention that has an effective filing date before March 16, 2013.

Note [pre-AIA 35 U.S.C. 103\(c\)](#) disqualifies [pre-AIA 35 U.S.C. 102\(f\)/103](#) or [102\(g\)/103](#) prior art which was, at the time the second invention was made, owned by or subject to an obligation of assignment to, the person who owned the first invention. Further note that [pre-AIA 35 U.S.C. 103\(c\)](#) disqualifies [pre-AIA 35 U.S.C. 102\(e\)/103](#) prior art for applications filed on or after November 29, 1999. See [MPEP §§ 2146 - 2146.02](#).

16. Watch out for information picked up or disclosed by the inventors and others at conventions, plant

visits, in-house reviews, etc. See, for example, *Dale Electronics v. R.C.L. Electronics*, 488 F.2d 382, 386-87, 180 USPQ 225, 228 (1st Cir. 1973).

17. Make sure that all of the individuals who are subject to the duty of disclosure, such as spelled out in [37 CFR 1.56](#), are informed of and fulfill their duty.

18. If information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

19. Finally, where relevant documentation is submitted to a regulatory review body, such as the Food & Drug Administration (FDA), and is material to a pending patent application, such documentation should be submitted for examiner review. While the considerations made by the FDA for approving clinical trials are different from those made by the USPTO in determining whether a claim is patentable, submissions, particularly opposing arguments, may be material to ongoing patent prosecution. *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353-54, 2021 USPQ2d 909 (Fed. Cir. 2021).

## **2005 Comparison to Requirements for Information [R-07.2022]**

Under [37 CFR 1.56](#), each individual associated with the filing and prosecution of a patent application has a duty to disclose on their own initiative information material to patentability under [37 CFR 1.56](#). By contrast, under [37 CFR 1.105](#), an examiner or other Office employee is authorized to require, from parties identified in [37 CFR 1.56](#), information reasonably necessary to examine or treat a matter in an application. The provisions of [37 CFR 1.105](#) are detailed in [MPEP § 704.10 - MPEP § 704.14 et seq.](#)

The criteria for requiring information under [37 CFR 1.56](#), i.e., materiality to the patentability of

claimed subject matter, is substantially higher than the criteria for requiring information under [37 CFR 1.105](#), i.e., reasonable necessity to the examination of the application. See, e.g., *Star Fruits S.N.C. v. United States*, 61393 F.3d 1277, 1282, 73 USPQ2d 1409, 1413 (Fed. Cir. 2005) ("We think it clear that 'such information as may be reasonably necessary to properly examine or treat the matter,' 37 C.F.R. 1.105(a)(1), contemplates information relevant to examination either procedurally or substantively. It includes a zone of information beyond that defined by section 1.56 as material to patentability, and beyond that which is directly useful to support a rejection or conclusively decide the issue of patentability."). See also *Hyatt v. USPTO*, 797 F.3d 1374, 116 USPQ2d 1331 (Fed. Cir. 2015). Information required by the examiner pursuant to [37 CFR 1.105](#) would not necessarily be considered material to patentability in itself, but would be necessary to obtain a complete record from which a determination of patentability will be made.

Therefore, when an examiner has a reasonable basis to conclude that an individual identified under [37 CFR 1.56\(c\)](#) or any assignee has information that would aid in the examination of the application or treatment of some matter, the examiner may require additional information. This requirement could include statements made or information submitted to other Government agencies such as the FDA. For example, when examining a claim directed to a process of manufacturing a particular drug product that was effectively filed more than one year after FDA approval of the drug product, an examiner may appropriately require an applicant to submit to the USPTO information submitted to the FDA (e.g., in a New Drug Application or Biologics License Application) on how the drug product was manufactured.

## **2006-2009 [Reserved]**

## **2010 Office Handling of Duty of Disclosure/Inequitable Conduct Issues [R-08.2017]**

It is the courts and not the Office that are in the best position to fashion an equitable remedy to fit the



precise facts in those cases where inequitable conduct is established. Furthermore, inequitable conduct is not set by statute as a criteria for patentability but rather is a judicial application of the doctrine of unclean hands which is appropriate to be handled by the courts rather than by an administrative body. Because of the lack of tools in the Office to deal with this issue and because of its sensitive nature and potential impact on a patent, examiner determinations generally will not deter subsequent litigation of the same issue in the courts on appeal or in separate litigation. In addition, examiner determinations would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest.

Accordingly, the examiner does not investigate and reject original or reissue applications under [37 CFR 1.56](#). Likewise, the examiner will not comment upon duty of disclosure issues which are brought to the attention of the Office except to note, in appropriate circumstances, that such issues are not considered by the examiner during examination of patent applications, or during reexamination proceedings or supplemental examination.

Issues of fraud and/or inequitable conduct in an interference proceeding before the Board may be considered by the Board if there is a showing of good cause.

## **2011 Correction of Errors in Application [R-07.2022]**

In some instances an application may be filed containing an error. For example, an application may be filed with an inventorship error.

### **35 U.S.C. 116 Inventors.**

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(c) CORRECTION OF ERRORS IN APPLICATION.— Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

For applications filed on or after September 16, 2012, an inventorship error may be corrected without disclosure of the circumstances of the error. Previously under [pre-AIA 35 U.S.C. 116](#), applicants

had to specify that such changes “arose without any deceptive intent”. Even though the “deceptive intent” language has been removed from the law, applicants still have a duty to exercise candor and good faith in all dealings with the Office. When an error is discovered, applicant should take steps to ensure that the error is corrected as soon as possible. See [MPEP § 602.01](#) *et seq.* and [MPEP § 602.09](#) for additional information.

In instances when an applicant submits other information (i.e., errors other than inventorship) to the Office that is incorrectly or incompletely characterized, applicant should:

expressly advise the PTO of [the misrepresentation’s] existence, stating specifically wherein it resides. . . . It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions.

See *Intellect Wireless v. HTC Corp.*, 732 F.3d 1339, 1343, 108 USPQ2d 1563, 1565 (Fed. Cir. 2013). Applicants should disclose to the USPTO any information that 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. See [37 CFR 1.56\(b\)\(2\)](#).

In order to assure that any correction is fully considered by the examiner, applicants should file the correction “openly”, as in filing the correction under separate cover so that the examiner will not be left to determine what is correct. *Id.* See also *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1572, 220 USPQ 289, 301 (Fed. Cir. 1983). [37 CFR 1.4\(c\)](#) requires that each distinct subject must be contained in a separate paper to avoid confusion and delay in responding.

## 2012 Reissue Applications Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure [R-08.2017]

*[Editor Note: This MPEP section is **only applicable** to reissue applications filed before September 16, 2012. For reissue applications filed on or after September 16, 2012, the requirement to state that the errors arose "without any deceptive intention" was eliminated consistent with the America Invents Act (AIA) amendments to 35 U.S.C. 251.]*

Questions of “fraud,” “inequitable conduct,” or violation of “duty of disclosure” or “candor and good faith” can arise in reissue applications.

### “ERROR WITHOUT ANY DECEPTIVE INTENTION”

For reissue applications filed prior to September 16, 2012, both [pre-AIA 35 U.S.C. 251](#) and [pre-AIA 37 CFR 1.175](#) require that the reissue oath or declaration must state that the error arose “without any deceptive intention.” Further, the examiner should determine whether applicant has averred in the reissue oath or declaration, as required by [pre-AIA 37 CFR 1.175\(a\)\(2\)](#), [\(b\)\(1\)](#), and [\(b\)\(2\)](#), that all “errors” arose “without any deceptive intention.” However, the examiner should not normally comment or question as to whether the averred statement as to lack of deceptive intention appears correct or true. See [MPEP § 1414](#).

*In re Heany*, 1911 C.D. 138, 180 (1911), unequivocally states:

Where such a condition [fraudulent or deceptive intention] is shown to exist the right to reissue the patent is forfeited.

Similarly, the court in *In re Clark*, 522 F.2d 623, 627, 187 USPQ 209, 213 (CCPA 1975) indicated:

Reissue is not available to rescue a patentee who had presented claims limited to avoid particular prior art and then had failed to disclose that prior art . . . after that failure to disclose has resulted in invalidating of the claims.

It is clear that “fraud” cannot be purged through the reissue process. See conclusions of Law 89 and 91 in *Intermountain Research and Eng’g Co. v. Hercules Inc.*, 171 USPQ 577, 631-32 (C.D. Cal. 1971).

Clearly, where several patents or applications stem from an original application which contained fraudulent claims ultimately allowed, the doctrine of unclean hands bars allowance or enforcement of any of the claims of any of the applications or patents. See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245, 19 USPQ 228, 230 (1933); *East Chicago Machine Tool Corp. v. Stone Container Corp.*, 181 USPQ 744, 748 (N.D. Ill.), *modified*, 185 USPQ 210 (N.D. Ill. 1974). See also *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D.Del. 1972) and *Strong v. General Electric Co.*, 305 F. Supp. 1084, 162 USPQ 141 (N.D. Ga. 1969), *aff’d*, 434 F.2d 1042, 168 USPQ 8 (5th Cir. 1970), *cert. denied*, 403 U.S. 906 (1971) where fraud or inequitable conduct affecting only certain claims or only one of related patents was held to affect the other claims or patent. Clearly, “fraud” practiced or attempted in an application which issues as a patent is “fraud” practiced or attempted in connection with any subsequent application to reissue that patent. The reissue application and the patent are inseparable as far as questions of “fraud,” “inequitable conduct,” or “violation of the duty of disclosure” are concerned. See *In re Heany, supra*; and *Norton v. Curtiss*, 433 F.2d 779, 792, 167 USPQ 532, 543 (CCPA 1970), wherein the court stated:

We take this to indicate that any conduct which will prevent the enforcement of a patent after the patent issues should, if discovered earlier, prevent the issuance of the patent.

Clearly, if a reissue patent would not be enforceable after reissue because of “fraud,” “inequitable conduct” or “violation of the duty of disclosure” during the prosecution of the patent sought to be reissued, the reissue patent application should not be allowed. Where no investigation is needed to establish such circumstances, an appropriate remedy would be to reject the claims in the reissue application in accordance with [35 U.S.C. 251](#).

See [MPEP § 1448](#) for information pertaining to the examination of a reissue application when there is an admission or judicial determination of fraud, inequitable conduct or violation of the duty of disclosure.

### 2012.01 Collateral Estoppel [R-08.2017]

*[Editor Note: This MPEP section is **only applicable** to reissue applications filed before September 16, 2012. For reissue applications filed on or after September 16, 2012, the requirement to state that the errors arose "without any deceptive intention" was eliminated consistent with the America Invents Act (AIA) amendments to 35 U.S.C. 251.]*

The Supreme Court in *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 169 USPQ 513 (1971) set forth the rule that once a patent has been declared invalid via judicial inquiry, a collateral estoppel barrier is created against further litigation involving the patent, unless the patentee-plaintiff can demonstrate "that he did not have" a full and fair chance to litigate the validity of his patent in "the earlier case." See also *Ex parte Varga*, 189 USPQ 209 (Bd. App. 1973). As stated in *Kaiser Industries Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 987, 185 USPQ 343, 362 (3rd Cir. 1975):

In fashioning the rule of *Blonder-Tongue*, Justice White for a unanimous Court made it clear that a determination of patent invalidity, after a thorough and equitable judicial inquiry, creates a collateral estoppel barrier to further litigation to enforce that patent.

Under [pre-AIA 35 U.S.C. 251](#), the Director can reissue a patent only if there is "error without any deceptive intention." The Director is without authority to reissue a patent when "deceptive intention" was present during prosecution of the parent application. See *In re Clark*, 522 F.2d 62, 187 USPQ 209 (CCPA 1975) and *In re Heany*, 1911 C.D. 138, 180 (1911). Thus, the collateral estoppel barrier applies where reissue is sought of a patent which has been held invalid or unenforceable for "fraud" or "violation of duty of disclosure" in

procuring of said patent. It was held in *In re Kahn*, 202 USPQ 772, 773 (Comm'r Pat. 1979):

Therefore, since the Kahn patent was held invalid, inter alia, for "failure to disclose material facts of which \* \* \* [Kahn] was aware" this application may be stricken under [37 CFR 1.56](#) via the doctrine of collateral estoppel as set forth in *Blonder-Tongue*, supra.

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The Patent and Trademark Office . . . has found no clear justification for not adhering to the doctrine of collateral estoppel under *Blonder-Tongue* in this case. Applicant has had his day in court. He appears to have had a full and fair chance to litigate the validity of his patent.

See [MPEP § 2259](#) for collateral estoppel in reexamination proceedings.

### 2013 Protests Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure [R-08.2017]

[37 CFR 1.291](#) permits protests by the public against pending applications.

Submissions under [37 CFR 1.291](#) are not limited to prior art documents such as patents and publications, but are intended to include any information, which in the protestor's opinion, would make or have made the grant of the patent improper (see [MPEP § 1901.02](#)). This includes, of course, information indicating the presence of "fraud" or "inequitable conduct" or "violation of the duty of disclosure," which will be entered in the application file, generally without comment on the inequitable conduct issues raised in it.

Protests should be in conformance with [37 CFR 1.291\(a\)](#) and [\(b\)](#), and include a statement of the alleged facts involved, the point or points to be reviewed, and the action requested. Any briefs or memoranda in support of the petition, and any affidavits, declarations, depositions, exhibits, or other material in support of the alleged facts, should accompany the protest.

## 2014 Duty of Disclosure in Reexamination Proceedings and Supplemental Examination [R-08.2017]

### *37 CFR 1.555 Information material to patentability in ex parte reexamination and inter partes reexamination proceedings.*

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective reexamination occurs when, at the time a reexamination proceeding is being conducted, the Office is aware of and evaluates the teachings of all information material to patentability in a reexamination proceeding. Each individual associated with the patent owner in a reexamination proceeding has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability in a reexamination proceeding. The individuals who have a duty to disclose to the Office all information known to them to be material to patentability in a reexamination proceeding are the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding. The duty to disclose the information exists with respect to each claim pending in the reexamination proceeding until the claim is cancelled. Information material to the patentability the patentability of a cancelled claim need not be submitted if the information is not material to patentability of any claim remaining under consideration in the reexamination proceeding. The duty to disclose all information known to be material to patentability in a reexamination proceeding is deemed to be satisfied if all information known to be material to patentability of any claim in the patent after issuance of the reexamination certificate was cited by the Office or submitted to the Office in an information disclosure statement. However, the duties of candor, good faith, and disclosure have not been complied with if any fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct by, or on behalf of, the patent owner in the reexamination proceeding. Any information disclosure statement must be filed with the items listed in § 1.98(a) as applied to individuals associated with the patent owner in a reexamination proceeding, and should be filed within two months of the date of the order for reexamination, or as soon thereafter as possible.

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(c) The responsibility for compliance with this section rests upon the individuals designated in paragraph (a) of this section and no evaluation will be made by the Office in the reexamination proceeding as to compliance with this section. If questions of compliance with this section are raised by the patent owner or the third party requester during a reexamination proceeding, they will be noted as unresolved questions in accordance with § 1.552(c).

As provided in [37 CFR 1.555](#), the duty of disclosure in reexamination proceedings applies to the patent owner and individuals associated with the patent owner. That duty is a continuing obligation on the

part of the patent owner throughout the proceedings. Any fraud practiced or attempted on the Office or any violation of the duty of disclosure through bad faith or intentional misconduct by any such individual results in noncompliance with [37 CFR 1.555\(a\)](#). Any such issues raised by the patent owner or the third party requester during a reexamination proceeding will merely be noted as unresolved questions under [37 CFR 1.552\(c\)](#). See [MPEP § 2258](#) for information material to patentability in *ex parte* reexamination proceedings and [MPEP § 2658](#) for *inter partes* reexamination proceedings.

For the patent owner's duty to disclose prior or concurrent proceedings in which the patent is or was involved, see [MPEP § 2282](#) (for *ex parte* reexamination), [§ 2686](#) (for *inter partes* reexamination), and [§ 2001.06\(c\)](#).

In supplemental examination, the duty of disclosure applies to the patent owner and individuals associated with the patent owner as defined in [37 CFR 1.555](#). However, as provided by [37 CFR 1.625\(d\)\(4\)](#), information material to patentability is defined by [37 CFR 1.56](#) in supplemental examination and any *ex parte* reexamination proceeding ordered under [35 U.S.C. 257](#). Furthermore, [37 CFR 1.620\(g\)](#) provides that, if the Office becomes aware, during the course of a supplemental examination or of any *ex parte* reexamination ordered under [35 U.S.C. 257](#) as a result of the supplemental examination proceeding, that a material fraud on the Office may have been committed in connection with the patent requested to be examined, the supplemental examination proceeding or any *ex parte* reexamination proceeding ordered under [35 U.S.C. 257](#) will continue. The matter will be referred to the U.S. Attorney General in accordance with [35 U.S.C. 257\(e\)](#).

For the patent owner's duty to disclose prior or concurrent proceedings in which the patent is or was involved in supplemental examination, see [MPEP § 2820](#).



## 2015 Duties of Disclosure and Reasonable Inquiry Arise in Dealings With Other Government Agencies [R-07.2022]

Each individual with a duty to disclose, or party with a duty of reasonable inquiry, should ensure that the statements made to the USPTO and other Government agencies, or any statements made on their behalf to other Government agencies regarding the claimed subject matter, are consistent. See *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 2021 USPQ2d 909 (Fed. Cir. 2021) (affirming a district court’s determination of inequitable conduct because the patent owner’s Chief Science Officer failed to provide to the USPTO submissions he made to the FDA about the prior art that were inconsistent with positions taken before the USPTO during the prosecution of a pending patent application). Furthermore, providing material information to other Government agencies, including the FDA, while simultaneously withholding the same information from the USPTO undermines both the intent and spirit of the duty of disclosure and violates those duties. For example, in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1354, 73 USPQ2d 1593, 1598 (Fed. Cir. 2005), the U.S. Court of Appeals for the Federal Circuit inferred intent to deceive and found inequitable conduct occurred when an official involved in both the FDA and the USPTO submissions chose to disclose material prior art to the FDA but not to the USPTO.

Activities or documents associated with market testing, marketing, or commercialization by the patent applicant can also be material to patentability, and therefore, when material, should be disclosed to the USPTO. See *GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 1330-1332, 2020 USPQ2d 10092 (Fed. Cir. 2020) (finding that a district court did not abuse its discretion in reaching its inequitable conduct determination where the district court concluded that the inventors and their lawyers made a deliberate decision to withhold material information from the USPTO regarding an offer for sale and reduction to practice of the claimed invention that would have implicated an on-sale bar to the granting of a patent; the lawyers filed with the USPTO a declaration containing a false statement about the timing of an offer for sale despite having

in their possession materials that would call into question the veracity of the statement; and the inventors and lawyers subsequently failed to correct the false declaration). By following this guidance, it is expected that patent applicants can obtain more reliable patent protection and avoid the findings of inequitable conduct and sanctions.

Similarly, each individual with a duty to disclose, or party with a duty of reasonable inquiry, should review documents it receives from other Government agencies to determine whether the information should be submitted to the USPTO. For example, when a company seeks FDA approval to market a generic drug before the expiration of patents related to the drug, the generic drug application (e.g., an Abbreviated New Drug Application (ANDA)) must contain a “paragraph IV certification” that the patents submitted to the FDA by the brand-name drug’s sponsor, listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), and related to the drug are invalid, are unenforceable, or will not be infringed by the generic product. Except in limited circumstances, notice of a paragraph IV certification must also be communicated to the owner of the patent subject to the certification and to the New Drug Application holder. Such a notice includes a detailed statement providing factual and legal bases for the paragraph IV certification. 21 CFR 314.95(c)(7). Consequently, to assist USPTO staff in evaluating patentability effectively and efficiently, the party receiving a paragraph IV certification should review such documents to determine whether they are material to the patentability of any pending matters before the USPTO, such as pending patent applications, reexamination proceedings, or issues in proceedings pending before the PTAB. If the content of the detailed statement, or other information that is part of the ANDA process, is deemed material to patentability in a pending USPTO matter, then such information must be submitted to the USPTO during the pendency of the matter, to meet the duties of candor and good faith and disclosure under [37 CFR 1.56](#), [1.555](#), [42.11\(a\) or \(c\)](#), or [11.18\(b\)\(2\)](#).

Deliberate schemes or established practices to prevent individuals with a duty to disclose under [37 CFR 1.56\(c\)](#) from obtaining knowledge of material

information is not acting in accordance with candor and good faith under [37 CFR 1.56\(a\)](#). For example, walling off the patent prosecution practitioners from the attorneys seeking FDA approval, as a way to prevent material information from being exchanged between the practitioners and attorneys, is inappropriate. The U.S. Supreme Court has refused to enforce patents where deliberate steps were taken to suppress material information. See, e.g., *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 19 USPQ 228 (1933) (patent owner’s suit dismissed where the patent owner paid a third party to keep a prior use secret); *Precision Instruments Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 65 USPQ 133 (1945) (suit dismissed where patent owner actively suppressed evidence of perjury to the USPTO).

Though the FDA compiles paragraph IV certifications and publishes a list on its website, submitting this list to the USPTO does not satisfy the duty of disclosure for any material information submitted with the paragraph IV certification. These lists do not include patent numbers, relevant claims, or an explanation of the basis for the certification. Therefore, information and documents submitted with the paragraph IV certification that are material to patentability or to issues in proceedings pending before the USPTO, including the PTAB, must be submitted directly to the USPTO and as described above, the examiner may appropriately require submission of information concerning the certifications in certain situations.

### **2016 Fraud, Inequitable Conduct, or Violation of Duty of Disclosure Affects All Claims [R-08.2017]**

A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. See *Therasense Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1288, 99 USPQ2d 1065, 1071 (Fed. Cir. 2011), *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D.Del. 1972) and *Strong v. General Electric Co.*, 305 F. Supp. 1084, 162 USPQ 141 (N.D. Ga. 1969), *aff’d*, 434 F.2d 1042, 168 USPQ 8 (5th Cir. 1970), *cert. denied*, 403 U.S. 906 (1971). In *J. P. Stevens*

*& Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561, 223 USPQ 1089, 1093-94 (Fed. Cir. 1984), the court stated:

Once a court concludes that inequitable conduct occurred, all the claims — not just the particular claims in which the inequitable conduct is directly connected — are unenforceable. See *generally*, cases collected in 4 Chisum, PATENTS, paragraph 19.03[6] at 19-85 n. 10 (1984). Inequitable conduct “goes to the patent right as a whole, independently of particular claims.” *In re Clark*, 522 F.2d 623, 626, 187 USPQ 209, 212 (CCPA).

The court noted in footnote 8 of *Stevens*:

In *In re Multiple Litigation Involving Frost Patent*, 540 F.2d 601, 611, 191 USPQ 241, 249 (3rd. Cir. 1976), some claims were upheld despite nondisclosure with respect to others. The case is not precedent in this court.

As stated in *Genveto Jewelry Co. v. Lambert Bros., Inc.*, 542 F. Supp. 933, 943, 216 USPQ 976, 984 (S. D. N. Y. 1984) (quoting Patent Law Perspectives, 1977 Developments, § G.1 [1]-189):

The gravamen of the fraud defense is that the patentee has failed to discharge his duty of dealing with the examiner in a manner free from the taint of “fraud or other inequitable conduct.” If such conduct is established in connection with the prosecution of a patent, the fact that the lack of candor did not directly affect *all* the claims in the patent has never been the governing principle. It is the inequitable conduct that generates the unenforceability of the patent and we cannot think of cases where a patentee partially escaped the consequences of his wrongful acts by arguing that he only committed acts of omission or commission with respect to a limited number of claims. It is an all or nothing proposition. [Emphasis in original.]

### **2017-2022 [Reserved]**