



[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2011-0030]

RIN 0651-AC58

**Revision of the Duty to Disclose Information in Patent Applications and
Reexamination Proceedings**

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office or PTO) is proposing revisions to the materiality standard for the duty to disclose information in patent applications and reexamination proceedings (duty of disclosure) in light of a 2011 decision by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). The Office previously issued a notice of proposed rulemaking on July 21, 2011, and due to the passage of time since the comment period closed in 2011, the Office considers it

appropriate to seek additional comments from our stakeholders before issuing a final rulemaking. In the current notice of proposed rulemaking, the Office is seeking public comments on the rules of practice, as revised in response to the comments received from our stakeholders.

DATES: *Comment Deadline Date:* The Office is soliciting comments from the public on this proposed rule change. Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure consideration. No public hearing will be held.

ADDRESSES: Comments concerning this notice should be sent by electronic mail message over the Internet (email) addressed to AC58.comments@uspto.gov. Comments may also be submitted by postal mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Matthew Sked, Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy. Comments may also be sent by email via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments via email to facilitate posting on the Office's Internet Web site. Plain text is preferred, but comments may also be submitted in ADOBE® portable document format

or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient scanning into ADOBE® portable document format.

The comments will be available for public inspection, upon request, at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site (<http://www.uspto.gov>) and at <http://www.regulations.gov>. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Matthew J. Sked, Legal Advisor ((571) 272-7627) or Nicole Dretar Haines, Senior Legal Advisor ((571) 272-7717), Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy.

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: This notice proposes changes to the relevant rules of practice to harmonize the materiality standard for the duty of disclosure before the Office with the but-for materiality standard for establishing inequitable conduct before the courts in light of the Federal Circuit's decision in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

Summary of Major Provisions: The Office proposes to revise the rules of practice to adopt the but-for standard for materiality required to establish inequitable conduct set forth in the Federal Circuit’s decision in Therasense as the standard for materiality for the duty to disclose information in patent applications and reexamination proceedings. The Office also proposes to revise the rules of practice to explicitly reference “affirmative egregious misconduct” as set forth in the Federal Circuit’s decision in Therasense.

Costs and Benefits: This rulemaking is not economically significant as that term is defined in Executive Order 12866 (Sept. 30, 1993).

Background: On May 25, 2011, the Federal Circuit issued the en banc Therasense decision, modifying the standard for materiality required to establish inequitable conduct before the courts. The Federal Circuit tightened the materiality standard to “reduce the number of inequitable conduct cases before the courts and . . . cure the problem of overdisclosure of marginally relevant prior art to the PTO.” Therasense, 649 F.3d at 1291. In Therasense, the Federal Circuit held that “the materiality required to establish inequitable conduct is but-for materiality.” Id. The Federal Circuit explained that “[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” Id. The Federal Circuit further explained that “in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference[,] . . . apply[ing] the

preponderance of the evidence standard and giv[ing] claims their broadest reasonable construction.” Id. at 1291-92. Examples of where the Federal Circuit found information to be but-for material include Transweb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295 (Fed. Cir. 2016), and Apotex, Inc. v. UCB Inc., 763 F.3d 1354 (Fed. Cir. 2014).

In addition, the Federal Circuit recognized that the materiality prong of inequitable conduct may also be satisfied in cases of affirmative egregious misconduct. Id. at 1292. See also The Ohio Willow Wood Co. v. Alps South, LLC, 735 F.3d 1333, 1351 (Fed. Cir. 2013); Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339, 1344 (Fed. Cir. 2013). The Federal Circuit explained that “[t]his exception to the general rule of requiring but-for proof incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with ‘deliberately planned and carefully executed scheme[s]’ to defraud the PTO and the courts.” Therasense, 649 F.3d at 1292. The Federal Circuit reasoned that “a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.” Id. Further, the Federal Circuit clarified that while the filing of an unmistakably false affidavit would constitute affirmative egregious misconduct, “neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct.” Id. at 1292-93. Rather, “claims of inequitable conduct that are based on such omissions require proof of but-for materiality.” Id. at 1293.

A notice of proposed rulemaking was previously published in the Federal Register (76 FR 43631) on July 21, 2011. Comments were due on September 19, 2011. The Office

received 24 written comments in response to the notice. In addition to considering the public comments, the Office monitored further Federal Circuit decisions regarding the application of the inequitable conduct standard. Based upon the passage of time since the end of the comment period and the significant changes to patent law as a result of the successful implementation of the Leahy-Smith America Invents Act, the Office considered it appropriate to obtain public comment on the proposed changes to the rules of practice regarding the duty of disclosure. Therefore, the Office is publishing the current notice of proposed rulemaking to provide the public with an opportunity to comment on the proposed revisions, which take into account the comments received in response to the 2011 notice of proposed rulemaking.

Like the previously proposed rule, the currently proposed rule would harmonize the materiality standard for the duty of disclosure before the Office with the but-for materiality standard set forth in Therasense for establishing inequitable conduct before the courts. Specifically, the currently proposed rule would modify 37 CFR 1.56(a) and 37 CFR 1.555(a) to recite that the materiality standard for the duty of disclosure is but-for materiality, and would modify 37 CFR 1.56(b) and 37 CFR 1.555(b) to define the but-for materiality standard as set forth in Therasense. Further, in view of the Federal Circuit's recognition that affirmative egregious misconduct satisfies the materiality prong of inequitable conduct, the currently proposed rule would amend 37 CFR 1.56(a) and 37 CFR 1.555(a) to explicitly incorporate affirmative egregious misconduct.

In the previous notice of proposed rulemaking, the Office proposed only to amend 37 CFR 1.56(b) and 37 CFR 1.555(b) by combining in the same provision both an explicit reference to the Therasense materiality standard and a definition of the materiality standard, which included an explicit recitation of affirmative egregious misconduct. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 FR 43631, 43634 (July 21, 2011). Prior to making a final decision on whether to modify the previously proposed rule, the Office considered all public comments and monitored the petition for certiorari to the Supreme Court in 1st Media, LLC v. Electronic Arts, Inc., 694 F.3d 1367 (Fed. Cir. 2012), cert. denied, 134 S.Ct. 418 (2013) and the further developments regarding the application of the inequitable conduct standard by the Federal Circuit. Accordingly, the Office has decided to modify the previously proposed rule language to avoid potential confusion by moving the language regarding affirmative egregious misconduct from the definition of the materiality standard for disclosure of information in 37 CFR 1.56(b)(2) and 37 CFR 1.555(b)(2), as previously proposed, to 37 CFR 1.56(a) and 37 CFR 1.555(a), respectively. Therefore, in the currently proposed rule, 37 CFR 1.56(b) and 37 CFR 1.555(b) would define the but-for materiality standard as set forth in Therasense, while 37 CFR 1.56(a) and 37 CFR 1.555(a) would incorporate affirmative egregious misconduct.

In the previous notice of proposed rulemaking, the Office also proposed to amend 37 CFR 1.56(b) and 37 CFR 1.555(b) to explicitly reference the Therasense ruling. Comments received in response to the previous notice of proposed rulemaking

questioned explicitly referencing the Therasense decision directly in the rules out of concern that the rules could be affected as the Therasense ruling is interpreted and applied, or if Therasense is overruled. While the currently proposed rule removes the explicit reference to the Therasense decision, explicitly referencing the court decision is not necessary to link the materiality standard for the duty of disclosure before the Office with the but-for materiality standard set forth in Therasense for establishing inequitable conduct before the courts. The recitation of but-for materiality in 37 CFR 1.56(a) and 1.555(a) and the definition of but-for materiality in 37 CFR 1.56(b) and 1.555(b) would establish that the materiality standard for the duty of disclosure in this currently proposed rule is the same as the but-for materiality standard set forth in Therasense and its interpretations and applications.

As discussed previously, Therasense was decided by the Federal Circuit en banc. This precedential decision can only be overturned by another en banc decision of the Federal Circuit or by a decision of the Supreme Court. See, e.g., Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 n.5 (Fed. Cir. 1998) (Federal Circuit precedent may not be changed by a panel.). The Office's explicit reference to and definition of the but-for materiality standard set forth in Therasense in currently proposed 37 CFR 1.56 and 37 CFR 1.555 would avoid divergence between the Office's materiality standard for the duty of disclosure and the but-for inequitable conduct materiality standard set forth in Therasense. This approach should benefit the public by providing a consistent materiality standard without the need for continuous revisions to the rules as the Therasense standard is interpreted or applied. In the event the Supreme Court, or Federal

Circuit acting en banc, chooses to revise the but-for materiality standard in Therasense, the Office will reconsider the rules at that time. Further, the Office will keep the public informed of its understanding of how the Federal Circuit interprets the standard through future revisions to the Manual of Patent Examining Procedure (MPEP).

Historically, the Federal Circuit connected the materiality standard for inequitable conduct with the Office's materiality standard for the duty of disclosure. That is, the Federal Circuit has invoked the materiality standard for the duty of disclosure to measure materiality in cases raising claims of inequitable conduct. In doing so, the Federal Circuit has utilized both the "reasonable examiner" standard set forth in the 1977 version of 37 CFR 1.56(b) and the prima facie case of unpatentability standard set forth in the 1992 version of 37 CFR 1.56(b). See, e.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352-53 (Fed. Cir. 2005). In Therasense, the Federal Circuit eliminated what existed of the historical connection between the two materiality standards and did not indicate that the Office must apply the but-for standard for materiality required to establish inequitable conduct under Therasense as the standard for determining materiality under 37 CFR 1.56 or 37 CFR 1.555. Thus, while Therasense does not require the Office to harmonize its materiality standard underlying the duty of disclosure and the Federal Circuit's but-for materiality standard underlying the inequitable conduct doctrine, there are important reasons to amend 37 CFR 1.56 and 37 CFR 1.555 to do so.

A unitary materiality standard is simpler for the patent system as a whole. Under the single but-for standard of materiality, patent applicants will not be put in the position of having to meet one standard of materiality as set forth in Therasense in defending against inequitable conduct allegations and a second, different materiality standard when complying with the duty of disclosure before the Office. Also, the Office expects that by adopting the Therasense but-for standard for materiality in this currently proposed rule, the frequency with which charges of inequitable conduct are raised against applicants and practitioners for failing to disclose material information to the Office will be reduced.

Similarly, the Office expects that adopting the but-for materiality standard would reduce the incentive to submit marginally relevant information in information disclosure statements (IDSs). As such, this currently proposed rule would further the Office's goal of enhancing patent quality. The adoption of the but-for standard for materiality should lead to more focused prior art submissions by applicants, which in turn will assist examiners in more readily recognizing the most relevant prior art.

At the same time, the Office also expects this currently proposed rule would continue to encourage applicants to comply with their duty of candor and good faith. The Office recognizes that it previously considered, and rejected, a but-for standard for the duty of disclosure in 1992 when it promulgated the prima facie case of unpatentability standard that would be replaced under this proposed rule. Duty of Disclosure, 57 FR 2021, 2024 (Jan. 17, 1992). The Office was concerned about the types of potential misconduct that could occur unchecked under a pure but-for standard. By including a provision for

affirmative egregious misconduct in the currently proposed rule, the Office’s long-standing concern would be mitigated. In Therasense, the Federal Circuit stated, “creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision . . . strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.” Id. at 1293.

Discussion of Specific Rules

The following is a description of the amendments PTO is proposing:

Section 1.56: Section 1.56(a) as proposed to be amended would provide that the materiality standard for the duty of disclosure is but-for materiality. Further, § 1.56(a) as proposed would provide that a patent will not be granted on an application in which affirmative egregious misconduct was engaged in.

Section 1.56(b) as proposed to be amended would replace the prima facie case of unpatentability materiality standard with the definition of the but-for materiality standard. As proposed, § 1.56(b) would provide that information is but-for material to patentability if the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.

Previously proposed § 1.56(b) included two discrete sentences. The first sentence stated information is material to patentability if it is material under the standard set forth in Therasense, and the second sentence stated information is material to patentability under Therasense if (1) the Office would not allow a claim if it were aware of the information, or (2) the applicant engages in affirmative egregious misconduct before the Office as to the information. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 FR at 43634. The explicit reference to the Therasense decision and the recitation of affirmative egregious misconduct in previously proposed § 1.56(b) have not been retained in this currently proposed rule in view of public comments received. Currently proposed § 1.56(a) now recites that the materiality standard for the duty of disclosure is but-for materiality. Currently proposed § 1.56(b) defines the but-for materiality standard as set forth in Therasense.

As set forth above, an explicit reference to the Therasense decision is not necessary to link the materiality standard for the duty of disclosure to the but-for materiality standard for inequitable conduct set forth in Therasense. The Office has determined that reciting “but-for material[ity]” and its definition as it is recited in Therasense makes clear that the standard for materiality is the but-for standard set forth in Therasense and its interpretations and applications. Also, by moving the language regarding affirmative egregious misconduct from previously proposed § 1.56(b)(2) to § 1.56(a), the Office has separated the definition of the materiality standard for the duty to disclose information from the recitation of affirmative egregious misconduct.

Additionally, the Office has modified the previously proposed rule language to state that a claim is given its broadest reasonable construction “consistent with the specification.” The Office did not intend the previously proposed omission of this language that is present in existing §§ 1.56(b) and 1.555(b) as an indication that claims would no longer be given their broadest reasonable construction consistent the specification. While the Federal Circuit in Therasense did not specifically state that the broadest reasonable construction is a construction that is consistent with the specification, the Federal Circuit referenced MPEP § 2111 (8th ed. 2001) (Rev. 9, Aug. 2012) in establishing that a claim is given its broadest reasonable construction. Therasense, 649 F.3d at 1292. MPEP § 2111 states that “(d)uring patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’” See also Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (“The Patent and Trademark Office (‘PTO’) determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’”). In addition, the Federal Circuit has indicated that the phrases “broadest reasonable interpretation” and “broadest reasonable interpretation consistent with the specification” have the same meaning as it would be unreasonable to ignore any interpretive guidance afforded by the written description. See In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Nevertheless, in order to make clear that any construction made by the Office in the application of § 1.56 must be consistent with the specification, the currently proposed rules have been amended accordingly.

Section 1.555: Section 1.555(a) as proposed to be amended would provide that the materiality standard for the duty of disclosure in a reexamination proceeding is but-for materiality. Further, § 1.555(a) as proposed to be amended would provide that the duties of candor, good faith, and disclosure have not been complied with if affirmative egregious misconduct was engaged in by, or on behalf of, the patent owner in the reexamination proceeding.

Section 1.555(b) as proposed to be amended would provide that information is but-for material to patentability if, for any matter proper for consideration in reexamination, the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification. The explicit reference to the Therasense decision and recitation of affirmative egregious misconduct in previously proposed § 1.555(b) have not been retained in this currently proposed rule in view of public comments received. Currently proposed § 1.555(a) now recites that the materiality standard for the duty of disclosure in a reexamination proceeding is but-for materiality. Currently proposed § 1.555(b) defines the but-for materiality standard as set forth in Therasense.

Additionally, § 1.555(b) as proposed would provide that the but-for materiality standard covers the disclosure of information as to any matter that is proper for consideration in a reexamination proceeding. Previously proposed § 1.555(b) was silent as to the types of information that are appropriate for consideration in a reexamination proceeding, and

existing § 1.555(b) limits the types of information that could be considered in reexamination to patents and printed publications. In view of public comments received, this currently proposed rule would amend § 1.555(b) to again recite the types of information that are appropriate for consideration in a reexamination proceeding but, unlike the existing rule, this currently proposed rule encompasses disclosure of information as to any matter that is appropriate for consideration in a reexamination proceeding (e.g., admissions by patent owner), as opposed to being limited to patents and printed publications.

It is noted that § 1.933 is also directed to the duty of disclosure in inter partes reexamination proceedings; however, the statement as to materiality of information in § 1.933 incorporates § 1.555. Thus, § 1.933 has not been amended in this currently proposed rule.

Comments and Response to Comments: The Office published a notice on July 21, 2011, proposing to change the rules of practice to revise the standard for materiality of the duty to disclose information in patent applications and reexamination proceedings in light of the decision of the Federal Circuit in Therasense. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 FR at 43631. The Office received 24 written comments (from intellectual property organizations, academic and research institutions, companies, and individuals) in response to that notice. The comments and the Office's responses to the comments follow:

- A. Previously Proposed §§ 1.56(b)(1) and 1.555(b)(1)
- B. Cumulative Information
- C. Affirmative Egregious Misconduct
- D. Therasense Language
- E. General Language Comments
- F. Application of Rule Standards
- G. General Comments

A. Previously Proposed §§ 1.56(b)(1) and 1.555(b)(1)

Comment 1: Several comments suggested amending previously proposed §§ 1.56(b)(1) and 1.555(b)(1) to add the phrase “consistent with the specification” following the phrase “broadest reasonable construction” to ensure the Office would be giving a claim its broadest reasonable construction consistent with the specification.

Response: As discussed in the preamble, the Office has modified the previously proposed rule language to add “consistent with the specification” after “broadest reasonable construction.”

Comment 2: One comment suggested amending previously proposed §§ 1.56(b)(1) and 1.555(b)(1) to change the perspective from the present to the time when information was withheld from the Office. In particular, this comment suggested changing the phrase

“would not allow a claim if it were aware of the information” in proposed § 1.56(b)(1) to “would not have allowed a claim if it were aware of the information,” and changing the phrase “would not find a claim patentable if it were aware of the information” in proposed § 1.555(b)(1) to “would not have found a claim patentable if it were aware of the information.” Another comment requested clarification regarding whether proposed §§ 1.56(b)(1) and 1.555(b)(1) would apply to any application pending on, or applications filed after, the effective date of any final rule.

Response: While the first comment suggested specific language found in the Therasense holding be added to the rules, the Therasense holding pertains to inequitable conduct analysis by the courts, which is applied from a different perspective than the duty of disclosure analysis by applicants. The duty of disclosure is a prospective analysis, while inequitable conduct is a retrospective analysis. In other words, an applicant determines materiality in the present, not retroactively as a court would determine inequitable conduct. Additionally, with respect to Office proceedings, §§ 1.56(b) and 1.555(b) as proposed in this rule would apply to any application or reexamination proceeding pending on, filed on, or filed after the effective date of any final rule.

Comment 3: Several comments requested clarification regarding whether “a claim” in proposed §§ 1.56(b)(1) and 1.555(b)(1) is the finally allowed claim or any claim pending during prosecution, such as restricted claims, withdrawn claims, amended claims, etc.

Response: Currently proposed §1.56(a) explicitly states “[t]he 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.” Similarly, § 1.555(a) states “[t]he duty to disclose the information exists with respect to each claim pending in the reexamination proceeding until the claim is cancelled.” Therefore, the duty of disclosure pertains to all claims while they are pending. The duty does not pertain to information that is only material to claims that have been cancelled or withdrawn.

B. Cumulative Information

Comment 4: Several comments suggested the rules maintain the language from existing §§ 1.56(b) and 1.555(b), which provide that information is material to patentability “when it is not cumulative to information already of record or being made of record.”

Response: Sections 1.56 and 1.555 in this currently proposed rule do not include the language regarding cumulative information set forth in existing §§ 1.56 and 1.555. The Office, however, is not requesting that applicants submit cumulative information. Information that is merely cumulative to information already on the record would not be material under the but-for standard.

Comment 5: One comment stated that non-disclosed cumulative information may meet the but-for test in the situation where the Office erred in allowing a claim over the

originally cited art and the applicant is in possession of art that is cumulative to the originally cited art.

Response: The applicant is under a duty to refrain from filing and prosecuting claims that are known to be unpatentable whether based on information already of record and not recognized by the examiner or cumulative information not submitted. See §§ 11.18, 11.301, and 11.303. In such an instance, the applicant should amend the claims accordingly.

C. Affirmative Egregious Misconduct

Comment 6: Several comments stated that combining the but-for test of §§ 1.56(b)(1) and 1.555(b)(1) and the affirmative egregious misconduct test of §§ 1.56(b)(2) and 1.555(b)(2) in the previously proposed rules will lead to confusion because the but-for test involves the materiality of information while the “affirmative egregious misconduct” test is related to the nature of the conduct. Several comments, in particular, suggested moving the “affirmative egregious misconduct” exception into §§ 1.56(a) and 1.555(a).

Response: In order to alleviate any potential confusion by including affirmative egregious misconduct in §§ 1.56(b) and 1.555(b), this currently proposed rule amends §§ 1.56 and 1.555 by moving the language regarding affirmative egregious misconduct from previously proposed §§ 1.56(b)(2) and 1.555(b)(2) to §§ 1.56(a) and 1.555(a), respectively. In particular, § 1.56(a) as currently proposed would provide that a patent

will not be granted on an application where any individual associated with the filing or prosecution of the application engages in affirmative egregious misconduct. Section 1.555(a) as currently proposed would provide that the duties of candor, good faith, and disclosure have not been complied with if any individual associated with the patent owner in a reexamination proceeding engages in affirmative egregious misconduct. Thus, §§ 1.56(b) and 1.555(b), as currently proposed, are limited to defining the but-for materiality standard for the duty to disclose information.

Comment 7: Several comments stated that the phrase “affirmative egregious misconduct” in previously proposed rules §§ 1.56(b)(2) and 1.555(b)(2) is a vague and undefined term and, therefore, should not be included in the rules. In addition, several comments requested that the Office incorporate the definition of affirmative egregious misconduct from Therasense directly into the rule. Several comments requested guidance, such as examples, on what sort of conduct constitutes affirmative egregious misconduct in previously proposed §§ 1.56(b) and 1.555(b). One other comment suggested clarifying affirmative egregious misconduct to prevent affirmative egregious misconduct from “swallowing” the but-for rule and requiring affirmative egregious misconduct to have a realistic potential to impact patentability. Several comments also stated that it is unclear how affirmative egregious misconduct relates to the Office’s other rules such as §§ 1.56(a) and 10.23. (While § 10.23 was in effect at the time the comment was made, it has since been removed and § 11.804 was adopted. See Changes to Representation of Others Before The United States Patent and Trademark Office, 78 FR

20188 (Apr. 3, 2013).) These comments are applicable to the currently proposed rules as well.

Response: As discussed previously, the Office has retained and moved the recitation of affirmative egregious misconduct to currently proposed §§ 1.56(a) and 1.555(a).

Affirmative egregious misconduct is recited in currently proposed § 1.56(a) in addition to the other forms of misconduct that would preclude a patent from being granted.

Similarly, affirmative egregious misconduct is recited in currently proposed § 1.555(a) in addition to the other forms of misconduct engaged in by, or on behalf of, the patent owner in the reexamination proceeding that would cause a violation of the duties of candor, good faith, and disclosure. The discussion of affirmative egregious misconduct in Therasense and subsequent cases, as well as the lengthy jurisprudence of the unclean hands doctrine, offers guidance as to the boundaries of affirmative egregious misconduct. Specifically, in Therasense, the Federal Circuit likened affirmative egregious misconduct to the doctrine of unclean hands that “dealt with ‘deliberately planned and carefully executed scheme[s]’ to defraud the PTO and the courts.” Therasense, 649 F.3d at 1292. The Federal Circuit also described several examples of behavior that would constitute affirmative egregious misconduct including “perjury, the manufacture of false evidence, and the suppression of evidence,” as well as filing an “unmistakably false affidavit.” Id. at 1287, 1292. See also The Ohio Willow Wood Co. v. Alps South, LLC, 735 F.3d at 1351 (finding that misrepresenting evidence to the Board of Patent Appeals and Interferences was “tantamount to filing an unmistakably false affidavit”); Intellect Wireless, Inc. v. HTC Corp., 732 F.3d at 1344 (stating “the materiality prong of

inequitable conduct is met when an applicant files a false affidavit and fails to cure the misconduct”). The Federal Circuit clarified, however, that “neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct.” Therasense, 649 F.3d at 1292-93. Further, the Federal Circuit has provided additional guidance on the type of activity that would not constitute affirmative egregious misconduct. See, e.g., Powell v. Home Depot U.S.A., Inc., 663 F.3d 1221, 1235 (Fed. Cir. 2011) (failing to update a Petition to Make Special “is not the type of unequivocal act, ‘such as filing an unmistakably false affidavit,’ that would rise to the level of ‘affirmative egregious misconduct.’”).

Comment 8: Several comments suggested that acts of “affirmative egregious misconduct” in previously proposed §§ 1.56(b) and 1.555(b) should not be limited solely to “the applicant.”

Response: The Office does not interpret the Federal Circuit’s use of “patentee” in Therasense when describing affirmative egregious misconduct as limiting the misconduct to only the applicant or patent owner. All of the parties identified in §§ 1.56(c) and 1.555(a) are subject to the affirmative egregious misconduct provisions of currently proposed §§ 1.56(a) and 1.555(a), respectively.

Comment 9: One comment suggested striking previously proposed § 1.555(b)(2), which was directed to affirmative egregious misconduct, as unnecessary. The comment asserts that the previously proposed rule invites potential third party abuse and confusion during

reexamination since third parties will see the rule as a license to argue a lack of candor with respect to previous patent holder submissions to the Office.

Response: While the currently proposed rule no longer includes § 1.555(b)(2), the recitation of affirmative egregious misconduct has been moved to currently proposed § 1.555(a). As proposed, this rule would address a patent owner's duty of candor and good faith in dealing with the Office, including the patent owner's duty of disclosure. It would not establish an opportunity in a reexamination proceeding for a third party to challenge the duty of candor and good faith of a patentee. Conduct is not grounds on which reexamination may be requested and is not appropriate to be raised during a reexamination proceeding. See MPEP § 2616. The conduct of the patent owner may be raised by the patent owner during a supplemental examination proceeding. If the conduct of the patent owner is raised by the patent owner in the supplemental examination proceeding, it may be addressed by the Office in the supplemental examination proceeding and in any reexamination proceeding resulting from that supplemental examination proceeding.

D. Therasense Language

Comment 10: Several comments stated that the previously proposed rules should not explicitly reference Therasense. The comments questioned whether an explicit reference would allow the rules to change as the Therasense standard changes or lock the Office into the standard set forth in the decision even if the standard is later changed. Further,

the comments asserted that an explicit reference creates uncertainty in the rules since the rules will become a moving target not subject to interpretation on their face and that a rule cannot be understood on its face without need to interpret the Therasense decision. The comments also asserted that tying the rule to an evolving standard will cause currently pending applications to stand as test cases until the standard is fully articulated. Finally, the comments asserted that the incorporation by reference sets a standard based on private litigation where the Office is not a party and grants an administrative agency's rulemaking authority to the judicial branch, which has different goals than the Office.

Response: The currently proposed rules no longer include the language addressed by the comment. Notwithstanding the removal of an explicit reference to Therasense in currently proposed §§ 1.56(b) and 1.555(b), the recitation of the but-for materiality standard for the duty to disclose information in currently proposed §§ 1.56(b) and 1.555(b) accomplishes what a reference to the court decision would accomplish in adopting the but-for standard set forth in Therasense. As discussed previously, the Office has determined that to adopt the but-for standard of materiality set forth in Therasense, § 1.56 need not incorporate a specific reference to the court decision that has created that standard. Accordingly, the reference to the Therasense court decision in § 1.56, as previously proposed, has not been retained in the currently proposed rule.

The reference to the but-for standard should benefit the public by providing a consistent materiality standard for the duty to disclose information without the need for continuous revisions to the rules as the but-for standard in Therasense is interpreted or applied. As

discussed previously, Therasense was decided by the Federal Circuit en banc and can only be overturned by another en banc decision of the Federal Circuit or by a decision of the Supreme Court. In the event that the Supreme Court, or Federal Circuit acting en banc, chooses to revise the but-for materiality standard set forth in Therasense, the Office will reconsider the rules at that time.

Finally, the Office is not conveying its rulemaking authority to the judicial branch. Instead, the Office is exercising its rulemaking authority to adopt a standard used by the Federal Circuit. By using its rulemaking authority to adopt a common standard, the Office is providing the public with a uniform materiality standard for the duty to disclose information. If the Office should determine the uniform standard no longer provides a benefit to the public, the Office retains the ability to invoke its rulemaking authority and change the rules at any time.

Comment 11: One comment stated that the previously proposed rules incorporate two alternative statements within the rules. Specifically, the previously proposed rules include a first sentence that states that information is material to patentability if it is material under the standard set forth in Therasense and a second sentence that states information is material to patentability under Therasense if (1) the Office would not allow a claim if it were aware of the information, or (2) the applicant engages in affirmative egregious misconduct before the Office as to the information. The comment questioned whether these two sentences were equivalent and, if they were, whether they would remain equivalent as the Therasense decision evolves in the Federal Circuit.

Response: As discussed previously, this currently proposed rule modifies previously proposed §§ 1.56(b) and 1.555(b) to remove the sentence that explicitly references the Therasense decision. Sections 1.56(b) and 1.555(b) in this currently proposed rule would define the but-for materiality standard for the duty to disclose information as set forth in Therasense.

E. General Language Comments

Comment 12: One comment suggested that previously proposed rule § 1.555(b) should preserve the language that patents and printed publications are the appropriate types of information for consideration in reexamination.

Response: As discussed previously, unlike existing § 1.555(b), which limits the types of information that could be considered in reexamination to patents and printed publications, the currently proposed rule broadly recites that it is applicable to any matter proper for consideration in a reexamination (e.g., admissions by patent owner as well as patents and printed publications).

Comment 13: Several comments asserted the previously proposed rules are difficult for applicants to apply and interpret prospectively. Specifically, the comments assert that the proposed rules require the applicant to make legal conclusions in determining how to comply with the rule.

Response: As stated in the previous notice of proposed rulemaking, the Office recognizes the tension in basing the disclosure requirement on unpatentability. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 FR at 43633. However, since the existing provisions of §§ 1.56(b) and 1.555(b) require applicants to determine if there is a prima facie case of unpatentability, applicants are accustomed to making such determinations when complying with the duty of disclosure. Further, the but-for standard set forth in this currently proposed rule should not be any more difficult for applicants to apply during prosecution than the prima facie case of unpatentability standard that would be replaced by this currently proposed rule. Both standards require the applicant to reassess materiality as claims are amended, cancelled, and added. Lastly, the Office believes the but-for standard, as articulated by the Federal Circuit in Therasense, would also provide applicants with guidance on what information the applicant is required to submit to the Office.

F. Application of Rule Standards

Comment 14: Several comments addressed the scope of evidence to be considered when materiality or egregious misconduct determinations are made by the Office during application of these proposed rules, including whether the Office would take into account rebuttal evidence or whether the scope would be limited to the record before the Office.

Response: The Office would utilize all available evidence when making determinations of materiality or affirmative egregious misconduct, including rebuttal evidence. Limiting determinations of materiality or affirmative egregious misconduct to the record before the Office might promote fraud and bad faith in practicing before the Office and may lead to erroneous decisions.

Comment 15: Several comments requested the Office to stay Office of Enrollment and Discipline (OED) proceedings until a final court resolution regarding inequitable conduct is obtained in the courts.

Response: This currently proposed rule would only modify the materiality standard for the duty of disclosure required in §§ 1.56 and 1.555. OED proceedings are governed by procedures outlined in 37 CFR part 11, and the timeline under which the OED must commence disciplinary proceedings is subject to 35 U.S.C. 32 as amended by the America Invents Act (AIA). See Pub. L. 112–29, section 3(k), 125 Stat. 340, section 3(k) (2011).

G. General Comments

Comment 16: One comment proposed the Office tailor the discipline for failing to comply with the duty of disclosure to sanctions other than rendering patents unenforceable.

Response: The Office does not render a patent unenforceable for an applicant's failure to comply with the duty of disclosure. Rather, a court may hold a patent unenforceable due to inequitable conduct.

Comment 17: Several comments suggested proposing rules for materiality for each new post-issuance proceeding under the America Invents Act (AIA), such as post grant review, inter partes review, and covered business method patents review. The comment suggested that, since each post-issuance proceeding is different, separate materiality standards may be necessary.

Response: This comment is outside the scope of this rulemaking. The Office, however, has adopted § 42.11 to govern the duty of candor owed to the Office in the new post-issuance proceedings under the AIA. Additionally, the existing regulations at § 42.51 require a party to serve relevant information that is inconsistent with a position advanced during the proceedings.

Comment 18: Several comments asserted the Office should not require applicants to explain or clarify the relationship of the prior art to the claimed invention as suggested by the Office in the previous notice of proposed rulemaking. See Revision of the Materiality to Patentability Standard for the Duty to Disclose Information in Patent Applications, 76 FR at 43632. In addition, several comments suggested that, if the Office requires such an explanation, applicants should be given a safe harbor so that such explanation would not be regarded as an act of affirmative egregious misconduct.

Response: The contemplated required explanation from the previous notice of proposed rulemaking addressed by the comment is not included in this currently proposed rulemaking.

Comment 19: Several comments stated that the proposed but-for standard for materiality will not reduce the incentive to submit marginally relevant information to the Office. In addition, one comment asserted that the stated rationale for the but-for standard does not justify the rule change since the 1992 version of the rule, which contained a prima facie case of unpatentability standard, did not contribute to the over-disclosure to the Office or the overuse of inequitable conduct in litigation. This comment stated that, as long as the penalty for inequitable conduct is the loss of enforceability of the patent, applicants will continue to submit voluminous amounts of information to the Office to avoid a finding of inequitable conduct.

Response: The Office appreciates that a patent may be found unenforceable due to a finding of inequitable conduct. However, the Office's proposed adoption of the but-for standard of materiality articulated by the Federal Circuit in the Therasense decision, as well as the Therasense decision itself, should incentivize applicants not to submit marginally relevant information to the Office as this information would not meet the articulated standard.

Comment 20: Several comments requested that the Office no longer require the cross-citation of prior art found in related applications. The comments also requested the Office to provide a safe harbor provision under which information from related applications is not material and need not be submitted or, in the alternative, the definition of a related application is limited to “family cases” (i.e., those cases for which there is some chain of priority claim), “similar claims cases” (i.e., those cases under a common obligation of assignment for which the claims are not patentably distinct), and “team exception cases” (i.e., those cases for which the provisions of 35 U.S.C. 102(b)(2)(c) apply (35 U.S.C. 103(c) for pre-AIA applications)).

Response: An applicant is under a duty of disclosure to provide all known material information to the Office no matter how the applicant becomes aware of the information. An applicant is in the best position to know of any material information, especially when an applicant learns about the information from prosecution in related applications such as in applications for which priority or benefit is claimed. Having all material information in front of the examiner as early as possible will expedite prosecution and improve examination quality. But under the standard in this currently proposed rule, an applicant would be under no duty to provide information from related applications unless that information is but-for material.

Comment 21: Several comments requested the Office provide a standard method of cross-citation for information in related cases so examiners will automatically review the

information in the corresponding application without the applicant having to submit the information in an IDS.

Response: The Office is currently exploring an initiative to provide examiners with information (e.g., prior art, search reports, etc.) from applicant's related applications as early as possible to increase patent examination quality and efficiency. In the interim, applicants must comply with the requirements of §§ 1.97 and 1.98.

Comment 22: Several comments suggested incentivizing the filing of non-material disclosures. Essentially, the comments believed that the submission of a reference will be interpreted as an admission that it meets that materiality standard and, therefore, applicants will not submit non-material information. As an incentive to submit non-material information, the comments suggested relaxing or eliminating any burdens, such as waiving fees.

Response: The Office does not construe any submission of information as an admission of materiality. Section 1.97(h) specifically states, "[t]he filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b)." Therefore, the proposal to incentivize the submission of non-material information is not necessary.

Comment 23: One comment stated that, while the Office will not regard information disclosures as admissions of unpatentability for any claims in the application under § 1.97(h), the Office does not have the authority to make this promise on behalf of the courts. The comment asserted that the courts will inevitably hold that any disclosure of prior art is an admission that some pending claim is unpatentable.

Response: The comment did not provide any support for the asserted proposition that the courts treat the disclosure of prior art as an admission that at least one pending claim is unpatentable, and the Office is not aware of any court decision with such a holding.

Comment 24: Several comments requested the duty of disclosure end upon payment of the issue fee rather than the patent grant.

Response: It is in the applicant's and the public's best interest to have all material information known to the applicant considered by the examiner before a patent is granted. This will result in a stronger patent and avoid unnecessary post-grant proceedings and litigation. Section 1.97(d) thus provides for information to be submitted to the Office after a final action, notice of allowance, or action that otherwise closes prosecution is mailed, provided the IDS is filed on or before payment of the issue fee and is accompanied by the appropriate fee and statement under § 1.97(e). If the conditions of § 1.97(d) cannot be met, an applicant must file a request for continued examination (RCE) to have information considered by the examiner. Further, once the issue fee has been paid, the applicant must comply with § 1.313(c) (i.e., file a petition to withdraw

from issue for consideration of an RCE) in order to have information considered by the examiner. In order to alleviate the burden on applicants in this situation, the Office has instituted the Quick Path Information Disclosure Statement (QPIDS) pilot program. The QPIDS pilot program eliminates the requirement for processing an RCE with an IDS after payment of the issue fee where the IDS is accompanied by the appropriate fee and statement under § 1.97(e) and the examiner determines that no item of information in the IDS necessitates reopening prosecution. For more information visit the QPIDS Web site at www.uspto.gov/patents/init_events/qpids.jsp.

Comment 25: Several comments proposed giving an applicant a “safe harbor” so the duty of disclosure for the applicant ends when the applicant provides the information to counsel.

Response: The purpose of the duty of disclosure requirement is to ensure that all material information known by the applicant is provided to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. Ending that duty upon the submission of the documents to counsel could potentially delay or prevent material information from being filed with the Office, resulting in, for example, a reduction in patent quality or a delay in the patent grant.

Comment 26: Several comments requested the Office abrogate the duty of disclosure. The comments provided numerous reasons, such as harmonization with the patent offices that do not have such a duty. In the alternative, several comments suggested modifying

the materiality standard to include only information that is not available to the public because most of the information submitted is readily searchable public information.

Response: The public interest is best served, and the most effective and highest quality patent examination occurs, when the Office is aware of, and evaluates the teachings of, all information material to patentability during examination. Since the applicant is in the best position to be aware of material information in the art, it serves the public interest to require that the applicant submit this information to the Office during examination. Even if this information is publicly available, there is no guarantee that the examiner will find the information. Further, requiring the examiner to locate this information when the applicant is already aware of it unnecessarily expends government resources, increases search time, and could reduce examination quality. It is also noted that limiting materiality to information that is not available to the public would essentially abrogate the duty of disclosure because most information that is not available to the public is unlikely to meet the prior art requirements of 35 U.S.C. 102, hence preventing pertinent prior art from being seen by the examiner.

Comment 27: One comment asked the Office to clarify whether the new rules create any duty to investigate.

Response: Sections 1.56 and 1.555 in the currently proposed rule would not create any new or additional duty to investigate. However, practitioners and non-practitioners are

reminded of the duty under § 11.18(b)(2) to make an “inquiry reasonable under the circumstances” when presenting any paper to the Office.

Rulemaking Considerations

A. Administrative Procedure Act: This currently proposed rule would harmonize the rules of practice concerning the materiality standard for the duty of disclosure with the but-for materiality standard for inequitable conduct set forth in Therasense. The changes in this currently proposed rule would not alter the substantive criteria of patentability. Therefore, the changes in this currently proposed rule involve rules of agency practice and procedure and/or interpretive rules. See Bachow Commc’ns, Inc. v. F.C.C., 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.); Nat’l Org. of Veterans’ Advocates, Inc. v. Sec’y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.).

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law). See Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for ““interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”” (quoting

5 U.S.C. 553(b)(3)(A))). The Office, however, is publishing the currently proposed rule for comment to seek the benefit of the public's views on the Office's proposed revision of the materiality standard for the duty to disclose information to the Office.

B. Regulatory Flexibility Act: For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes proposed in this notice will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This notice proposes to harmonize the standard for materiality under §§ 1.56 and 1.555 for the duty of disclosure with the but-for materiality standard for inequitable conduct set forth in Therasense. The harmonized materiality standard should reduce the incentives to submit marginally relevant information in information disclosure statements (IDSs). The changes in this currently proposed rule involve rules of agency practice and procedure and/or interpretive rules and would not result in any additional fees or requirements on patent applicants or patentees. Therefore, the changes proposed in this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible: (1) used the best available techniques to quantify costs and benefits and considered values such as equity, fairness, and distributive impacts; (2) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided on-line access to the rulemaking docket; (3) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (4) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (5) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the PTO will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this

notice do not result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this notice is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes in this notice do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995

(15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The changes in this rulemaking involve information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collection of information involved in this final rule has been reviewed and approved by OMB under OMB control number 0651-0031. This rulemaking proposes to harmonize the standard for materiality under §§ 1.56 and 1.555 for the duty of disclosure with the but-for standard for materiality for inequitable conduct set forth in Therasense. This notice does not adopt any additional fees or information collection requirements on patent applicants or patentees.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and record keeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is proposed to be amended as follows:

PART 1 — RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Section 1.56 is amended by revising paragraphs (a) and (b) to read as follows:

§ 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 under the but-for materiality standard as defined in paragraph (b) of 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) through (d) and 1.98. However, no patent will be granted on an application in connection with which affirmative egregious misconduct was engaged in, 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) Information is but-for material to patentability if the Office would not allow a claim if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.

* * * * *

3. Section 1.555 is amended by revising paragraphs (a) and (b) to read as follows:

§ 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 under the but-for materiality standard as defined in paragraph (b) of this section. 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 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 affirmative egregious misconduct was engaged in, 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.

(b) Information is but-for material to patentability if, for any matter proper for consideration in reexamination, the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.

* * * * *

Dated: October 21, 2016.

Michelle K. Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
[FR Doc. 2016-25966 Filed: 10/27/2016 8:45 am; Publication Date: 10/28/2016]