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AN OVERVIEW & PRIMER ON THE NEW RULES: THE CAUTION LIGHT AT THE INTERSECTION OF PROSECUTION & LITIGATION IN THE 21ST CENTURY

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In an effort to improve the quality and efficiency of patent examination, the United States Patent and Trademark Office (USPTO) has proposed substantial changes to the rules that regulate patent prosecution. Specifically, the USPTO has put in place new rules for continuation practice and has also submitted for comment proposed rules covering new procedures for submitting Information Disclosure Statements (IDSs).[3]

In this paper we provide a brief outline of the new continuation practice rules and the proposed IDS rules and discuss the implications of these rules packages on patent prosecutors and litigators alike. Specifically, we will highlight the new burdens on patent prosecutors created by these rules and use these burdens to identify new or enhanced dangers of running afoul of 37 C.F.R. Section 1.56 (Rule 56). We seek to initiate a discussion on how litigators might exploit these dangers to bring inequitable conduct arguments, and also suggest possible new prosecution practices to limit inequitable conduct liability.

I. INTRODUCTION

Both the continuations rule package and the proposed IDS rules package will likely result in more efficient prosecution and a reduction in pendency for new applications, however these advantages cause an increase in the responsibilities incurred by the Applicant. The divergence between the increased demands on applicants caused by the USPTO's proposed rule changes and courts increasing propensity to find inequitable conduct on the part of Patent Owners have placed practitioners in a difficult predicament. Litigators will measure each new duty against the metric which all applicant duties have always been measured - Rule 56 - which remains unchanged. As the USPTO notes, "If an applicant acts with candor and good faith in dealing with the Office, there should be no increased risk that the applicant will be accused of inequitable conduct."[4]

While Rule 56 continues to require candor and good faith, the new rules impose new duties that correspond with a potential for new avenues to raise inequitable conduct arguments. Therefore, we will investigate these new and proposed rules and discuss the inequitable conduct arguments to which they may give rise. We also illuminate the increasing importance of in-depth

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2 The Author would like to thank Brian McKnight, James Murphy, Suni Sukduang and Andrew Weaver for their contributions to this paper. This select Houston based group is dedicated to handling complex prosecution matters as well as reexaminations in support of litigation and are guided by the principle of litigation minded prosecution practices. Each is an associate of Novak Druce + Quigg LLP.

3 Additionally, the proposed IDS rules have been submitted to the Office of Management and Budget (OMB) for review and publication. Publication by the OMB, is expected between October and November of 2007.

4 72 Fed. Reg. 46716 at 46768.

reviews of file histories by advanced prosecution attorneys. Just as a successful reexamination requires litigators working in concert with skilled litigation-focused prosecutors as litigation support, a successful inequitable conduct attack on a patent's enforceability will be best effectuated by the cooperation between litigation-minded prosecutors and litigation counsel.

II. CHANGES TO PRACTICE FOR CONTINUED EXAMINATION FILINGS, PATENT APPLICATIONS CONTAINING PATENTABLY INDISTINCT CLAIMS, AND EXAMINATION OF CLAIMS IN PATENT APPLICATIONS[5]

The implementation of the USPTO's strategic plan for reducing pendency times and improving overall patent examination quality has resulted in the publication of controversial new rules on claims and continuations.[6] Under the new claim and continuation rules, applicants will only be permitted to file two new continuing applications and one request for continued examination (RCE) as a matter of right.[7] Additionally, under the new rules each application may contain up to 25 claims, with no more than five independent claims, without any additional effort on the part of the Applicant.[8] Finally, under the new rules the USPTO has outlined new guidelines with respect to multiple applications "that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common ownership."[9]

The timing of the implementation of these rules requires applicants to modify or to otherwise adjust their practice for both pending and not yet filed applications. For example, the continuation rules are impacted by activity prior to release of the rules, during the time between publication of the rules (21 August 2007) and the effective date (1 November 2007), as well as activity after implementation. In another example, when citing applications under 37 C.F.R. Section 1.78(f), time periods for listing applications are provided under a complex set of timing implementations discussed later.

Importantly, 1 February 2008 is a date that all patent owners should have on their calendars to insure compliance with citing applications as covered by 37 C.F.R. Section 1.78(f). The 5/25 claims requirement must also be considered for all applications that have not received a First Office action of the merits by 1 November 2007. In order to comply with these dates and to ensure protection of portfolios, updates to docketing software and procedures will be necessary. Some deadlines will become unextendable for applications filed after 1 November 2007.[10]

1. Continuation and RCE practice

Under the new rules 37 C.F.R. Sections 1.78(d) & 1.114(f), an applicant may only file one RCE and two continuations in any "application family" without having to provide a petition or justification for doing so.[11] Under 37 C.F.R. Section 1.78(d), a nonprovisional application that is claiming benefit to one or more prior-filed nonprovisional or international applications must satisfy at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of Section 1.78. The rules provide for limited circumstances in which the Applicant can file an additional continuation application without violating the two-continuation rule.[12]

The rules set forth the number of continuation applications that can be filed in light of whether an application has its benefit claimed in no more than one other nonprovisional application, not including any provisional applications.[13] Furthermore, the rules state that "[t]he Office's entry of, or failure to delete, a specific reference to a prior-filed application that is not permitted by at least one

5 For applicability dates, *See* "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" 72 Fed. Reg. 46716 at 46716.
6 72 Fed. Reg. 46716 at 46716.
7 *See* 37 C.F.R. Section 1.78(d) and 37 C.F.R. Section 1.114.
8 37 C.F.R. Section 1.75(b).
9 72 Fed. Reg. 46716 at 46716.
10 *See* 37 C.F.R. Section 1.136.
11 *See* 37 C.F.R. Sections 1.78(d)(1) & 1.114(f)
12 *See* 37 C.F.R. Section 1.78(d)(1)(v) and (vi).
13 *See* 37 C.F.R. Section 1.78(d)(1)(i)(B).

of paragraphs (d)(1)(i) through (d)(1)(vi) of this section does not constitute waiver of the provision of paragraph (d)(1) of this section.[14]

Thus, the Applicant must be careful when filing an application that claims the benefit under 35 U.S.C. Sections 120, 121, or 365(c) to a prior-filed application. If the Applicant has previously filed two continuations from a prior-filed application and would like to file a third continuation, the Applicant must follow the appropriate patent office procedure for doing so.[15] If the Office enters the claim of benefit when it was improper under the rules, the patent could be later overturned based upon the disclaimer from the rules that the provisions still apply regardless of whether the office has entered the claim of benefit. While it is unlikely that an application will be awarded an incorrect benefit claim by the office, litigators should review this when contesting a patent that is a continuation of a prior-filed application under one of the above statutes.

In addition to addressing continuations, the rules create different standards for divisional applications. Namely, a divisional application must comply with the guidelines set forth in 37 C.F.R. Section 1.78(d)(ii):

> (A) The nonprovisional application is a divisional application as defined in paragraph (a)(2) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior filed application that was subject to a requirement to comply with a requirement of unity of invention under PCT Rule 13 or requirement for restriction under 35 U.S.C. 121; and
>
> (B) The divisional application contains only claims directed to an invention or inventions that were identified in such requirement to comply with the requirement of unity of invention or requirement for restriction, but were not elected for examination and were not examined in the prior-filed application or in any other nonprovisional application, except for a nonprovisional application that claims the benefit under Section 35 U.S.C 120, 121, or 365(c) of such divisional application and satisfies the conditions set forth in paragraph (d)(1(iii) or (d)(1)(vi) of this section.

If a divisional meets the above criteria, the Applicant is entitled to file two continuation applications off of the divisional application, but the continuation applications cannot be continuation-in-part ("CIP") applications.[16] Thus, the Applicant must be careful when filing a divisional application for similar reasons cited above which could lead to the divisional and any other continuation application filed from it being determined "not allowable" under the rules.

Further, CIP applications have been restricted under the rules. When an applicant files a CIP application, the Applicant must identify the claim or claims in the CIP application for which the subject matter is disclosed in the manner provided by the first paragraph of 35 U.S.C. Section 112 in the prior-filed application.[17] Thus, the Applicant will be required to make a statement in the file history indicating the application to which the claim has a proper benefit claim. This aids the Office in determining what prior art should be used against the claim. If the Applicant makes a statement in this regard, later litigation may bring up the point that the application did not provide support under 35 U.S.C. Section 112 for the claim as indicated by the Applicant. This may even rise to the level of inequitable conduct in some circumstances. Furthermore, if the Applicant is only able to indicate the support in the newly filed CIP application of the claim, the Applicant will not gain any benefit from listing the application as a CIP application - instead the Applicant will be giving up both terms and one of the continuation applications that can be filed from the previously filed applications.

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14 *See* 37 C.F.R. Section 1.78(d)(1).
15 Namely, the Applicant must file a petition under 37 C.F.R. Section 1.78(d)(1)(vi), which will allow the Applicant to obtain consideration of an amendment, argument, or evidence that could not have been submitted during prosecution of the prior-filed application.
16 *See* 37 C.F.R. Section 1.78(d)(1)(iii).
17 *See* 37 C.F.R. Section 1.78(d)(3).

The above references to the continuation rules are provided as examples of a few of the situations that should be considered by practitioners and litigators in light of the rule changes. For the most part, continuation application practice will be most suspect to destruction in litigation if an incorrect claim of priority or benefit is made and the Office does not catch it. Thus, the Applicant should thoroughly review the application to ensure compliance before asserting the patent against another party. Litigators facing these situations are advised to consult with litigation minded prosecutors prior to beginning litigation to ensure compliance of continuation applications filed on or after 1 November 2007.

In addition to the rules affecting continuation practice, the Office has promulgated final rules that allow the Applicant to file an RCE, without petition, if any of Sections (f)(1)-(f)(3) of 37 C.F.R. Section 114(f) have been satisfied. Essentially, the rules allow the Applicant to file an RCE without a petition in an application as long as an RCE has not been filed in that application, any application whose benefit is claimed under 35 U.S.C Section 120, 121, or 365(c) in such application, and any application that claims the benefit under 35 U.S.C Section 120, 121, or 365(c) of such application, not including any nonprovisional application that satisfies the conditions set forth in Section 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).[18] Special exceptions are made for divisional applications and their continuation applications.[19]

2. Claims – the new 5/25 rule

Prior to the institution of the final rule in 37 C.F.R. Section 1.78(b), there was no limit to the number of claims that could be filed in an application, so long as a fee was paid. This practice resulted in some applications being filed with hundreds of claims. Therefore the claim count rules package comes as a result of the USPTO's goal of reducing examination pendency while also creating more thorough records of patentability for issued patents.

Under the new claim count rules, if an application (including those applications that are currently pending and do not have a First Office action on the merits as of November 1, 2007) contains more than five independent claims or more than twenty five-total claims,[20] the Applicant must file an examination support document (ESD) in compliance with 37 C.F.R. Section 1.265.[21] Additionally, the Applicant may make use of the suggested restriction requirement practice as provided by the rules.[22]

In light of the USPTO's goals for creating a more complete record for examination purposes, the ESD requirement will require a practitioner to conduct a thorough review and analysis of the prior art before examiner will consider any claims beyond the 5/25 threshold. These new ESD requirements do not permit a mere disclosure of related references; rather, the ESD requirement requires a practitioner to submit: a statement of a pre-examination search report, a listing of references most closely related to the subject matter of the claims, an identification of the limitations of each of the claims that are disclosed in the cited reference, a detailed explanation of how the claims are patentable over the cited reference, and a showing of where each claim finds support under 35 U.S.C. Section 112.[23]

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18 *See* 37 C.F.R. Section 1.114(f)(1).

19 *See* 37 C.F.R. Section 1.114(f)(2) and (3).

20 *See* 37 C.F.R. Section 1.75(b)(5) "Claims withdrawn from consideration under Sections 1.141 through 1.146 or Section 1.499 as drawn to a nonelected invention or inventions will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in paragraphs (b)(1), (b)(3), and (b)(4) of this section." *See also* 37 C.F.R. Section 1.75(c) "any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in Section 1.16(j). A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered." *See also* 37 C.F.R. Section 1.75(b)(2) "A claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for fee calculation purposes under Section 1.16 (or Section 1.492) and for purposes of paragraph (b) of this section. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes under Section 1.16 (or Section 1.492) and for purposes of paragraph (b) of this section."

21 37 C.F.R. Section 1.78(b)(1). Also note that for applications pending as of 1 Novemeber 2007, compliance must be achieved by 1 February 2007. Additional timelines for compliance are provided by 37 C.F.R. Section 1.78(f).

22 *See* 37 C.F.R. Section 1.142(c). The suggested restriction requirement allows an applicant to propose a restriction requirement which may or may not be accepted by the Office without recourse. Appropriate use of suggested restriction requirement practice should be considered by advanced prosecutors in light of concerns with respect to the overall portfolio.

23 *Id.*

Understandably, an ESD will give the USPTO a jump start on examining the claims; however, many applicants will be reluctant to file ESDs in light of increasing inequitable conduct concerns. As of November 1, 2007, when the new ESD requirements take effect, applicants who choose to seek more than 25 claims will be forced to characterize the significance of known prior art references with respect to each claim. This will create prosecution history estoppel and potential for inequitable conduct charges in relation to what is said in the ESD.

In light of these new ESD requirements and the potential litigation issues they entail, the ability to claim a large number of embodiments, without having to subject oneself to creating unnecessary prosecution history, has diminished. What remains is a new bargained for exchange; if a broader claim scope is desired, an applicant (instead of the USPTO) will have to bear more of the burden than has been tradition. In part of the new bargained for exchange, the Applicant receives an additional set of 5/25 claims for each continuation application filed pursuant to 37 C.F.R. Section 1.78(d).

3. Disclosure of Applications/Patents

The Office has further promulgated rules that require the Applicant to cite applications that fit within a given set of criteria in other applications also within the same criteria.[24] If an application is filed within 2 months of another application's filing date and has one common inventor, and same ownership, then the Applicant must disclose all such applications.[25] If the applications that are filed on the same day, have one common inventor, the same ownership, and a substantial overlapping disclosure, then a refutable presumption is established that there is at least one claim in the application that is not patentably distinct from at least one claim in the other application.[26]

Furthermore, the rules provide that "[i]n absence of good and sufficient reason for there being two or more pending nonprovisional applications owned by the same person or subject to an obligation of assignment to the same person, the Office may require elimination of the patently indistinct claims from all but one of the applications."[27] Thus, the earlier provisions are directed towards the Applicant disclosing applications filed within a given time period so that the Office may determine if two or more applications filed by the Applicant claim inventions that are not patentably distinct from one another.

When an applicant is faced with indicating whether claims are patentably distinct or not from each other, the scope of the claim can further be defined. The Office has generally indicated that in determining whether a claim is patently indistinct from another claim, an obviousness type test will be used.[28] If a claim is determined to be patentably distinct from another claim, there must be some grounds on which there is subject matter not covered literally by either of the patentably distinct claims. An applicant must be careful in construing these patentably distinct claims in prosecution so as to not lose the doctrine of equivalents in order to cover this subject matter. Alternatively, if the claims are determined to be patentably indistinct, the patent owner will have a greater ability to argue that these claims are indeed covered under the doctrine of equivalents or alternatively provide for some assistance in a claim construction hearing. When an applicant is faced with trying to determine if the claims fall within this patentably indistinct characterization they should consult a litigation conscious prosecutor who gives thought to litigation concerns.

III. INFORMATION DISCLOSURE STATEMENTS

The USPTO has proposed changes to the IDS requirements and other related matters to assure that the examiners are only provided with the most pertinent citations of prior art so as to

24 *See* 37 C.F.R. Sections 1.78(f)(1) and (2).
25 *See* 37 C.F.R. Section 1.78(f)(1). Also note that the phrase 'taking into account any filing date for which a benefit is sought under title 35, United States Code' is further explained in the Federal Register at page 46735.
26 *See* 37 C.F.R. Section 1.78(f)(2). The Applicant may rebut the presumption or file a terminal disclaimer and explain why two or more applications are required.
27 *See* 37 C.F.R. Section 1.78(f)(3).
28 *See* Comment 141 at Fed. Register 46785.

improve the quality and efficiency of the examination process.[29] The USPTO believes that the current 37 C.F.R Sections 1.97 and 1.98 requirements "do not encourage applicants to bring the most relevant information to the attention of the examiner early in the examination process, at least, in part because applicants and practitioners mistakenly believe that people associated with a patent application must submit questionably or marginally relevant documents in order to ensure compliance with the Section 1.56 duty of disclosure."[30]

This "mistaken" belief is no accident in the eyes of many practitioners. In light of the ever-growing fears of inequitable conduct, practitioners are deliberately submitting anything and everything even remotely related to the application. Thus, in order to strike a balance between submitting only relevant materials within the duty to disclose under Section 1.56, the PTO has proposed significant changes to Sections 1.97 and 1.98. To address the basic aspects of these proposed changes, the following outline is submitted.

1. Information Disclosure Statement proposed Rule Change Outline

Following the pattern set forth in the current IDS rules, the USPTO has provided time periods with increased responsibilities for each successive time period in which to file an IDS. The most notable of the proposed changes include: a requirement to provide an explanation of the relevance of submissions, a requirement to indicate the non-cumulative matter of additional references, and most worrisome, the proposed rule provides the possibility that a submission of prior art admits unpatentability and requires amendment of the claims. The following paragraphs will detail the very basics for submitting an IDS in conformance with the proposed rules.

Summary Table of IDS Submission Time Periods

	1st period	2nd period	3rd period	4th period
Duration	Filing through later of 3 months after filing or 1st Office Action	1st period until Notice of Allowance, Notice of Allowability, or NIRC	2nd period until Payment of Issue Fee	After payment of issue fee
IDS Documents Requiring Additional Disclosure	Docs 25 pages or more Foreign language docs All documents when total exceeds 20	All	All	All
IDS Documents Exempt from Additional Disclosure	Foreign search report Requirement for information	Foreign search report Requirement for information	Requirement for information	Requirement for information
Additional Disclosure Required	None, unless one of the three situations listed above apply	Explanation of docs Description of non-cumulative matter	Explanation of docs Description of non-cumulative matter Patentability justification	Explanation of docs Description of non-cumulative matter Patentability justification must include emended claims

* **First Time Period** (Section **1.97(b)(1)-(3):**
Start – File application;
End – Later of 3 months after filing, or 1st Office action.

Under the proposed requirements for submitting an IDS in the First Time Period (Sections 1.98(a)(3)(i)(A)-(C)), the general rule is much the same as the current rule; an IDS filed during this period does not need to comply with the additional disclosure requirements of Section 1.98(a)(3)(iv).

29 "Changes to Information Disclosure Statement Requirements and Other Related matters," 71 Fed. Reg. 38808 (July 10, 2006).
30 71 Fed. Reg. at 38809.

However, there are several exceptions to this general rule. Specifically, an "explanation" is required for all:

1. English-language documents with 25 pages or more (excluding sequence & computer listings);

2. Foreign-language documents[31] and any submitted translation if the translation exceeds 25 pages; and

3. All submitted documents when the cumulative number exceeds 20 documents whether one or multiple IDS submissions are used.

If any one of the references falling into the group requiring an explanation is the result of an International Search/Examination Report or is submitted in response to a Requirement for Information, then that prior art does not require the added disclosure nor counts against the 20 document limit for triggering the added disclosure requirement for all submitted documents.[32]

* **Second Time Period (Section 1.97(c)):**
Start – End of Time Period 1;
End – Notice of Allowance, Notice of Allowability, or Notice of Intent to Issue Reexamination Certificate ("NIRC") in a reexamination proceeding.

Under the proposed rules, the requirements for submitting an IDS in the Second Time Period provide that ALL documents submitted during this time period must be accompanied by additional disclosure in accordance with Section 1.98(a)(3)(iv). Similar to the First Time Period, the Second Time Period provides that references submitted as a result of an International Search/Examination Report or in response to a Requirement for Information avoid the added disclosure requirements normally required for all documents submitted during the Second Time Period.[33] Further, any submission must not be merely cumulative such that the "description may be of a specific feature, showing, or teaching in a document that is not found in any other document of record."[34]

* **Third Time Period (Section 1.97(d)(1)):**
Start – End of Time Period 2;
End – Payment of Issue Fee.

The Third Time Period, while similar to the Second Time Period, is even more demanding. Like the Second Time Period, ALL documents submitted in the Third Time Period are required to be accompanied by additional disclosure requirements. However, the disclosure requirements for the Third Time Period require an explanation and non-cumulative description and also require a certification in accordance with Section 1.97(e)(1) or (e)(2), which states that the documents were first cited in a foreign proceeding not more than three months prior to the submission or a certification that the document was not known to any Section 1.56(c) persons and that a reasonable investigation did not reveal the reference cited in a foreign proceeding more than 3 months before the

31 *See* 71 Fed. Reg. at 38822 citing proposed Section 1.98(a)(3)(xi) (submitting "non-English language documents of any length, a copy of a translation in English thereof must be submitted along with the document where a translation is within the possession, custody, or control of, or is readily available to, any individual listed in Section 1.56(c). A translation does not count towards the cumulative total of paragraph (a)(3)(i)(C) of this section, but is subject to the over twenty-five page threshold value of paragraph (a)(3)(i)(B) of this section.")

32 The two exceptions include: "documents cited within a time frame set forth in Section 1.97(b) [the First Time Period] that result from a foreign search or examination report where a copy of the report is submitted with the information disclosure statement" (Section1.98(a)(3)(viii)(A)); and "documents submitted in a reply to a requirement for information pursuant to Section 1.105" (Section 1.98(a)(3)(viii)(C)).

33 Under 1.98 (a)(3)(viii)(B) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents cited within the time frame set forth in Section 1.97(c) [the Second time period] when submitted with a certification pursuant to Section 1.97(e)(1) and a copy of the foreign search or examination report." Further still, under Section 1.98(a)(3)(viii)(C) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents submitted in reply to a requirement for information pursuant to Section 1.105."

34 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(v) (stating that a "non-cumulative description requires a description of how each document is not merely cumulative of any other information disclosure statement cited document, document cited by the examiner, or document cited under Sections 1.99, or 1.291, as citation of merely cumulative information must be avoided pursuant to paragraph (c) of this section. The description may be of a specific feature, showing, or teaching in a document that is not found in any other document of record.") Please note that under 1.98 (a)(3)(viii)(B) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents cited within the time frame set forth in Section 1.97(c) when submitted with a certification pursuant to Section 1.97(e)(1) and a copy of the foreign search or examination report." Further still, under Section 1.98(a)(3)(viii)(C) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents submitted in reply to a requirement for information pursuant to Section 1.105."

IDS was filed.[35] In addition, any document submitted must be accompanied by a patentability justification describing why the independent claims (or concurrently filed amended claims, which admits unpatentability of the previous claims over that reference) are patentable over the art submitted in the IDS.[36] Unlike the First and Second Time Periods, the only exception to the disclosure requirement is if the reference is submitted in response to a Requirement for Information.[37]

* **Fourth Time Period (Section 1.97(d)(2)):**
Start – Payment of Issue Fee, or Mailing of NIRC in reexamination proceeding;
End – Lack of Sufficient time for the Examiner to Consider the IDS Prior to Issuance.

An IDS submitted in the Fourth Time Period follows the same requirements as the Third Time Period, with one very notable additional requirement. An IDS submitted in the Fourth Time Period requires an explanation, a non-cumulative description, a certification that the documents were not known three months prior to submitting the IDS, and a patentability justification. The Fourth Time Period also includes the additional requirement that the patentability justification, which must include a concurrently filed amendment to the claims with reasons stating why the amendments make the claims patentable.[38] This amendment is necessary because by submitting an IDS in the Fourth Time Period, the Applicant admits the claims are unpatentable over the submitted reference, either alone or in combination with any information previously of record.[39] Also, an IDS submission during the Fourth Time Period further requires a petition to withdraw the application from issue pursuant to Section 1.3131(c)(1), or a withdrawal from publication in a reexamination proceeding, and accompanied by a fee in accordance with Section 1.17(h).[40] The only exception to the disclosure requirement is if the reference is submitted in response to a Requirement for Information.[41]

2. General: Applying to All Time Periods

Of particular concern to most practitioners is the level of detail necessary to comply with the explanation requirement. The USPTO does, however, provide the following guideline for submitting an explanation:

> An explanation must include:
>
> (A) *Identification:* Identification of specific feature(s), showing(s), or teaching(s) that caused a document to be cited, and a representative portion(s) of the document where the specific feature(s), showing(s), or teaching(s) may be found; and

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35 71 Fed. Reg. at 38820 citing proposed Section 1.97(e) provides that a "certification under this section referenced in Sections 1.98(a)(3)(iii) and 1.98(a)(3)(viii)(B) must certify either:
(1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement."

36 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(vi):
(vi) *Patentability Justification*: A patentability justification requires either:
(A) An explanation pursuant to paragraph (a)(3)(iv) of this section, a non-cumulative description pursuant to paragraph (a)(3)(v) of this section, and reasons why the independent claims are patentable over the information in the information disclosure statement being submitted, considered together, and in view of any information already of record; or
(B) An explanation pursuant to paragraph (a)(3)(iv) of this section, a non-cumulative description pursuant to paragraph (a)(3)(v) of this section, and reasons why an amendment causes claims, admitted to be unpatentable over the information in the submitted information disclosure statement, either alone or in combination with any information already of record, to now be patentable over such information when considered together, and in view of any information already of record...

37 The only exception in the Third Time Period is under Section 1.98(a)(3)(viii)(C) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents submitted in reply to a requirement for information pursuant to Section 1.105."

38 *See* 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(iii)(B), "When [the IDS is] submitted during the time period defined in Section 1.97(d)(2), the information disclosure statement must be accompanied by…the patentability justification pursuant to paragraph (a)(3)(vi)(B)."

39 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(vi)(B):
(B) An explanation pursuant to paragraph (a)(3)(iv) of this section, a non-cumulative description pursuant to paragraph (a)(3)(v) of this section, and reasons why an amendment causes claims, admitted to be unpatentable over the information in the submitted information disclosure statement, either alone or in combination with any information already of record, to now be patentable over such information when considered together, and in view of any information already of record...

40 *See* 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(iii).

41 The only exception in the Third Time Period is under Section 1.98(a)(3)(viii)(C) "compliance with paragraphs (a)(3)(iv) and (a)(3)(v) of this section is not required for documents submitted in reply to a requirement for information pursuant to Section 1.105."

(B) *Correlation:* A correlation of the specific feature(s), showing(s), or teaching(s) identified in paragraph (a)(3)(iv)(A) of this section to corresponding specific claim language, or to a specific portion(s) of the specification that provides support for the claimed invention, where the document is cited for that purpose.

Another concern arises when amendments to the claims are made. Applicants have a continuing duty to update the required explanation in view of the amendments and a statement to that effect must be submitted.[42]

2. Public Concerns

In spite of the widespread appreciation of the problems the USPTO is having with the voluminous backlog of patent applications, the community nevertheless remains concerned with the recent proposed rule changes to IDS submissions. It is unquestionable whether these rules would actually benefit the prosecution of applications - they will, even if they only marginally help the USPTO achieve its goal of reducing the backlog. However, for practitioners and applicants, the meaning and implementation of the rules will change their prosecution strategy for filing an IDS.[43]

Under the proposed IDS rules an Applicant is presented with new challenges including additional judgment calls such as whether a reference is merely cumulative, or whether a document might give rise to an obviousness rejection when considered in view of art previously submitted.[44] Additionally, the proposed rule creates the challenge of complying with undefined standards such as certifying that a "reasonable inquiry" has been undertaken to determine if the reference has been cited in a foreign examination greater than three months prior to the submission of the IDS.[45] The new rules also provide a duty to update the required explanation to parallel the shifting of the claims.[46] Each of these challenges provides room for potential error.

Even the careful applicant, whom conscientiously undertakes and attempts to comply with the proposed IDS rules, runs the risk of additional exposure to inequitable conduct complaints. Therefore, the Applicant must consider legal ramifications that occur during litigation. Of particular concern is a recent decision where a finding of inequitable conduct seemingly turned on the courts evaluation of the prosecuting attorneys judgment calls.[47]

In *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.,* the court held a patent unenforceable for inequitable conduct before the USPTO because three items of information deemed material to patentability were not disclosed.[48]

The Applicant's downfall in this case is particularly relevant to the proposed rules. In *McKesson* the Applicant did not disclose the Baker patent to Examiner Trafton even though it was brought to the Applicant's attention in another matter by a different Examiner.[49] In support of his decision, the Applicant argued that the reference was cumulative to another, better reference.[50] In addition, the Applicant disclosed the existence of the similar application.[51] The court did not find these arguments persuasive and found the high materiality of the reference.[52] Regardless of whether the court came to the correct conclusion, this case illustrates how reasonable minds differ as to the cumulative nature of references.

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42 *See* 71 Fed. Reg. at 38822 citing proposed Section 1.98(a)(3)(ix).
43 *See e.g.* American Bar Association Section of Intellectual Property Law comments to 71 Fed. Reg. 38808 stating "[requiring additional disclosure] will expose Applicants to possible greater risk of having to defend charges of inequitable conduct and will impose an often unnecessary new burden of knowledgeable Applicant. Applicants will be required to identify the most pertinent portion of a cited reference, apply the pending claims to the reference and eliminate any reference which are 'cumulative' without citation."
44 71 Fed. Reg. at 38821 citing proposed Section 1.98(a)(3)(vi).
45 71 Fed. Reg. at 38820 citing proposed Section 1.97(e)
46 *See* 71 Fed. Reg. at 38822 citing proposed Section 1.98(a)(3)(ix).
47 *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).
48 *McKesson Info. Solutions, Inc.,* 487 F.3d at 926.
49 *McKesson Info. Solutions, Inc.,* 487 F.3d at 914.
50 *Id.*
51 *Id.*
52 *Id.*

McKesson also illustrates the issue of inequitable conduct for failing to identify and disclose possible rejections.[53] In *McKesson,* the Applicant also failed to disclose to the Examiner that the claims of another disclosed application had been allowed.[54] The court admonished the Applicant for failing to realize that the Examiner could have potentially issued a double patenting rejection.[55] While not exactly on point, the issue is clearly illustrated. The proposed IDS rules require an Applicant to make a judgment call as to whether or not a reference in light of a previously cited reference might provide grounds for a rejection.

It's important to note that this Federal Circuit opinion outlines the difficulty of determining whether practices before the USPTO will be deemed inequitable. In this split decision, Judge Pauline Newman dissented and stated that:

> It is not clear and convincing evidence of deceptive intent that the Applicant did not inform the examiner of the examiner's grant of a related case of common parentage a few months earlier, a case that was examined by the same examiner and whose existence has previously been explicitly pointed out by the same applicant. Nor is it clear and convincing evidence of deceptive intent that the Applicant did not cite a reference that the Applicant had cited in the same related case, and that had been explicitly discussed with the same examiner in the related case
> …
>
> this court returns to the 'plague' of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.[56]

This paper does not comment on whether or not the *McKesson* court reached the correct verdict. Rather the decision exemplifies the concern of many practitioners about the interplay between the proposed IDS rules and inequitable conduct. While others might argue that inequitable conduct is only a concern where some intent is present the *McKesson* case demonstrates that incorrect judgment call can provide the necessary intent with respect to inequitable conduct.[57]

Judge Pauline Newman's dissent is important as it shows at least one Judge has the same opinion of inequitable conduct as many practitioners - that it's a "plague." Unfortunately for patent applicants and fortunately for defendants, the divergence between the USPTO's proposed IDS rules and the Federal Circuits law on inequitable conduct feed the "plague."

While prosecuting attorneys strive to make sound judgment calls and attempt comply with undefined standards, defendants might now breathe easier. Inequitable conduct arguments might even arise from applicants with the best intentions. The proposed rules open up each judgment call on the part of the Applicant to inequitable conduct scrutiny.

For example, the Applicant might have art that is considered to be marginally relevant - for instance, background art - to at least the general technology. If the Applicant knows of several (around 20 or more pieces of art) that are substantially related to the claimed elements, the Applicant may desire to avoid disclosing the details of the marginally related information in order to avoid having to discuss each reference. The Applicant is forced to make a choice: either withhold the background art and face scrutiny for that decision, or disclose the background art and face scrutiny for the Applicant's choice of characterization.

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53 *McKesson Info. Solutions, Inc.,* 487 F.3d at 925.
54 *Id.*
55 *Id.*
56 *McKesson Info. Solutions, Inc.,* 487 F.3d at 926.
57 *See generally, McKesson Info. Solutions, Inc.,* 487 F.3d at 897-927.

Once an applicant decides to characterize a reference, litigators have fertile ground for which to grow their case. A litigator may argue the Applicant did not disclose the best portion of the reference or may argue that the Applicant's claims must mean x, y and z because the cited portion of a reference discusses x, y and z; therefore, that is what the Applicant saw as relevant to their invention. The description requirement is a dangerous path to take, but it is equally dangerous to choose to withhold even background and cumulative references.

Cumulative references provide yet another judgment call subject to attack. As seen in the *McKesson* case, while an applicant might think a reference is cumulative, the courts may disagree. The proposed rules require an applicant not only to determine if a reference is cumulative, but to consider whether the reference, when combined with previously submitted art, could be grounds for unpatentability. This amounts to asking applicants to theorize on possible obviousness rejections the Examiner might issue, and an incorrect determination results in a charge of inequitable conduct. Obviousness is already a standard in flux, now applicants must fear inequitable conduct for a judgment that their claim in not obvious over the prior art.

Further ground to attack an applicant's judgment is with respect to updating. Litigators will easily find a reference that is not updated perfectly, and will assert inequitable conduct. To make matters worse, the litigant will have the element of intent provided because the Applicant is required to make a statement saying that they considered the previously submitted references in light on the proposed amendments.

For a patent owner there is a greater potential to have a Patent Owner's patent declared unenforceable due to the proposed rules. The divergence between the increased demands on applicants caused by the USPTO's proposed rule changes and courts increasing propensity to find inequitable conduct on the part of applicants has practitioners in a tough position.

In light of decisions like *McKesson Info. Solutions, Inc*, the proposed IDS rules are a major burden for practitioners that will be passed through to applicants. As the commenter from the American Intellectual Property Law Association points out,

> …[t]he proposed rules would impose substantial new analytical burdens on patent applicants seeking to bring information to the attention of the PTO to be considered during the prosecution of patent applications and reexamination proceedings…These additional burdens would impose substantial costs on applicants, who would be motivated to seek to reduce those costs by reducing or eliminating activities (e.g., conducting a search of prior art) presently practiced to identify information that may be relevant to patentability. The proposed rules would also expose applicants to a substantially greater risk of having to defend against charges of inequitable conduct. The PTO has failed to justify the imposition of these burdens and risks in the great majority of applications.[58]

With the increasing role of inequitable conduct as outlined in *McKesson Info. Solutions, Inc.*, the Applicant and practitioner face a dilemma in regards to citing information that is covered by the duty of candor under Section 1.56 and the proposed IDS rules. This dilemma can continue throughout the prosecution of the patent application as well as its continuation and divisional applications. In order to comply with the additional description requirements a practitioner will have to conduct an exhaustive and laborious review of the available prior art to assure compliance, while simultaneously considering implications as per enforceability before the court. An important consideration will be whether to withhold what might be considered a marginally relevant reference or to submit the reference with the necessary description and pass through this cost to the Applicant.

The rules obviously encourage careful consideration of possible prior art references early in the application process. But as we have illustrated above, judgment calls are necessary and in turn

58 American Intellectual Property Law Association comments to 71 Fed. Reg. 38808.

those judgment calls will be scrutinized by litigators. One possible mechanism that we foresee is a prior art log recording why a reference was not disclosed and what the Applicant believes the reference teaches. Such a log might provide evidence that combats the intent requirement of inequitable conduct in the event the application is litigated in the future. Along the same lines, perhaps, if the inequitable conduct climate continues on its current trajectory, practitioners will seek opinions to validate their judgment calls.

However practitioners learn to deal with the new IDS rules once they come into being, inequitable conduct complaints will continue to plague patent litigations.

IV. CONCLUSION

The implementation of the USPTO's 21st Century Strategic plan has resulted in a flood of rule changes that is turning the industry on its head. Although the goal of improved application examination quality is desirable for many reasons, the means for obtaining that goal has been questionable.

With these proposed rules, applicants will bear significantly increased duties as practitioners will have to assure compliance with the Applicant's prosecution strategy, the new and proposed rules, and the "plague" of inequitable conduct concerns. In turn litigants can expect fertile file histories to cultivate inequitable conduct arguments in effort to render plaintiff's patents unenforceable. As a result, applicants are sure to develop new strategies to comply with the USPTO's requirements and litigators will become increasingly dependant on litigation minded prosecution counsel to support unenforceability and invalidity arguments.

Under these proposed rules, as well as the finalized continuation and claim count rules, the USPTO has essentially outsourced the application grunt work to the Applicant , thereby "freeing up" the examiner to prosecute applications that are further refined. Although this makes sense from a practical perspective of reducing pendency times for prosecuting applications, it places a significant burden on applicants and practitioners.

IV. UPDATE

Several months after this article was originally authored, Smithkline Beecham Corporation d/b/a/ GlaxoSmithKline, et al. (collectively, "GSK") and Triantafyllos Tafas ("Tafas") brought a motion for preliminary injunction in the District Court for the Eastern District of Virginia that sought to enjoin the implementation of the Final Rules that were set to implement on November 1, 2007.[59] Much to the relief of patent practitioners in the United States, the joint motion was granted prior to the implementation of the Final Rules thus temporarily preventing the rules from being implemented while the Court prepared for trial on the issue of whether the Final Rules were lawful under the Administrative Procedure Act (the "APA").

In the lawsuit, GSK and Tafas argued on motion for summary judgment that the implementation of the new rules was unlawful since the rules were "substantive in nature" and exceeded the scope of the USPTO's rulemaking authority under 35 U.S.C. Section 2 (b)(2).[60] The Court, siding with GSK and Tafas granted summary judgment to GSK and Tafas and voided the Final Rules as "not in accordance with law" and "in excess of statutory jurisdiction [and] authority."[61]

Specifically, the Court noted that Section 2(b)(2) "does not vest the USPTO with any general substantive rulemaking power" notwithstanding their authority to "engage in notice and

59 *See Tafas v. Dudas*, Docket no. 1:07-CV-846 (E.D. Va. 2007) (stating that "[d]efendants are preliminary enjoined from issuing new regulations restricting the number of continuing applications, the number of requests for continued examinations, and the number of claims that maybe filed with the PTO...")
60 *Id.* at "Memorandum Opinion" dated April 1, 2008.
61 *Id.* at "Memorandum Opinion" p. 10 citing 5 U.S.C. Section 706 (2).

comment rulemaking in accordance with 5 U.S.C. Section 553."[62] While Section 2(b)(2) empowers the USPTO to establish regulations (not inconsistent with the law) that govern proceedings before the Office, Section 2(b)(2) also requires that the USPTO's rulemaking be consistent with notice and comment provision of 5 U.S.C. Section 553.[63]

The USPTO has since appealed the district court ruling to the Federal Circuit and filed their opening appeal brief.[64] The USPTO argues on appeal that "the rules regulate the conduct of proceedings in the Office and the conduct of attorneys and other representatives, and by discouraging unnecessarily repetitive filings and providing examiners with needed information, they facilitate and expedite the processing of patents."[65] Furthermore, that the "court mischaracterized the effects of the Final Rules, misconstrued the statutory provisions, misunderstood the judicial precedents concerning those provisions, and failed to give the USPTO's construction of the provisions the deference required by Chevron."[66]

The Appellee's have yet to file their brief at the time of this update.

62 *Id.* at "Memorandum Opinion" p. 11-12.
63 *See Id.* at "Memorandum Opinion" p. 13 (stating that "it is clear that the USPTO must engage in notice and comment rulemaking when promulgating rules it is otherwise empowered to make – namely, procedural rules.").
64 *Tafas v. Dudas* Docket no. 2008-1352 (Fed. Cir. 2008) at "Brief for Appellants".
65 *Id.* at p. 14.
66 *Id.*