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# Protecting Patents From The Beginning: The Importance of Information Disclosure Statements During Patent Prosecution

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I. INTRODUCTION .....	578
II. THE BASIS FOR FILING AN IDS	
A. <i>Presumption of Validity</i> .....	579
B. <i>Duty to Disclose</i> .....	580
III. THE APPROPRIATE MANNER AND TIME TO FILE AN IDS	
A. <i>General Requirements</i>	
1. <i>The Listing Requirement</i> .....	581
a. <i>Exceptions to the listing requirement—reliance on information in response to Office actions</i> .....	582
2. <i>Filed Separately from the Specification</i> .....	583
3. <i>Submission of Copies of Disclosed Prior Art References</i> .....	583
4. <i>Timely Submission</i> .....	583
IV. CONTENT OF AN IDS: WHAT MUST AN IDS DISCLOSE?	
A. <i>Information “Material to Patentability”</i> .....	584
B. <i>Classes of Information Considered to be Material</i> .....	585
C. <i>Classes of Information <u>not</u> Considered Material</i> .....	586

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D. 'Cumulative' Defined .....	587
E. Burying References .....	587
V. REMEDIES & CONSEQUENCES OF FILING AN INCOMPLETE IDS.....	588
A. Corrective Measures	
1. Reissue Application.....	589
2. Re-examination Proceedings .....	589
B. Consequences	
1. Inequitable Conduct.....	590
2. Gross Negligence & Inference of Intent to Deceive.....	593
3. Antitrust Implications.....	594
VI. CONCLUSION .....	595

### I. INTRODUCTION

Filing a comprehensive Information Disclosure Statement (IDS) is essential to ensure validity and enforceability of a U.S. patent. In its simplest form, an IDS is a list of prior art such as other patents or publications which are relevant to the invention claimed in a patent application. This list should be submitted to the U.S. Patent and Trademark Office (PTO) on a specific form along with copies of the prior art cited therein. The issue of disclosure, or lack of disclosure, of material prior art is the subject of an extensive history of litigation. Considering the fact that the statutes and regulations governing the disclosure of prior art on their face appear to be quite straightforward, the vast number of cases concerning this topic is somewhat surprising. In actuality, these rules and regulations are complicated and fluid. As in all areas of the law, statutes turn on the definition(s) of the term therein and the element(s) that these terms qualify. Uncertainty surrounds terms such as "material," "filed in a timely fashion," and "inequitable conduct." As such, there is a real need for comprehension of the statutory laws, the caselaw and the rules governing Information Disclosure Statements, especially in light of the very serious ramifications of non-disclosure.

This article discusses the importance of filing comprehensive Information Disclosure Statements during patent prosecution. It also examines the duties which are unique to patent law and which are imposed on all those substantively associated with the preparation and prosecution of a patent application. The requirements for filing an IDS such as the appropriate format to be used, the timeliness of submission and what an IDS must disclose are outlined. Finally, the serious consequences of both intentional and unintentional non-disclosure are discussed.

## II. THE BASIS FOR FILING AN IDS

The principal reason for filing an IDS during patent prosecution is to ensure that a patent is valid and enforceable. One defense to a claim of patent infringement is the counterclaim of patent invalidity. One study has shown that the probability that a patent will be held invalid based on uncited prior art was 40.8%, while another study reported that 66–80% of patents held invalid involve prior art which was not cited to the PTO.<sup>1</sup> Thus, an IDS should be filed and should disclose all material prior art in order to avoid patent invalidity or unenforceability based on uncited prior art.

There are two main issues which must be addressed in order to ensure patent validity and enforceability. First, information which has been “considered” by an Examiner of the Patent Office during the prosecution of an application directly translates into a patent which is better able to withstand challenge by an infringer due to a strong presumption of validity. Hence, all material prior art must be disclosed to an Examiner in order to enjoy this presumption of validity. Second, every person substantively associated with the filing and prosecution of a patent application has an affirmative duty under 37 C.F.R. § 1.56 to disclose information which is material to patentability to the Patent Office. This duty must be discharged and a failure to do so can result in an unenforceable patent.

### A. *Presumption of Validity*

By law, patents are presumed to be valid during patent infringement proceedings and this presumption must be overcome by an infringer who asserts invalidity as a defense.<sup>2</sup> This presumption is strong when prior art was before and considered by the Patent Office and weak when it was not.<sup>3</sup> When an IDS is filed during prosecution and the information therein is “considered” by an Examiner, the resulting patent is subject to a much higher standard of review than that employed for a patent wherein the disclosure of prior art was minimal or lacking.

Further, the burden to overcome this presumption of patent validity requires not only evidence of invalidity, but clear and convincing evi-

<sup>1</sup> See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Quarterly 185, 234 (1998); see also *In re Portola Packaging Inc.*, 110 F.3d 786, 789, 42 U.S.P.Q.2d 1295, 1298 (Fed.Cir. 1997) (citing Patent Reexamination: Hearings on S.1679 before the Senate Committee on the Judiciary, 96th Cong. § 14 (1980) (testimony of Commissioner Sidney Diamond, referring to a 1974 study showing that 66–80% of the patents held invalid involved uncited prior art).

<sup>2</sup> 35 U.S.C. § 282.

<sup>3</sup> See *Bolkcom v. Carborundum Co.*, 523 F.2d 492, 498, 186 U.S.P.Q. 466, 471 (6th Cir. 1975).

dence or else the defense will not be considered by the court.<sup>4</sup> Even if an infringer provides clear and convincing evidence of invalidity, there is an additional burden of overcoming the deference given to the PTO by the courts. Because a qualified government agency, which includes one or more examiners who are assumed to have some expertise in interpreting references and to be familiar with the level of skill in the art, is presumed to have done its job properly, a very high level of deference is created.<sup>5</sup>

The Court of Appeals for patent infringement lawsuits ensures that federal courts actually provide this deference to the PTO by requiring that "any" fact findings made by the PTO are reviewed by the Court of Appeals under the Administrative Procedures Act (APA) standard.<sup>6</sup> This means that the PTO's basis for granting a patent will not be overturned unless the agency's findings of fact are determined to be: (i) arbitrary, capricious or an abuse of discretion, or (ii) unsupported by substantial evidence.<sup>7</sup> The Supreme Court recognized this seemingly arcane area of the law to be of such importance that it overruled decades of previous decisions, and held that the Court of Appeals for the Federal Circuit must apply this "court/agency" framework rather than the traditional "court/court" standard of reviewing for clear error.<sup>8</sup> Thus, review under the APA standard is a high hurdle to overcome for any challenger. To take advantage of these procedural and evidentiary rules, patent applicants should disclose all material prior art in an IDS prior to issuance of the patent.

#### B. *Duty to Disclose*

The second issue to be addressed in order to ensure patent validity and enforceability is that of the duty of disclosure. Under federal patent regulations, specifically title 37 C.F.R. § 1.56, every individual associated with the filing and prosecution of a patent application has a duty to disclose information which is material to patentability, and a duty of candor and good faith in dealing with the PTO.<sup>9</sup> Failure to discharge these duties can result in an unenforceable patent.

These duties apply to: (1) each inventor named in the application; (2) each attorney or agent who prepares or prosecutes the application:

4 See *Hughes Aircraft Co v. United States*, 717 F.2d 1351, 219 U.S.P.Q. 473 (C.C.P.A. 1983).

5 See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* 725 F.2d 1350, 220 U.S.P.Q. 763 (Fed. Cir. 1984), *cert. denied*, 463 U.S. 821; *Markman v. Westview Instruments, Inc.* 52 F.3d 967, 968 (Fed. Cir. 1995), *affirmed* 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).

6 See *Dickinson v. Zurko*, 527 U.S. 150, 50 U.S.P.Q.2d (BNA) 1930 (1999).

7 See cases cited *supra* note 6.

8 See cases cited *supra* note 6.

9 37 C.F.R. § 1.56(a).

and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. Individuals other than the attorney, agent or inventor can disclose information to either the attorney, agent, or inventor.

These duties exist with respect to each pending claim until the claim is canceled, withdrawn from consideration, or the application is granted or abandoned.<sup>10</sup> This duty to disclose is only deemed to be discharged if all information known to be material to patentability of any claim issued in a patent was cited by, or submitted to, the Office in the manner prescribed by Sections 1.97(b)–(d) and 1.98 of the Code of Federal Regulations (C.F.R.).

### III. THE APPROPRIATE MANNER AND TIME TO FILE AN IDS

An IDS must be compiled and submitted to the Patent Office in compliance with a number of rules and regulations. These rules and regulations, set forth in both the Manual of Patent Examining Procedures (M.P.E.P.) and in title 37 of the C.F.R., are discussed below and concern the format in which the IDS is presented, the timeliness of submission and the requisite copies of prior art references disclosed. The goal of the applicant in complying with these rules and regulations is to get the prior art references “considered” by the Patent Examiner.

#### A. *General Requirements*

Sections 1.97(b)–(d) and 1.98 of the C.F.R. state that information disclosed in an IDS will be considered by an Examiner of the Patent Office when: 1) listed, preferably using the Patent’s Office’s Form PTO-1449; 2) filed separately from the filing of the specification; 3) a copy of each document is provided (unless it is a copending application); and 4) the IDS is filed in a timely fashion.<sup>11</sup>

##### 1. *The Listing Requirement*

37 C.F.R. § 1.98(b) requires that a list of all patents, publications, or other information be submitted for consideration by the Patent Office. Therefore, unless the references have been cited by the Examiner on a form, such as Form PTO-892, technically they have not been considered and the Examiner should notify the applicant of such in the next Office action.

<sup>10</sup> See *supra* note 11.

<sup>11</sup> 37 C.F.R. §§ 1.97(b)–(d) and 1.98.

This listing requirement also applies to abstracts of references. Abstracts may be submitted, but should be cited as such on the Form PTO-1449. For example, an abstract of an article by Holt *et al.* published in 1996 from Chemical Abstracts Service (CAS) would be cited as "Holt, Chemical Abstract, vol. 125:86501, 1996."

*a. Exceptions to the listing requirement—reliance on information in response to Office actions*

In certain situations, information may be "considered" by the P.T.O. even if it was not submitted in an IDS. The Examiner's note to M.P.E.P. Section 6.49 provides various examples of such disclosures of information (e.g.: 37 C.F.R. §§ 1.97 and 1.98). In particular, it states that evidentiary documents submitted when replying to an Office action, such as a rejection or other official communication from the PTO, may be relied upon by an applicant for example to show that an element recited in the claim is operative or that a term used in the claim has a recognized meaning in the art. These evidentiary documents may be in any form but are typically in the form of an affidavit, declaration, patent, or printed publication. To the extent that a document is submitted as evidence directed to an issue of patentability raised in an Office action, and the evidence is timely presented, the applicant need not satisfy the requirements of 37 C.F.R. §§ 1.97 and 1.98 in order to have the Examiner consider the information contained in the document. In other words, compliance with the information disclosure rules is not a threshold requirement to have information considered when submitted by an applicant to support an argument being made in a reply to an Office action.

If the information is submitted by an applicant to support an argument being made in a reply to an Office action, the record should reflect whether the evidence was considered, but listing on a form (e.g., PTO-892, PTO-1449, or PTO/SB/08A and 08B) and appropriate marking of the form by the Examiner is not required. For example, if the applicant submits and relies on three patents as evidence in reply to an Office action and also lists those patents on a Form PTO-1449 along with two journal articles, but does not file a statement under 37 C.F.R. 1.97(e) or the fee set forth in 37 C.F.R. 1.17(p), it would be appropriate for the Examiner to indicate that the teachings relied on by the applicant in the three patents have been considered, but to line through the citation of all five documents on the Form PTO-1449 and to inform applicant that the Information Disclosure Statement did not comply with 37 C.F.R. § 1.97(c). Thus, situations may occur where some prior art gets considered even though the entire IDS did not comply with the regulations.

## 2. *Filed Separately from the Specification*

Apart from the aforementioned situations, prior art must be disclosed in compliance with Sections 1.97(b)–(d) and 1.98. For example, references listed in the background section of the patent application are not considered to be properly disclosed. Although caselaw, regulations, and the M.P.E.P. do not entirely foreclose the disclosure of information material to patentability by any other method than an IDS, M.P.E.P. Section 6.49.06 does specifically state that the listing of references in the specification or the body of a patent application is not considered a proper disclosure statement.

## 3. *Submission of Copies of Disclosed Prior Art References*

In addition to the listing requirement, a copy of each reference, including U.S. Patents, must be provided to the Examiner. M.P.E.P. Section 6.49.07 states:

The information disclosure statement. . . [will] comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

Copies of other copending U.S. patent applications need not be supplied according to M.P.E.P. § 6.49.06, as long as they are properly cited on a separate form. The Examiner should obtain access to that application file within the Patent Office.

## 4. *Timely Submission*

The phrase “filed in a timely fashion” means filed: 1) before the first Official action on the merits is mailed by the Patent Office, 2) within three months of receiving the first Official action on the merits from a foreign patent office, 3) within three months of any person having a duty to disclose becoming aware of the information, 4) after the first Official action on the merits along with a fee, or 5) after the Examiner has indicated he or she will grant the patent provided the applicant files a petition to the Examiner after the Notice of Allowance but before the patent issues along with a fee and statement of reasons why it was not submitted earlier.<sup>12</sup>

If the IDS is not timely filed, it will be placed in the application file with the non-complying information not being considered.<sup>13</sup> Therefore,

<sup>12</sup> 37 C.F.R. § 1.97(i); M.P.E.P. Section 6.51.

<sup>13</sup> See cases cited *supra* note 1.

despite identifying, collecting and submitting the information, if it is not timely submitted, the IDS afford no protection if the patent is challenged.

#### IV. CONTENT OF AN IDS: WHAT MUST AN IDS DISCLOSE?

Under 37 C.F.R. § 1.56, any information that is deemed to be "material to patentability" must be disclosed in an IDS. The language of this statute was modified in 1992 to emphasize a duty of candor and good faith in dealing with the Patent Office. Although the latter is broader than a duty to disclose material information, this does not affect the nature of the information required to be disclosed in an IDS.

##### A. Information "Material to Patentability"

Information is not material unless it comes within the definition of 37 C.F.R. § 1.56(b)(1) or (2). The relevant portion of this statute states:

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) opposing an argument of unpatentability relied on by the Office, or
  - (ii) asserting an argument of patentability.

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

The test for materiality is not whether the prior art affects the novelty or obviousness of the invention but rather what a reasonable examiner would consider important in deciding whether to allow the patent application to issue as a patent.<sup>14</sup> References do not need to be anticipatory, i.e. novelty-destroying, to be considered material to patentability. Thus, information is deemed material if a reasonable examiner would have considered it important to the patentability of a claim.<sup>15</sup>

In *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, Fox Industries, Inc. sued the defendant, Structural Preservation Systems, Inc., for patent infringement.<sup>16</sup> During the suit, the district court found that

<sup>14</sup> See *supra* note 11.

<sup>15</sup> See *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984).

<sup>16</sup> See *Fox Industries, Inc. v. Structural Preservation Systems, Inc.* 922 F.2d 801, 17 U.S.P.Q.2d 1579 (Fed. Cir. 1990).



more than a year prior to filing a continuation application of the original application, Fox had published a sales brochure describing the invention in the original patent application. Under title 35 U.S.C. § 102 (b), disclosure of the invention more than one year before filing the patent application destroys the novelty of the invention. Although the attorney used this brochure as source material for drafting the claims of the continuation application, he did not disclose it in an IDS in any of the four later applications which ultimately led to the patent in question. During litigation, these facts were uncovered by the defendants and used in their defense. The court found that the brochure was more relevant than any other single reference cited during prosecution and refused to enforce any of the claims in the patent at issue. On appeal, the court affirmed and ruled that a withheld reference which anticipates a claim in a patent satisfies the most stringent standard of material.<sup>17</sup> The Court of Appeals determined that Fox had knowledge of material prior art, had knowingly failed to disclose this art to the PTO and had an intent to deceive.<sup>18</sup> As a result, the court refused to enforce any of the patent's claims because of Fox's inequitable conduct and therefore determined that it was unnecessary to consider whether Structural Preservation Systems, Inc. had infringed the patent.<sup>19</sup>

#### B. *Classes of Information Considered to be Material*

The issue of what is "material" is frequently misunderstood by patent practitioners and thought to be restricted to prior art patents and publications. However, specific examples of information that is also considered "material to patentability"<sup>20</sup> are: information concerning possible prior public uses, sales, offers to sell, derived knowledge, prior inventions by others, inventorship conflicts, and the like.<sup>21</sup> This also includes prior art cited in search reports of a foreign patent office in a counterpart application,<sup>22</sup> information from or relating to copending U.S. patent applications,<sup>23</sup> information from related litigation<sup>24</sup> and, in particular, evidence of possible prior public use or sales, questions of inventorship or

<sup>17</sup> *See id.*

<sup>18</sup> *See id.*

<sup>19</sup> *See id.*

<sup>20</sup> M.P.E.P. § 2001.04.

<sup>21</sup> *See id.*

<sup>22</sup> *See supra* note 11.

<sup>23</sup> *See* *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779, 175 U.S.P.Q. 70, 79 (7th Cir. 1972).

<sup>24</sup> *See* *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258, 1259, 43 U.S.P.Q.2d 1666, 1670-71 (Fed. Cir. 1997) (patent held unenforceable due to inequitable conduct based on patentee's failure to disclose a relevant reference and for failing to disclose ongoing litigation).

prior art, allegations of "fraud," "inequitable conduct," "violation of duty of disclosure" and any assertion made during litigation which is contradictory to assertions made to the Examiner during pleadings, admissions, discovery (interrogatories, depositions, etc.) and testimony.<sup>25</sup> Information relating to claims copied from a patent, for example during interference proceedings to determine who the first inventor of an invention was, is also considered material.<sup>26</sup> The duty of disclosure also applies to statements or experiments introduced or discussed in the specification of the patent application.<sup>27</sup> For example, a statement that an experiment "was run" or "was conducted," when in fact the actual experiment was not run or conducted, is a misrepresentation of facts. Paper examples should not be described using the past tense.<sup>28</sup> Misrepresentations can also occur when experiments, although actually conducted, are inaccurately reported in the specification, such as when an experiment is changed by omitting one or more chemical reagents.<sup>29</sup>

### C. *Classes of Information not Considered Material*

The above being said, the question arises as to what is not considered material to patentability or required as part of the duty under 37 C.F.R. § 1.56. There are some types of information that do not need to be disclosed. For example, disclosure of private unpublished documents is not required.<sup>30</sup> Information to show favorability of a patent such as evidence of commercial success of the invention does not need to be provided. Similarly, disclosure of information concerning the level of skill in the art for purposes of determining obviousness is not required.<sup>31</sup> Copies of references already cited to the PTO in a previous "parent" patent application are not required to be submitted again in a later application. Lastly, there is no duty to submit information which is not material to the patentability of any existing claim,<sup>32</sup> to explain the relevance

25 See *Environ Prods., Inc. v. Total Containment, Inc.*, 43 U.S.P.Q.2d 1288, 1291 (E.D. Pa. 1997).

26 Where claims are copied or substantially copied from a patent, 37 C.F.R. § 1.607(c) requires applicant shall, at the time he or she presents the claim(s), identify the patent and the numbers of the patent claims. Failure to comply with 37 CFR 1.607(c) may result in the issuance of a requirement for information as to why an identification of the source of the copied claims was not made. Clearly, the information required by 37 CFR 1.607(c) as to the source of copied claims is material information under 37 CFR 1.56 and failure to inform the PTO of such information may violate the duty of disclosure.

27 See *Steierman v. Connelly*, 192 U.S.P.Q. 433 (Bd. Pat. Int. 1975); 192 U.S.P.Q. 446 (Bd. Pat. Int. 1976).

28 See *id.*

29 See *id.*

30 See *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 698, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983).

31 See case cited *supra* note 27.

32 See *supra* note 11.

of English language references, nor to disclose references which are merely cumulative. Accordingly, it is of paramount importance to pay close attention to the claims of the patent application and exactly how the invention has been set forth.

D. *'Cumulative' defined*

Caselaw defines the term 'cumulative' as information which has the same features as, or is not substantively different from, the information already before the Examiner.<sup>33</sup>

In *Rolls-Royce Ltd. v. GTE Valeron Corp.*, the Court found that a reference that had not been cited was merely cumulative to another reference which had already been cited in an IDS. In this case, both references were novelty-destroying and anticipated the claims but they were structurally different from each other. The Court found that the structural differences did not render the second reference more material than the first, previously cited reference and found the references to be cumulative even though they were not identical.<sup>34</sup>

In determining whether uncited prior art is more material than that already before the Examiner, similarities and differences between the prior art and the claims of the application should be considered. Also of relevance are any portion of the art which teach away from the claimed invention.<sup>35</sup> Although this is admittedly a difficult and subjective decision to be made by experienced patent practitioners, submitting everything in your possession in order to err on the side of caution is to improperly place the applicant's duty at the Examiner's doorstep.

E. *Burying References*

The question of citing "too many" references is a highly subjective area of patent law.<sup>36</sup> Caselaw has held in some circumstances that the references were not "considered" by the Examiner, even though the citations in the IDS were initialed by the Examiner as having been considered, simply because of the number of references cited in an IDS. This is, of course, a hindsight judgment made during litigation in an attempt to reconstruct events after the fact and to second guess the reasons that a patent was granted.

<sup>33</sup> *See id.*

<sup>34</sup> *See Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 231 U.S.P.Q. 185 (Fed. Cir. 1986).

<sup>35</sup> *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-9 (Fed. Cir. 1986).

<sup>36</sup> *See Molins v. Textron*, 48 F.3d 1172, 33 U.S.P.Q.2d (BNA) 1823 (Fed. Cir. 1995).

<sup>37</sup> *See Golden Valley Microwave Foods v. Weaver Popcorn Co.*, 837 F.Supp. 144, 24 U.S.P.O.2d (BNA)

On the other hand, "patent fraud," officially known as inequitable conduct, may be claimed by an infringer. The infringer may rely on the fact that certain references appear to be 'buried' among other, less relevant references in an IDS in order to obtain a judgment that the patent is unenforceable due to equitable concerns, despite not being invalid. In one such case, *Haney v. Timesavers, Inc.*, one defense raised against the claim of infringement was the allegation that the plaintiffs had 'buried' the relevant references amongst a group of ninety-one other, mostly far less relevant references. The Court of Appeals ruled that the references in question were not buried, but rather that they were listed in accordance with the applicable regulations.<sup>37</sup>

One possible option to avoid an assertion of "burying" a reference might be to point out in a letter to the Examiner particularly pertinent references or references which should be reviewed first or which relate to particular claims. The M.P.E.P. suggests highlighting particularly significant references submitted in a long list of references.

Another option might be to break up a particular unwieldy IDS into smaller IDS's containing more manageable numbers of references. This will hopefully increase the chances that the Examiner may actually read your submission, but should also reduce the acrimony created when you show up with a box of paper to the Examiner's art unit.

Yet a third option may be, if your client's budget allows, the creation and maintenance of a customized searchable database of references. Although you may have to file your IDS the old-fashioned way, an Examiner should have no problem signing off on your Forms PTO-1449 if you have also submitted a customized CD-ROM or private webpage where they can quickly search and retrieve documents considered material by the inventor(s) and attorney(s).

Although roadmapping and compartmentalizing are above and beyond the actual duty required, it may provide for better relations with the Examiner and take away a distracting challenge from future opponents.

## V. REMEDIES AND CONSEQUENCES OF FILING AN INCOMPLETE IDS

Some may decide to take their chances rather than go to all the trouble to submit the information. This is not advisable, however, experience has shown that good litigators will discover any documents in your files which were not, but which should have been, submitted to the Patent Office in an IDS.

<sup>37</sup> See *Haney v. Timesavers, Inc.*, 900 F. Supp. 1378 (1995).

Should material prior art be discovered by anyone substantively involved in the preparation or prosecution of the application after the patent has been granted, there are two possible corrective measures: reissue and re-examination. Both of these are limited to unintentional non-disclosure.

If material prior art was intentionally withheld, it is quite likely that the art will be discovered during any future litigation. Upon a finding of intentional non-disclosure, claims (or counterclaims) of inequitable conduct can be raised, threatening a patent's validity as well as an attorney's practice. Inequitable conduct can also involve antitrust implications which entitle a successful challenger to treble damages.

#### A. *Corrective Measures*

##### 1. *Reissue Application*

Reissue proceedings are available to correct unintentional errors which make the patent invalid or inoperative.<sup>38</sup> Thus, reissue proceedings cannot cure inequitable conduct committed during the prosecution of the original application.<sup>39</sup> A reissue application is filed by the original applicants or their representatives and surrenders the entire patent for a new examination. Once reissued, the patent, according to 35 U.S.C. § 252, will be viewed as if the original patent had been granted in the amended form provided by the reissue.

If submission of previously unconsidered prior art is the only concern and the art raises a substantial new question of patentability, then re-examination is probably the more appropriate method to correct the error. If the considered prior art does not raise a substantial new question of patentability, there is a good chance it may in fact be a cumulative reference and no action need be taken. However, to ensure validity and remove any distracting challenges from an infringers arsenal, reissuing a patent is a good preparatory step prior to enforcement actions.

##### 2. *Re-examination Proceedings*

Re-examination proceedings are limited solely to re-examination of prior art, and are not available to correct intentional errors.<sup>40</sup> 35 U.S.C. § 304 is the statute that governs re-examination proceedings. This statute requires an examiner to determine whether a substantial new question of

<sup>38</sup> M.P.E.P., Chapter 14, Correction of Patents.

<sup>39</sup> See *In re Clark*, 522 F.2d 623, 187 U.S.P.Q. 209 (CCPA) 1975.

See *Hewlett Packard v. Bausch & Lomb Inc.*, 882 F.2d 1556, 11 U.S.P.Q.2d 1750 (Fed. Cir. 1989).

<sup>40</sup> See *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 601, 225 U.S.P.Q.2d 243, 248 (Fed. Cir. 1985).

patentability is raised by a re-examination request. Only if a substantial new question of patentability is raised, can a patent be re-examined.

In *In re Recreative Technologies Corp.*, the court reviewed the legislative history of the statute and determined that it reflected a "serious concern that reexamination not create new opportunities for abusive tactics and burdensome procedures."<sup>41</sup> The requirement that "[n]o grounds of reexamination were to be permitted other than on new prior art and sections 102 and 103" was a well-considered balance of the arguments for and against reexamination.<sup>42</sup>

Re-examination is barred for questions of patentability that were decided in the original examination.<sup>43</sup> Therefore, if the references were considered, but were not submitted in an IDS, reexamination is not available. The court in *In re Recreative Technologies Corp.* held that a prior art reference that served as a basis of a rejection in the prosecution of the original patent application could not support a substantial new question of patentability that would permit the institution of a reexamination proceeding.<sup>44</sup>

In another case, *In re Portola Packaging*, the court held that prior art which was previously before the original examiner could not support a reexamination proceeding despite the fact that it was not the basis of a rejection in the original prosecution.<sup>45</sup> The court held that, as long as the reference was before the original examiner, it was to be considered "old art."<sup>46</sup> Thus, re-examination is available for the sole purpose of considering completely unconsidered prior art which raises a substantial new question of patentability.

It should be noted that the American Inventor's Protection Act, signed into law on November 29, 1999, provides for the possibility of substantial third party involvement during reexamination. Accordingly, this decision should be made carefully in a highly competitive environment.

## B. Consequences

### 1. Inequitable Conduct

Since 1976, the laws regarding disclosure of prior art have undergone substantial changes. Rules 56 (C.F.R. § 1.56) was adopted in 1977

41 See H.R. Rep. No. 96-1307, at 3 (1980), reprinted in 1980 U.S.C.A.A.N. 6460, 6462.

42 See *id.*

43 See *id.*

44 See *In re Recreative Technologies Corp.*, 83 F.3d 1394, 1397, 38 U.S.P.Q.2d 1776, 1778 (Fed. Cir. 1996).

45 See case cited *supra* note 1.

46 See *id.*

and amended in 1982, 1983, 1984, and again in 1985. The amendments permitted these matters to be appealed to the Board of Patent Appeals and Interferences.<sup>47</sup> Additionally, the amended Rule 56 made applicants, associates, and attorneys partners with the PTO for consideration of prior art. In this partnership, members bear a "duty of disclosure," violation of which constitutes "inequitable conduct."<sup>48</sup>

Under the present Rule 56, if inequitable conduct is found, under an 'abuse of discretion' standard, patents are held invalid and/or unenforceable.<sup>49</sup> Thus, a court will not, out of fairness, use a fraudulently obtained document to hold someone liable.<sup>50</sup> The penalty for inequitable conduct is rejection of all claims under 35 U.S.C. §§ 131 and 132, not "striking" of an application as in the pre-1977 rule.<sup>51</sup>

Inequitable conduct is comprised of two elements: materiality and intent. Thus, the doctrine of inequitable conduct requires a two-step analysis. First, it must be determined whether the withheld references satisfy a threshold level of materiality and whether the applicant's conduct satisfies a threshold showing of intent to mislead. If and only if these two determinations conclude that the thresholds are satisfied, are materiality and intent balanced. The more material the omission, the less culpable the intent required, and vice versa.<sup>52</sup>

As previously discussed, prior art is deemed material if it is likely that a reasonable examiner would consider it important in deciding whether or not to allow the application to issue as a patent, but materiality of an undisclosed reference does not presume an intent to deceive.<sup>53</sup> Further, a mere showing that information material to patentability was not disclosed does not establish inequitable conduct.<sup>54</sup>

An infringer asserting an inequitable conduct defense must prove by clear and convincing evidence that the applicant or his or her attorney failed to disclose material information or submitted false information to the PTO with an intent to deceive.<sup>55</sup> The infringer must, therefore, provide clear and convincing proof of: (1) prior art or information that is

47 See *In re Harita*, 847 F.2d 801, 6 U.S.P.Q.2d 1930 (1988).

48 See case cited *supra* note 48.

49 See *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 U.S.P.Q.2d 1384, 1392 (Fed. Cir. 1988).

50 See *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 17 U.S.P.Q.2d 1834 (Fed. Cir. 1991).

51 See case cited *supra* note 48.

52 See case cited *supra* note 51.

53 See *Allen Organ Co. v. Kimball International, Inc.* 839 F.2d 1556 (Fed. Cir. 1988).

54 See *Litton Industrial Products, Inc. v. Solid State Systems Corp.*, 755 F.2d 158, 225 U.S.P.Q. 34 (Fed. Cir. 1985).

55 See case cited *supra* note 17.

material; (2) knowledge chargeable to the applicant of that prior art or information and of its materiality; and (3) failure by the applicant to disclose the art or information resulting from an intent to mislead the PTO.<sup>56</sup>

An allegation of inequitable conduct can be rebutted by showing that (a) the prior art or information was not material, (b) if it was material, applicant did not know about it, (c) if the applicant knew about it, they did not know of its materiality, or (d) that the failure was not as a result of an intent to mislead the PTO.<sup>57</sup> For example, if the information is material, but was not disclosed, the failure to disclose will not alone support a finding of inequitable conduct if the reference is "simply cumulative to other references."<sup>58</sup>

In *In re Harita*, after a discussion with the inventor about whether or not to inform the U.S. attorney of a newly discovered material reference, a Japanese foreign associate who did not know of the duty of disclosure in U.S. practice advised the inventor not to forward the document.<sup>59</sup> Months after grant of the patent, the inventor discovered that the advice given by the Japanese associate was erroneous. Hence, the applicant submitted the document to the Patent Office and filed for reissue to narrow the scope of claims in order to avoid the prior art. A Special Program Examiner at the Patent Office rejected the request for reissue on the sole ground that the Japanese attorney did not disclose the newly discovered art to the Patent Office before the patent had issued.<sup>60</sup> The Examiner claimed that there was an intent to mislead which constituted 'inequitable conduct,' and thus based the rejection on 37 C.F.R. § 1.56 (d).

On appeal, the court noted that the events occurred from 1974–1976, before the adoption of Rule 56. The court held that the case must be considered in the light of the situation as it existed when the acts took place. The rule that was in existence at that time stated that any application filed fraudulently or in connection with fraud on the Patent Office may be stricken from the files. To constitute fraud, both materiality of the prior art and intent to act inequitably so as to mislead the Patent

<sup>56</sup> See *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 5 U.S.P.Q.2d 1112 (Fed. Cir. 1987); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F.2d 292, 294 (Fed. Cir.), cert. denied, 479 U.S. 820, 107 S. Ct. 85 (1986); *Braun Inc. v. Dynamics Corp. of America*, 975 F.2d 815, 822 (Fed. Cir. 1992); *Prevue Interactive, Inc. v. Starsight Telecast, Inc.*, 1999 U.S. Dist. LEXIS 1956.

<sup>57</sup> See case cited *supra* note 58.

<sup>58</sup> See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 U.S.P.Q.2d 1001, 1014 (Fed. Cir. 1991).

<sup>59</sup> See case cited *supra* note 51.

<sup>60</sup> See *id.*



Office must be established. In this case, materiality was not contested thus the only issue was the element of intent. It was determined that the Japanese associate did not have the requisite intent to mislead, despite his gross negligence, due to the particular circumstances of the case including the fact that prior art did not have to be disclosed to the Japanese Patent Office after filing the application in Japan and the fact that the associate was very inexperienced with U.S. patent laws. The court ultimately held that the reissue should be granted.<sup>61</sup>

## 2. *Gross Negligence & Inference of Intent to Deceive*

Intent to act inequitably is a required element of inequitable conduct which is rarely presumed.<sup>62</sup> Although not directly concerned with prior art, the Court of Appeals in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, the Federal Circuit declined to infer a finding of deceitful intent where an attorney was grossly negligent during prosecution of an application by mis-listing the correspondence between the allowed claims of a parent and the amended claims of its continuation.<sup>63</sup> The holding was that gross negligence does not of itself justify an inference of intent to deceive.<sup>64</sup> Additionally, the court held that negligence can support an inference of intent only when, "viewed in light of all the evidence, including any evidence indicative of good faith," the negligent conduct is culpable enough "to require a finding of intent to deceive."<sup>65</sup> This was later confirmed by the Court of Appeals for the Federal Circuit in *Manville Sales Corp. v. Paramount Systems Inc.*<sup>66</sup>

One example which is related to submission of prior art had an interesting outcome. In *Halliburton Co. v. Schlumberger Technology Corp.*, the plaintiff sued Schlumberger Technology Corp. for patent infringement.<sup>67</sup> The district court found that, during the application process, the Examiner had cited six patents but that Halliburton had not disclosed any prior art to the Patent Office. In agreement with Schlumberger, the court determined that Halliburton should have cited the seven other prior art references of which they were aware. The district court determined that this failure to disclose constituted inequitable conduct which led to the enforceability the patents in question. On appeal, the

61 *See id.*

62 *See id.*

63 *See id.*

64 *See id.*

65 *Id.* at 807.

66 *See Manville Sales Corp. v. Paramount Systems Inc.*, 917 F.2d 544, 16 U.S.P.Q.2d 1587 (Fed. Cir. 1990).

67 *See case cited supra* note 54.

Court of Appeals held that the analysis of such a case required a showing of threshold levels of materiality and intent and the application of the balancing test enunciated in *J.P. Stevens*.<sup>68</sup> This court reasoned that, because the references cited by the Examiner were more closely related to the patent claims than the uncited prior art, the latter were cumulative and did not need to be disclosed. The element of intent was then addressed as follows: although Halliburton was aware of the withheld references, their counsel did not consider the references material. The Court of Appeals held that counsel's assertion that he did not intend to mislead was objectively reasonable, and, therefore, that, despite his gross negligence, he did not engage in inequitable conduct.<sup>69</sup>

### 3. Antitrust Implications

Although the hurdles involved in proving inequitable conduct are substantial, once proven, they can lead to antitrust implications for patent owners. Patent owners who sue for infringement may incur antitrust liability for enforcement of a patent known to be obtained or maintained through fraud.<sup>70</sup> In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, Walker Process Equipment, Inc., the defendant in a patent infringement suit, filed a counterclaim which alleged that the plaintiff, Food Machinery & Chemical Corp., had illegally monopolized interstate and foreign commerce through a patent obtained and maintained fraudulently and in bad faith.<sup>71</sup> Walker Process claimed that such a monopoly would be in violation of § 2 of the Sherman Act (15 U.S.C. § 2), under which a successful party is entitled to treble damages under § 4 of the Clayton Act (15 U.S.C. § 15). Prior common law dictated that only the government, not private parties, possessed the statutory authority to bring suit for such a claim. Walker Process claimed that this action was justified based on the fact that the existence of the plaintiff's patent deprived the defendant of business it would have otherwise enjoyed. The Supreme Court agreed and held that this action could be brought by a private party in cases involving patents procured by intentional fraud, that is, by knowingly and willfully misrepresenting facts or willfully withholding information in dealings with the Patent Office.<sup>72</sup>

<sup>68</sup> See case cited *supra* note 17.

<sup>69</sup> See case cited *supra* note 54.

<sup>70</sup> See *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 14 U.S.P.Q.2d 1034 (Fed. Cir. 1990).

<sup>71</sup> See *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 147 U.S.P.Q. (BNA) 404 (1965).

<sup>72</sup> See cases cited *supra* note 74-75.

A *Walker Process* antitrust claim therefore requires proof of intentional fraud.<sup>73</sup> Although inequitable conduct may render a patent unenforceable, this differs from the type of fraud required to support a *Walker Process* type antitrust claim.<sup>74</sup> A finding of *Walker Process* fraud requires higher threshold showings of both materiality and intent than does a finding of inequitable conduct.<sup>75</sup>

## VI. CONCLUSION

In summary, a patent is better able to withstand challenge in litigation and enjoys a higher standard of review when one or more Information Disclosure Statements have been filed during the prosecution of the application. Additionally, the statutory duty to disclose information material to the patentability of any claim in the application is owed by every individual associated with the prosecution of a patent application and is only discharged by filing proper and complete Information Disclosure Statements. All those substantively associated with the preparation and prosecution would be wise to protect their future patent from the beginning of the application's prosecution by timely filing a comprehensive IDS in the proper form and citing all material prior art.

<sup>73</sup> See *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 5 U.S.P.Q.2d 1112 (Fed. Cir. 1987).

<sup>74</sup> See *FMC Corp. v. Hennessy Industries Co., Inc.*, 836 F.2d 521, 5 U.S.P.Q.2d 1272 (Fed. Cir. 1987).

<sup>75</sup> See *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2d 1097 (Fed. Cir. 1998).