

(19) Security Clearance Reciprocity Hotline Records (ODNI-20).

(20) IT Network Support, Administration and Analysis Records (ODNI-21).

(b) \* \* \*

(7) From subsection (c)(3) (accounting of disclosures) because an accounting of disclosures from records concerning the record subject would specifically reveal an intelligence or investigative interest on the part of the ODNI or recipient agency and could result in release of properly classified national security or foreign policy information.

(8) From subsections (d)(1), (2), (3) and (4) (record subject's right to access and amend records) because affording access and amendment rights could alert the record subject to the investigative interest of intelligence or law enforcement agencies or compromise sensitive information classified in the interest of national security. In the absence of a national security basis for exemption, records in this system may be exempted from access and amendment to the extent necessary to honor promises of confidentiality to persons providing information concerning a candidate for position. Inability to maintain such confidentiality would restrict the free flow of information vital to a determination of a candidate's qualifications and suitability.

(9) From subsection (e)(1) (maintain only relevant and necessary records) because it is not always possible to establish relevance and necessity before all information is considered and evaluated in relation to an intelligence concern. In the absence of a national security basis for exemption under subsection (k)(1), records in this system may be exempted from the relevance requirement pursuant to subsection (k)(5) because it is not possible to determine in advance what exact information may assist in determining the qualifications and suitability of a candidate for position. Seemingly irrelevant details, when combined with other data, can provide a useful composite for determining whether a candidate should be appointed.

(10) From subsections (e)(4)(G) and (H) (publication of procedures for notifying subjects of the existence of records about them and how they may access records and contest contents) because the system is exempted from subsection (d) provisions regarding access and amendment, and from the subsection (f) requirement to promulgate agency rules. Nevertheless, the ODNI has published notice concerning notification, access, and contest procedures because it may in

certain circumstances determine it appropriate to provide subjects access to all or a portion of the records about them in a system of records.

(11) From subsection (e)(4)(I) (identifying sources of records in the system of records) because identifying sources could result in disclosure of properly classified national defense or foreign policy information, intelligence sources and methods, and investigatory techniques and procedures. Notwithstanding its proposed exemption from this requirement, ODNI identifies record sources in broad categories sufficient to provide general notice of the origins of the information it maintains in its systems of records.

(12) From subsection (f) (agency rules for notifying subjects to the existence of records about them, for accessing and amending records, and for assessing fees) because the system is exempt from subsection (d) provisions regarding access and amendment of records by record subjects. Nevertheless, the ODNI has published agency rules concerning notification of a subject in response to his request if any system of records named by the subject contains a record pertaining to him and procedures by which the subject may access or amend the records. Notwithstanding exemption, the ODNI may determine it appropriate to satisfy a record subject's access request.

Dated: July 14, 2011.

**Mark W. Ewing,**

*Chief Management Officer.*

[FR Doc. 2011-18187 Filed 7-20-11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

#### 37 CFR Part 1

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

RIN 0651-AC58

#### Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications

**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 to revise the standard for materiality for the duty to disclose information in patent applications and reexamination proceedings in light of the decision by the U.S. Court of

Appeals for the Federal Circuit (Federal Circuit or Court) in *Therasense, Inc. v. Becton, Dickinson & Co.* Specifically, the Office is proposing to revise the materiality standard for the duty to disclose to match the materiality standard, as defined in *Therasense*, for the inequitable conduct doctrine. While *Therasense* does not require the Office to harmonize the materiality standards underlying the duty of disclosure and the inequitable conduct doctrine, the Office believes that there are important reasons to do so. The materiality standard set forth in *Therasense* should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicants to be more forthcoming and helpful to the Office. At the same time, it should also continue to prevent fraud on the Office and other egregious forms of misconduct. Additionally, harmonization of the materiality standards is simpler for the patent system as a whole.

**DATES:** The Office solicits comments from the public on this proposed rule change. Written comments must be received on or before September 19, 2011 to ensure consideration. No public hearing will be held.

**ADDRESSES:** Comments concerning this notice should be sent by electronic mail message over the Internet addressed to [AC58.comments@uspto.gov](mailto:AC58.comments@uspto.gov). Comments may also be submitted by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Hiram H. Bernstein, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy. Although comments may be submitted by mail, the Office prefers to receive comments via the Internet.

Comments may also be sent by electronic mail message over the Internet 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. The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available via the Internet (<http://www.uspto.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:**

Hiram H. Bernstein, Senior Legal Advisor; Kenneth M. Schor, Senior Legal Advisor; or Nicole D. Haines, Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy, by telephone at (571) 272-7707, (571) 272-7710, or (571) 272-7717, respectively, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Hiram H. Bernstein.

**SUPPLEMENTARY INFORMATION:** The Office is proposing to revise the materiality standard for the duty to disclose information to the Office in patent applications and reexamination proceedings set forth in §§ 1.56(b) and 1.555(b) in light of the Federal Circuit's decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, \_\_\_ F.3d \_\_\_, 2011 WL 2028255 (Fed. Cir. 2011) (*en banc*). Specifically, the Office is proposing to adopt the standard for materiality required to establish inequitable conduct as defined in *Therasense* as the standard for materiality under §§ 1.56(b) and 1.555(b).

In *Therasense*, the Court defined materiality using a “but-for-plus” standard. As the general rule, the Court 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.” *Therasense*, 2011 WL 2028255, at \*11. Said differently, the Court explained: “[I]n 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.* The Court also recognized that “affirmative acts of egregious misconduct,” *Id.* at \*12, before the PTO are unacceptable: “Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct.” *Id.* The Court 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.* The Court clarified 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.” *Id.* Lastly, the Court identified the submission of an unmistakably false affidavit as an example of affirmative egregious misconduct. *Id.*

Historically, the Federal Circuit connected the materiality standard for inequitable conduct with the PTO's materiality standard for the duty of disclosure. That is, the Court has invoked the materiality standard for the duty of disclosure to measure materiality in cases raising claims of inequitable conduct. In doing so, the Court has utilized both the “reasonable examiner” standard set forth in the 1977 version of § 1.56(b) and current § 1.56(b) promulgated in 1992. *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., Inc.*, 394 F.3d 1348, 1352–53 (Fed. Cir. 2005). While the *Therasense* Court severed what existed of the historical connection between the two materiality standards, as most recently articulated in *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006) (identifying the PTO's current standard as one of many standards the courts could apply), it did not indicate that the Office must apply the standard for materiality required to establish inequitable conduct under *Therasense* as the standard for determining materiality under § 1.56(b) or § 1.555(b). As the dissent in *Therasense* noted, “the scope of the court-made [inequitable conduct] doctrine is not inseparably tied to the breadth of the PTO's disclosure rules.” *Therasense*, 2011 WL 2028255, at \*33. The Office, however, believes that there are important reasons to amend § 1.56(b) and § 1.555(b) so that the PTO's materiality standard for the duty of disclosure matches the materiality standard for inequitable conduct.

While not as inclusive as current § 1.56(b), the Office expects that the “but-for-plus” standard from *Therasense* will result in patent applicants providing the most relevant information and reduce the incentive for applicants to submit information disclosure statements containing only marginally relevant information out of an abundance of caution. The Court stated that its “but-for-plus” standard, “[b]y 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.” *Therasense*, 2011 WL 2028255, at \*12. Thus, the Office expects that the “but-for-plus” standard will reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, thereby reducing the incentive for applicants to submit marginally relevant information to the Office. At the same time, it will continue to prevent applicants from deceiving the Office and breaching their duty of candor and good faith.

The Office also believes that a unitary materiality standard is simpler for the patent bar to implement. Under the single “but-for-plus” standard of materiality, patent applicants will not be put in the position of having to meet one standard for materiality as defined in *Therasense* in defending against inequitable conduct allegations and a second, different materiality standard to fulfill the duty to disclose before the Office.

The Office recognizes that it previously considered, and rejected, a “but-for” standard for the duty of disclosure in 1992 when it promulgated current § 1.56(b). Duty of Disclosure, 57 FR 2021, 2024 (Jan. 17, 1992). The affirmative egregious misconduct exception set forth in *Therasense* addresses the Office's long-standing concern about the types of unscrupulous conduct that could occur unchecked under a pure “but-for” standard.

Although the Office is proposing to revise §§ 1.56(b) and 1.555(b) to match the “but-for-plus” materiality standard announced in *Therasense*, the Office recognizes that *Therasense* could be reviewed by the U.S. Supreme Court. Because the rule making process is lengthy and because the Office prefers to receive and consider public comments before issuing a final rule, the Office is proceeding in parallel with the possibility of a *Therasense certiorari* petition. Should a petition for *certiorari* be filed and the Supreme Court grant review of the case, the Office will consider delaying issuance of a final rule until the Supreme Court has issued its decision.

Additionally, the Office is considering further actions that may provide an incentive for applicants to assist the Office by explaining/clarifying the relationship of prior art to the claimed invention. While this form of information would not implicate the standard of materiality as that term has been defined in *Therasense*, and therefore would not be required under the proposed changes to § 1.56, the

Office believes it is worthwhile to explore ways to encourage applicants to submit information, beyond that required under the *Therasense* materiality standard, that would be helpful and useful in advancing examination.

### Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is proposed to be amended as follows:

*Section 1.56:* Section 1.56(b) as proposed to be amended would provide that information is material to patentability if it is material under the standard set forth in *Therasense*, and that information is material to patentability under *Therasense* if: (1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or (2) the applicant engages in affirmative egregious misconduct before the Office as to the information. As stated in *Therasense*, neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious misconduct. *Therasense*, 2011 WL 2028255, at \*12.

The Office notes that, under the “but-for-plus” standard of *Therasense*, information is not material if the pending claim is allowable, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction, and the applicant does not engage in affirmative egregious misconduct before the Office as to the information. The Office recognizes the tension inherent in a disclosure standard based on unpatentability, but appreciates and expects that patent applicants are inclined to be forthcoming and submit information beyond that required by proposed Rule 56, in an effort to assist examiners in performing their duties. The Office wishes to facilitate and encourage such efforts by applicants. While applicants should avoid drafting claims that are unpatentable in the face of the prior art they disclose, the Office will not regard information disclosures as admissions of unpatentability for any claims in the application. *See* § 1.97(h). In addition, there is no duty under § 1.56 to submit information that is not material under the “but-for-plus” standard of *Therasense* and § 1.56(b).

*Section 1.555:* Section 1.555(b) as proposed to be amended would provide that information is material to patentability if it is material under the standard set forth in *Therasense*, and

that information is material to patentability under *Therasense* if: (1) The Office would not find a claim patentable if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or (2) the patent owner engages in affirmative egregious misconduct before the Office as to the information. Again as stated in *Therasense*, neither mere nondisclosure of information to the Office nor failure to mention information in an affidavit, declaration, or other statement to the Office constitutes affirmative egregious misconduct. *Therasense*, 2011 WL 2028255, at \*12.

Section 1.933 is directed to the duty of disclosure in *inter partes* reexamination proceedings; however, the statement as to materiality of information simply incorporates § 1.555. Thus, no revision is proposed for § 1.933.

### Rule Making Considerations

*A. 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 with the standard for materiality required to establish inequitable conduct. Additionally, the single harmonized materiality standard should reduce the incentives to submit information of marginal relevance. This notice does not propose any additional fees or requirements on patent applicants or patentees. Therefore, the changes proposed in this notice will not have a significant economic impact on a substantial number of small entities.

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

*C. 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 has 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 online access to the rule making 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, to the extent applicable.

#### *D. Executive Order 13132*

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

*E. Executive Order 13175 (Tribal Consultation):* This rule making 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).

*F. Executive Order 13211 (Energy Effects):* This rule making is not a significant energy action under Executive Order 13211 because this rule making 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).

*G. Executive Order 12988 (Civil Justice Reform):* This rule making 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).

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

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

*J. 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 United States Patent and Trademark Office will submit a report containing the 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 are not expected to 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).

**K. Unfunded Mandates Reform Act of 1995:** The changes proposed 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.*

**L. National Environmental Policy Act:** This rule making 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.*

**M. 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 rule making does not contain provisions which involve the use of technical standards.

**N. Paperwork Reduction Act:** The changes in this rule making 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 notice has been reviewed and approved by OMB under OMB control number 0651-0031. This rule making proposes to harmonize the standard for materiality under §§ 1.56 and 1.555 with the standard for materiality required to establish inequitable conduct. This notice does not propose 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, 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).

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

##### § 1.56 Duty to disclose information material to patentability.

\* \* \* \* \*

(b) Information is material to patentability if it is material under the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co.*, \_\_\_ F.3d \_\_\_ (Fed. Cir. 2011). Information is material to patentability under *Therasense* if:

(1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or

(2) The applicant engages in affirmative egregious misconduct before the Office as to the information.

\* \* \* \* \*

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

##### § 1.555 Information material to patentability in ex parte reexamination and inter partes reexamination proceedings.

\* \* \* \* \*

(b) Information is material to patentability if it is material under the standard set forth in *Therasense, Inc. v. Becton, Dickinson & Co.*, \_\_\_ F.3d \_\_\_ (Fed. Cir. 2011). Information is material to patentability under *Therasense* if:

(1) The Office would not find a claim patentable if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or

(2) The patent owner engages in affirmative egregious misconduct before the Office as to the information.

\* \* \* \* \*

Dated: July 15, 2011.

**David J. Kappos,**

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

[FR Doc. 2011-18408 Filed 7-20-11; 8:45 am]

BILLING CODE 3510-16-P

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 52

[EPA-R03-OAR-2011-0469; FRL-9441-9]

#### Approval and Promulgation of Air Quality Implementation Plans; West Virginia and Ohio; Determinations of Attainment of the 1997 Annual Fine Particle Standard for the Parkersburg-Marietta and Wheeling Nonattainment Areas

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to make a determination that the Parkersburg-Marietta, West Virginia-Ohio (WV-OH) nonattainment area and the Wheeling, WV-OH fine particle (PM<sub>2.5</sub>) nonattainment areas (hereafter referred to as "Areas") have attained the 1997 annual PM<sub>2.5</sub> National Ambient Air Quality Standard (NAAQS) by the applicable attainment date of April 5, 2010. These determinations are based upon complete, quality-assured, and certified ambient air monitoring data for the 2007-2009 monitoring period. EPA is finding these Areas to be in attainment, in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** Written comments must be received on or before August 22, 2011.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R03-OAR-2011-0469 by one of the following methods:

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:* [fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov).

C. *Mail:* EPA-R03-OAR-2011-0469, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.